

Sharing human milk in Australia: challenging regulatory regimes for infant feeding

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Declaration of originality

I, Libby Salmon, (28/7/2023) hereby declare that the thesis here presented is the outcome of the research project I have undertaken during my candidacy, that I am the sole author unless otherwise indicated, and that I have fully documented the source of ideas, references, quotations or paraphrases attributable to other authors.

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Abstract

Sharing human milk is an infant feeding practice with a long history in wet-nursing. From the early 20th century, wet-nursing was replaced by commercial milk formulas and, in some countries, by human milk banks, which provided pasteurized human milk under medical supervision to medically fragile infants. More recently, technological developments in breast pumps and the internet have enabled expressed milk to be shared without medical supervision and the emergence of markets for milk and novel milk products. Milk banking and informal milk sharing raise deep legal and social questions about safety, ethics and women's reproductive rights but remain obscure, at the margins of public health nutrition policy.

This thesis examines how the regulation of milk sharing affects breastfeeding. The research used Australia as a case study at a critical time in the governance of two rapidly developing milk sharing sectors, from 2010 to 2022, following the establishment of milk banking, the advent of social media pages to share milk and international trade in human milk. These developments occurred under specific political and economic conditions: Australia was a Western liberal democracy with a welfare state, universal public health system and paid parental leave, but weak policies to protect and support breastfeeding. Progress in breastfeeding policy had stalled, in the face of unprecedented pressure from the commercial power of milk formula companies, while the self-regulation of milk banking enabled consolidation in this sector. This complex three-way competition, between breastfeeding, commercial milk formulas and shared milk, ignited media reports of milk banks saving premature infants and 'black markets' in milk, that pitted mothers against health authorities and babies against body builders.

Drawing on regulatory theory and its broad conceptualization as the 'steering of events,' a multidisciplinary approach was used to investigate the regulation of diverse milk sharing practices through the state and 'beyond the state,' by government and civil society actors. The research approach combined a conceptual model of 'nodal governance' with a model of actor behaviour, based on actor awareness, motivations, pathways and rewards. These models linked micro- and macro-levels of governance, centred on women's embodied experiences of milk production, and reaching to the globalized biopolitics of infant feeding, leaving open to investigation how structure and individual agency shaped the flow of milk in society.

Empirical analyses were undertaken to investigate regulatory mechanisms at these different levels of governance. An examination of how institutions framed milk sharing focused on the legal structures that applied to milk sharing in a document analysis of relevant laws and policies from government

and non-government organizations. The conditions under which milk sharing occurred in health and community settings were examined through key informant interviews of four actor groups: mothers who shared milk, milk banks, health professionals and policy makers, with 95 participants. Data was collected from 2016-2019.

The results showed that across the regulatory regime for human milk, discontinuities in legal frameworks and actor knowledge, objectives, courses of action and feedback signals created regulatory incoherence. This incoherence was distilled to three regulatory themes: contested sources of legitimacy, multiple lines of resistance and conflicting objects of regulation. Targeting these themes will help refocus regulation from milk as a product to milk sharing that supports breastfeeding processes. These findings highlight that policy alone is unlikely to address the power imbalances in infant feeding. New, localized governance structures are required that protect milk sharing as part of women's vibrant breastfeeding systems, and empower mothers, rather than serve commercial or medical interests in milk.

Members of Supervisory panel

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Abbreviations and glossary

AAP	American Academy of Pediatrics
AAN	American Academy of Nursing
ABA	Australian Breastfeeding Association
ABM	Academy of Breastfeeding Medicine
ABMB	Australian Breast Milk Bank
ACT	Australian Capital Territory
Altruistic donation of milk	The milk donor is not paid or compensated.
AMA	Australian Medical Association
ACM	Australian College of Midwives
AHMAC	Australian Health Ministers' Advisory Council
ARCBS	Australian Red Cross Blood Service
Biological mother	The woman who gave birth to a child
BFHI	Baby-friendly Hospital (or Health) Initiative
Breastfeeding	Feeding at the breast
CMF	Commercial milk formula (infant formula, follow-on formula and toddler milk).
CMV	Cytomegalovirus
COAG	Council of Australian Governments
Codex	Codex Alimentarius, International food standards set by the Food and Agriculture Organization of the United Nations (FAO) and WHO.
Commercial milk sharing	A model of milk exchange that involves profit-taking at any point along the milk supply chain. Commercial milk sharing may involve unpaid donation, donor compensation or cost recovery by donors, milk banks or other actors and entities involved.
Community milk bank	A non-profit milk bank that is not affiliated with or administered by a hospital.
Compensation	Payment for costs incurred (reimbursement). Non-profit.
Cost recovery	Payment for costs (compensation or reimbursement). Non-profit.
Cross-feeding	Feeding someone else's child at the breast, irrespective of whether the donor is unpaid or paid (wet-nursing).
Directed donation	The provision of unpasteurized milk from a donor known to the recipient mother, under medical supervision, which may require prior testing of the donor and milk.
Donor milk	Milk provided by a lactating woman to someone other than her biological (birth) child.
EBM	Expressed breast milk
EC	European Commission
EMBA	European Milk Banking Association
EOF	Eats on Feets
EU	European Union
Expressed milk	Milk expressed by hand or an electric breast pump.
FAO	Food and Agriculture Organization of the United Nations
Formula	Commercial milk formula (CMF) for infants 0-12 months of age.
FSANZ	Food Standards Australia New Zealand
HDMP	Human donor milk product (see milk product).

HIV	Human Immunodeficiency Virus
HM4HB	Human Milk for Human Babies
HMBANA	Human Milk Banking Association of North America
HTA	Human Tissue Act or Transplantation and Anatomy Act
HTLV (I, II)	Human T Lymphotropic Virus, types I and II
Human milk fortifier	A supplement of protein, calories, calcium and phosphate added to human milk to meet the requirements of very low birth weight (VLBW) premature infants. Fortifiers may be made from dairy products or human milk (human-derived fortifier).
IBCLC	International Board Certified Lactation Consultant
IBLCE	International Board of Lactation Consultant Examiners
ILCA	International Lactation Consultant Association
Independent milk bank	A milk bank that is not affiliated or administered by a hospital, and which may be non-profit, semi-commercial or commercial.
Informal milk sharing	Milk sharing outside a milk bank. Donors in informal arrangements may be paid or unpaid.
Lactation consultant	International Board Certified Lactation Consultant
LCANZ	Lactation Consultants of Australia and New Zealand
milk	Human milk or breastmilk
MACH nurse	Maternal and child health nurse
Milk bank	An organization that collects, stores, processes and distributes milk.
Milk product	Donor milk that is processed beyond pasteurization or had a component extracted or modified into a product for sale.
Milk sharing	Providing donor milk through cross-feeding, a milk bank, directed donation or informal arrangement.
MMBC	Mothers Milk Bank Charity
MOM	A mother's own milk
NEC	Necrotizing enterocolitis
NHMRC	National Health and Medical Research Council
NICU	Neonatal intensive care unit
NT	Northern Territory
Non-commercial milk sharing	A model of milk exchange that does not involve the payment of donors or profit-taking by donors or any other party.
Non-profit milk sharing	Non-profit models of milk sharing may include compensation of donors or cost recovery by milk banks and other entities and actors.
NSW	New South Wales
Pasteurized milk	Donor milk treated by heat or in other ways to control microbial contamination, typically by a milk bank using the Holder method (62.5°C for 30 minutes).
PDHM	Pasteurized donor human milk
Qld	Queensland
RACGP	Royal Australian College of General Practitioners
RACP	Royal Australasian College of Physicians
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Raw milk	Milk that is fresh, chilled or frozen (not pasteurized).
SA	South Australia
TAS	Tasmania

TGA	Therapeutic Goods Authority
UKAMB	United Kingdom Association of Milk Banks
UN	United Nations
UNICEF	United Nations Children's Fund
Unpasteurized milk	Milk that has not been pasteurized and is in a 'raw' state (fresh, chilled or frozen).
UK	United Kingdom
US	United States of America (USA)
vCJD	variant Creutzfeldt-Jakob disease
VIC	Victoria
Wet-nursing	Cross-feeding in a commercial arrangement, in which the donor is paid or enslaved.
WA	Western Australia
WHO	World Health Organization
WHO Code	WHO International Code of Marketing of Breastmilk Substitutes and subsequent World Health Assembly resolutions.

Chapter 1. Introduction

At the start of my research, at an international conference on human milk, an expert in infant feeding policy from the World Health Organization (WHO) commented that milk sharing was a trivial matter, when breastfeeding faced so many challenges globally. Yet, in Australia, the 2023 federal budget allocated more funding to human milk banks than breastfeeding (1).¹ Whose interests were served by this decision? What system of regulation supported the donation of milk without investment in the capacity to breastfeed, which had languished from decades of policy neglect (2)?

The aim of this research is to provide a deep understanding of the complex regulation of human milk, shared through milk banks and less formal practices, and its implications for public health nutrition. This research sought to answer the overarching question: *How does the regulatory regime for milk sharing shape breastfeeding in Australia?*

Regulation is defined here broadly as ‘steering the flow of events’ (3) and a ‘regulatory regime’ consists of the actors, institutions and ideas that steer these events (4). In this conceptual framework, the meanings of ‘regulation’ and ‘governance’ describe a continuum, with regulation designating a focus on actors and their influence, while governance is focused more on institutions, their norms and mechanisms of ‘accountability, authority, legitimacy’ (5) (p.18).

This chapter provides the background and focus of my research. Section 1 presents an overview of historical and recent developments in milk sharing relevant to the current regulation of milk sharing in Australia. Section 2 delineates the research problem, as a complex public health policy issue, and milk sharing as an example of a regulatory problem. Section 3 describes the specific aims, objectives, questions and relevance of my research. Section 4 provides an outline of the dissertation.

1.1 Background

Milk sharing has both solved and created public policy problems for millennia, for example through wet-nursing. These public policy problems concern the social ordering of infant nutrition and survival, women’s roles and the transmission of infectious disease. However, this ordering is not straightforward. Milk sharing is positioned relative to breastfeeding and various substitutes for

¹ ‘There will be continued funding for donor breast milk bank services (\$6m), and the Australian Breastfeeding Association’s National Breastfeeding Helpline (\$4.8m)’ (1).

human milk, including modern commercial milk formulas (CMFs).² These ‘triangulated’ positions are in dynamic tension and shift, according to political economic conditions, as histories of infant feeding show. But first, some clarification is needed of the terms used to describe human milk sharing.

1.1.1 Core definitions and concepts in milk sharing

Milk and how it is shared

Terms used in infant feeding carry cultural assumptions and historical legacies that often obscure milk sharing. In this thesis, ‘milk’ refers to human milk (breastmilk) unless stated otherwise.

Breastfeeding means suckling a child directly at the breast, typically by the birth mother. However, in policy and practice, breastfeeding often means ‘fed breast milk,’ without distinguishing the method used to feed milk or whose milk is used (6-10).

Various types of milk sharing are differentiated by their relational, operational and commercial arrangements. I use ‘milk sharing’ as a general term for all practices in which a lactating mother provides her milk to someone other than her biological (birth) child. ‘Milk sharing’ is used in preference to ‘milk exchange’ to emphasise the social act of distributing milk rather than milk as a commodity. The term ‘donor milk’ means milk that is shared, irrespective of whether payment is involved or not (‘altruistic’ donation). Donor milk may be used in its ‘raw’ state, but is typically frozen for storage and transport, and may be pasteurized (PDHM) or treated with other methods or processed into ‘donor milk products.’

This broad definition of milk sharing includes cross-feeding (feeding someone else’s child at the breast) and sharing expressed milk through milk banks or private arrangements (‘informal’ milk sharing). ‘Wet-nursing’ means the act of cross-feeding, but has associations with payment.

Milk banks are organizations that collect, store, process and distribute donor milk (11). Their operations include recruitment, screening and testing of donors and, typically, pasteurizing and testing donor milk. Milk banks are often associated with hospitals but may be independent and located in the community. However, other forms of medically-supervised milk sharing also occur. For example, ‘directed donation’ is the provision of unpasteurized milk from a donor known to the recipient mother, with prior screening and testing of the donor and her milk.

Milk sharing may occur under a range of commercial arrangements. For example, milk banks may be non-profit or for-profit entities, but involve altruistic donation and cost recovery. Similarly, informal

² CMFs include a range of commercial products developed for infants and young children in various age groups: preterm infant formula (premature infants); infant formula (0-12 months); follow-on infant formula (6-12 months) and growing up formula (‘toddler milk’) (12-36 months).

milk sharing may involve payment, compensation or the sale of milk. Distinguishing these concepts requires knowledge of the actors involved in various 'supply chains' for shared milk, from producers to consumers, and the distribution of costs and value.

Gender and language in milk sharing

Lactation is generally a sequel to pregnancy and birth, functions that define the female sex and carry powerful associations with gendered, mothering roles. However, lactation and milk sharing can transcend conventional associations between reproduction, sex and gender, to include a variety of actors and family structures in milk production and consumption.

In this thesis, I use terms for gendered roles adopted by the actors in my research. My research includes participants recruited as 'mothers,' who presented as women and discussed their infant feeding issues from that perspective. The potential for gendered language to bias my research was balanced by the risk of alienating those who identify with gendered terms and obscuring the social, political and economic conditions of breastfeeding women (12, 13). To those who prefer gender neutral language, I apologise for any offence and recognize the discrimination experienced by many non-binary and gender fluid parents in their pursuit of the best nutrition for their infants (14).

Infant feeding as a three-way contest

The triangulated regulatory relationships between milk sharing, breastfeeding and CMFs entangles milk sharing in much larger conflicts between powerful public health and commercial interests –the 'politics of breastfeeding' (15). In these politics, milk sharing occupies an ambiguous position, with potential to destabilize breastfeeding or CMFs (16), and affect their supply and demand, as this thesis shows.

An important precursor to investigating the regulation of milk sharing is an understanding of the status of breastfeeding and the political economy of infant feeding. Breastfeeding is precarious globally and in Australia (17). The WHO recommends that infants are breastfed exclusively to six months, when complementary foods should be introduced, while breastfeeding continues to at least two years of age (7, 18). Globally, 48% of infants under six months are exclusively breastfed (17). In Australia, a 2010 survey showed that 96% of mothers initiated breastfeeding but only 15% of infants were breastfed exclusively to 5 months, and 2% to six months (19). By 12 months, only 20% of infants received any milk and 80% of infants were fed CMFs.

Breastfeeding helps prevent infant and young child mortality and morbidity from infectious and non-communicable disease and cognitive losses, and reduces lifetime risks of cancer and cardiovascular disease in women (20-29). The global cost of inadequate breastfeeding to health and human

development is estimated to be \$USD 341.3 billion annually (30, 31). In high income countries, the cost to health systems of infant illnesses attributed to suboptimal breastfeeding was \$13 billion in the USA (32) and £17 million annually in the UK (33). In one small Australian jurisdiction, the ACT, this cost to the hospital system was \$1-2 million annually (34).

The distribution of these breastfeeding and health outcomes is inequitable. In Australia, rates of breastfeeding exclusivity and duration follow a social gradient, with higher rates achieved by women with higher incomes and education (35-44). However, understanding trends and patterns in breastfeeding are hampered by inconsistent survey methodology or commercial conflicts of interest in infant feeding studies (45, 46). Milk sharing is not included in these studies.

The social and economic conditions that enable breastfeeding are shaped by an array of public policies to promote, protect and support breastfeeding and ensure the appropriate use of CMFs. However, these measures require investment by governments. Currently, demand for CMFs drives a globalized industry with sales worth US\$54 billion in 2022 (31, 47-50). In Australia, supplementation starts early, in the health system, with 30% of newborn infants fed CMF before discharge from hospital, and the highest rates of CMF feeding in hospitals in areas of social and economic disadvantage (51, 52).

Measures to protect breastfeeding include policies to restrict CMF marketing. Marketing CMFs to consumers and through the health system is restricted by two global policies, the *WHO International Code of Marketing of Breastmilk Substitutes* and subsequent World Health Assembly resolutions (the WHO Code) (53), and the *Baby-Friendly Hospital Initiative* (BFHI) (54). However, in Australia only 21% of maternity facilities are BFHI accredited (55) and Australia's implementation of the WHO Code as an industry self-regulated voluntary code of practice is among the weakest in the world (56). In addition, the Australian government has been described as a 'bad policy actor,' domestically and internationally, for enabling the CMF industry to interfere in food policy forums and subsidizing the marketing of Australian CMF exports in destination countries (57-61). These failures of government in infant feeding are grounds for concern that the regulation of milk will be subject to similar market forces, and fail to protect the interests of infants and mothers.

1.1.2 Historical overview of Australian milk sharing

This section provides an overview of historical developments in milk sharing relevant to its regulation. This overview emphasises milk sharing practices in Australia until the early 21st century, when milk banking was re-established (in 2006) and social media was used to share milk in the community (in 2010). These developments illustrate the ways that milk sharing is problematized and some of the social and institutional legacies that shape the current regulatory landscape.

Prior to European colonization, breastfeeding by Aboriginal and Torres Strait Islander (Indigenous) groups included cross-feeding practices that continue to the present (62). Following colonization, Aboriginal women were used as wet-nurses and domestic workers within exploitative systems of unpaid labour that persisted to the mid-20th century (63, 64). Breastfeeding the children of 'white bosses' created resentment and shame surrounding breastfeeding that, arguably, contributed to current low rates of breastfeeding in some Indigenous communities (64).

In Australian colonial society, wet-nursing was practiced in foundling hospitals and affluent households until the first decade the 20th century and was relatively well paid (65-67). These arrangements were riven with moral ambiguity (68). Wet-nursing was a respected profession, practiced by married rural women looking for additional income, but also an opportunity for poor, unmarried mothers, and stigmatized when used for infants who were unwanted or could not be cared for, or carried the threat of infectious diseases like syphilis (66, 67, 69, 70).

In the early 20th century, wet-nursing declined as other types of employment became available to women and public health measures reduced rates of maternal and infant mortality and ensured safer supplies of cows' milk and CMFs. In Australia, wet-nursing was not immediately replaced by milk banking, as occurred in the USA and some European countries. However, in 1941, a milk bank at George V Hospital in Sydney was established based on methods from the US (71) and in the 1940s and 1950s nurses in Australian maternity hospitals routinely pooled expressed milk from mothers on postnatal wards to feed fragile, hospitalized infants (66, 72). These medically-supervised mothers supplied a milk bank in Rockhampton in Queensland, for example (66), but from the 1950s, this type of milk donation was replaced by CMFs, which then dominated infant feeding (72, 73). Breastfeeding, which had been encouraged by the medical profession in the first half of the 20th century, then rapidly decreased, reaching a nadir in the early 1970s (74-76), displaced by the aggressive marketing of CMFs (74, 77).

In the 1970s, renewed interest in breastfeeding encouraged informal milk sharing in the community (78). Intermittent attempts were made by some regional hospitals to obtain supplies of donor milk from mothers (73, 79), and these projects often involved local collaborations with the Nursing Mothers Association of Australia (NMAA),³ a national non-government organization (NGO) to support breastfeeding. In response to demand, from 1975-77, NMAA developed a donor screening questionnaire and policies for supplying donor milk to hospitals (66) and sharing milk in the community. However, by 1979 these policies were withdrawn over concerns about legal liability (78).

³ NMAA was later renamed the Australian Breastfeeding Association (ABA)

Potential liability also inhibited the use of milk sourced informally in medical settings, which contributed to the 'hiddenness' of this practice and the 'mutedness' of health professionals ('questions not being asked') (80).

In 1985, the discovery that the human immunodeficiency virus (HIV) could be transmitted through breastfeeding (81) was cataclysmic for milk banks and informal milk sharing worldwide (82). Some overseas milk banks reopened within two years of HIV appearing, using protocols for testing donors and pasteurization of milk. However, in Australia, it took several decades for milk banking to recommence. In the late 20th century, the lack of milk banks and medically-supervised systems of donation meant that donor milk was only available through informal practices (62). NMAA provided advice on cross-feeding for adopted and surrogate infants (66), but cross-feeding was a private activity by mothers who knew each other (62, 80, 83). Inter-generational cross-feeding by aunts, great-aunts and grandmothers occurred in Indigenous (62, 66) and immigrant Pacific Islander families, 'as an extension of co-caring and an extended family style of child raising' (80).

The discontinuity between wet-nursing and the establishment of milk banking in Australia severed associations between milk sharing and payment. Payment was not part of providing milk to hospitals or through community arrangements (62, 80, 83). By the 1980s, public opinion in Australia was that milk donation should be unpaid, similar to donation of blood (62, 83) but the lack of support for milk sharing by public institutions left it under-resourced, under-developed and unregulated.

In contrast, in many other high income countries, milk banks were established immediately after the demise of wet nursing (82, 84) and continued the social and regulatory arrangements of wet-nursing (82), structured by social class and morality (65, 85-87). In some countries, the milk banking was administered by the state, for example France, while in others, for example the USA, the regulation of milk banking was 'minimal and irregular,' leading to governance through a mix of medical oversight, NGOs and free markets (88-90). Globally, demand for PDHM increased with improvements in the medical care and survival of extremely premature infants. By 2023 there were 31 milk banks in the USA and Canada (91). Globally, by 2022, there were 700 milk banks in 66 countries (92), of which about one third half were in Europe⁴ (93). This includes an extensive publicly funded national network of 222 milk banks and 219 milk collection stations in Brazil (94, 95).

1.1.3 Contemporary milk sharing

Milk banks and their governance in Australia

Australian milk banks were not established until 2006 (96), but by 2012 five not-for-profit milk banks were operating in four states (Table 1). Outside hospitals, supplies of PDHM to the public were very limited, and milk sharing in the community persisted in private arrangements (62, 80, 83, 97).

However, led by NICU demand, milk banking expanded, albeit in an unregulated manner. Annually, about 8% of Australia's roughly 330,000 births are premature, and the target 'market' for milk banks are those infants that require intensive support in Australia's 25 level 3 NICUs and whose mothers cannot provide their own milk (about 2.6% of all infants) (98). Despite the development of milk banking, it took time for PDHM to gain credibility with the medical establishment in Australia.

The principal clinical benefit of PDHM is reducing the incidence of necrotizing enterocolitis (NEC), a severe gastrointestinal disorder associated with extreme prematurity and very low birthweight, which affects approximately 4-7% of these infants in Australian NICUs (99-105). NEC has a case fatality rate of 20-40% (106) and the costs of treating surgical cases amount to hundreds of thousands of dollars, with the risk of lifelong impairment to the child's nutrition and development (107-111). However, milk banks face economic barriers in Australia⁵ (112, 113), and use of PDHM is restricted by its availability and price.⁶

In response to these issues, in 2014, a Commonwealth Department of Health discussion paper raised questions about access, safety, ethics and the wider role of shared milk in infant feeding (11).

Australia did not have a national milk banking association or standards and milk banks operated independently, mostly administered by hospitals within a range of state health systems. Proposals to formalize a national network for milk banking and the distribution of PDHM were unsuccessful (114). This meant that NICU access to PDHM was inequitable, leading to several petitions to establish milk banks in jurisdictions without them, and secure public funding (115-117). In 2019, a feasibility study for a milk bank in the ACT estimated that if 5% of local mothers donated milk, they could feed all the infants that needed CMF in the first week of life in the ACT (113). However, the cost-benefit analysis showed that it was cheaper to ship milk in from another milk bank, produced by mothers in another city. This decision did not address local informal milk sharing (113, 118). Existing milk banks responded to these demands by shipping PDHM interstate (Table 1) (119).

⁵ The cost of establishing a milk bank in Australia is approximately AUD\$150,000-\$1,010,500 (112, 113).

⁶ While data are not readily available in Australia, in other countries PDHM costs USD\$107-\$510 per litre (119, 125, 126).

Proposals to commercialise and import milk started in the mid-2010s. In 2016, a major development in Australian milk banking was the establishment of non-profit milk bank by the Australian Red Cross Blood Service, later rebadged Lifeblood Milk, the only country to do so outside Canada (90, 120). By the time the milk bank was launched in 2018, the program had expanded to supply all eligible NICUs in NSW (with approximately 1000 eligible infants) and South Australia (121-123).

Table 1 Australian milk banks.

Milk Bank	Location	Date established	Type	Commercial structure	Services
<i>Royal Prince Alfred Hospital</i>	Sydney, NSW	2005	Hospital-affiliated	Non-profit	In-hospital only
<i>PREM Bank at the King Edward Memorial Hospital</i>	Perth, WA	2006	Hospital-affiliated	Non-profit	In-hospital only
<i>Mothers' Milk Bank Charity</i>	South-east Qld	2009	Independent	Non-profit (Charity)	Hospitals in SE Qld, ACT, To public
<i>Mercy Health Breastmilk Bank</i>	Melbourne, VIC	2011	Hospital-affiliated	Non-profit	In-hospital only, expanding in 2019 to supply 4 other hospitals in VIC
<i>Queensland Milk Bank (formerly Royal Brisbane and Women's Hospital Milk Bank)</i>	Brisbane, Qld	2012	Hospital-affiliated	Non-profit	Hospitals in Qld, TAS
<i>Australian Breast Milk Bank*</i>	Sydney, NSW	2015 -2019*	Independent	For-profit	(Intended to supply public)
<i>Lifeblood Milk (formerly Australian Red Cross Lifeblood Milk Bank)</i>	Sydney, NSW	2018	Independent	Non-profit	Hospitals in NSW, SA, (WA from 2022)

*Product launched but sales did not proceed

By 2022, Lifeblood Milk had merged with the Queensland Milk Bank and dominated the milk banking sector (124), supplying six States and Territories, including hospitals in Western Australia not served by the PREM Bank (125). A potential concern about the involvement of blood banking in milk is blood banking's association with commerce. In Australia, the non-profit blood bank, Lifeblood, has contracts to provide plasma to CSL, an Australian for-profit company that is one of the world's largest manufacturers of biopharmaceutical products, with annual sales worth US\$10 billion in 2022 (126).

In 2016, the Australian Government granted an import licence to an Australian-Indian company, Neolacta Lifesciences, that intended to import milk from India to supply PDHM to hospitals and potentially the public (127). This proposal raised questions about potential exploitation and commodification of milk from poor countries, amplified by concerns about a milk export project in Cambodia around the same time (128-131). Concurrently, a US for-profit company, Prolacta Bioscience, was interested in export markets, including Australia, for its human-derived fortifier

product for premature infants (132-134).⁷ This company is reported to pay milk donors about \$USD1.00 per ounce. More recently, companies in India and the UK commenced producing commercial fortifiers and other milk products (135, 136),⁸ raising concerns about their regulation, specifically their efficacy, cost,⁹ marketing and the potential exploitation of donors (130, 137-139).

These power imbalances, between milk donors in low-income countries (LICs) and recipients in high-income countries (HICs), reproduce the class exploitation that occurred throughout the history of wet-nursing (65, 82, 84-90, 140, 141). Such arrangements challenge the moral framework of milk sharing and concepts of 'donation' and 'surplus,' when it is needed in countries or communities with inadequate rates of breastfeeding (142, 143).

In 2015, Australia's first commercial, for-profit milk bank, the Australian Breast Milk Bank, was launched in NSW (Table 1). The company aimed to process donor milk using novel technologies (high-pressure and freeze-drying) to improve its immunological activity, shelf life and transport costs (144, 145). This brought international attention to Australia, as the second country after the US to commercialize milk products (146). However, regulatory issues delayed product sales (144, 147) and the milk bank closed around 2020. Corresponding innovations are being developed overseas, building on practices in some European milk banks to freeze dry milk for storage or use as a fortifier (148-150). Other recent commercial developments include ultra-high temperature processing and retort pouches in the USA (133) and services in the USA, India and Australia for mothers to freeze dry their own milk, to use when they return to work (151-155). Regulatory frameworks are tested by these developments, and legal disputes, patenting, investor, ethical and contamination problems currently challenge the viability of commercial milk banks and milk products companies in the USA (Medolac)(156), UK (NeoKare Nutrition) (157) and India (NeoLacta Lifesciences and Neslak Biosciences) (137, 158). These commercial actors and their institutional relationships raise the stakes in the governance of milk banking, and the emerging 'politics of milk' adds to the complexity of the 'politics of breastfeeding.'

Technologies and milk sharing: scaling up

Modern milk sharing is also facilitated by more prosaic but important technological developments, that shape regulatory concepts of 'surplus' and 'wasted' milk. The supply of surplus milk is driven by the normalization of electric breast pumps in hospitals and homes from the early 2000s¹⁰ in Australia

⁹ These products cost up to 10 times the cost of fortifiers derived from bovine milk (166).

¹⁰ Breast pumps are used by over 80% of mothers in Australia (159-161).

(159-161) and the USA (162, 163). These norms are spurred by the promotion of expressed milk feeding as 'next-best' to breastfeeding by government nutrition advice, workplace policies and breast pump manufacturers, with breast pumps routinely given as gifts to pregnant women at baby showers (164-166).

However, milk expression also dysregulates the finely-tuned balance of milk production and intake by a breastfeeding mother and her infant (a breastfeeding 'dyad') (164, 167). Reports of women who donate hundreds of litres of milk show the risks, for some women, of overstimulation of lactation from excessive pumping (168-175). These women are sensationalized in the media and valued donors to milk banks and recipient mothers because they reduce the transaction costs of milk sharing (176).

Pumping and the accumulation of excess stored milk are important drivers of 'surplus' and 'wastage' of milk, which underpin milk sharing. Images of freezers full of milk are prominent on social media pages for milk sharing (177-180), and preventing the wastage of stored milk justifies milk banking (96, 116). These 'stashes' of milk also present business opportunities (181) and legal risks for lactation consultants. This surplus and wasted milk contrasts with the concept of 'lost milk,' which is the unrealized potential production of milk caused by inadequate breastfeeding (182).

A second major technological stimulus to modern milk sharing was the internet. From early 2000s, the internet was used to connect donors and recipients in altruistic arrangements and to sell milk in the USA (178, 183).¹¹ However these practices accelerated with the advent of social media pages to share milk from 2010 in the United States and 2011 in Australia (188). The details of these exchanges are obscured by the group structures and privacy settings of social media platforms, but they involve thousands of participants (168). Online milk sharing has been described as facilitating 'on a global scale, the establishment of local relationships' (189), but the status of informal sharing outside the USA is poorly understood. Soon after the emergence of informal milk via social media these practices were sensationalized in the media and reported as a clandestine 'black market' in milk, a framing that persists in scholarship on milk sharing (138, 142, 190-198). In response, health authorities issued warnings and position statements advising against informal milk sharing, portrayed as 'online' commercial exchanges between strangers (199-206) or competitors for the supply of milk to milk banks (207). These representations pitted informal milk sharing and milk banking as separate sectors in opposition with each other (208).

¹¹ However, from about 2006, general websites, including 'eBay' and 'Craigslist,' banned the sale of milk to comply with laws in four US states that classified human milk as a bodily fluid (183-187). However, a website established in 2009 to sell and donate milk, 'Only the Breast' (180) continued (187).

1.1.4 Milk sharing: a regulatory issue

This chapter has sketched out the various ways that milk is shared in Australia and some of their influences and regulatory issues concerning value, ownership and control. Figure 1 maps out the flow of milk from suppliers (mothers) to various users, and the different types of ‘processors’ and settings involved in Australia, through milk banking and informal arrangements, with potential pathways for imported milk and commercial transactions. At each branch in this milk ‘supply chain,’ actors make decisions, shaped by social, legal and economic factors that regulate who produces and can access milk, from fragile babies to bodybuilders. Whole sectors can be switched on or off, made visible or invisible, by policy or social repugnance. These ‘decisions’ are not simply about milk, but the way competition is structured between shared milk, breastfeeding, and CMFs in each setting. However, to contain the scope of my research, my main focus is on the uses of milk for infant feeding, mapped out in Figure 1, as the foundation for future work on commercial and other uses of milk.

The regulatory and technological developments outlined in this chapter flag a future for milk sharing shaped by markets and disputes over intellectual property in milk and the value of women’s labour (130, 156). Australia is uniquely positioned to engage in this market, but before moving in this direction, there is an urgent need for Australian authorities to understand the local terrain: the practices and cultures of various forms of milk sharing, their drivers and governance. It is equally important for Australian women to understand the regimes in which they share milk.

The chapter has also described how regulatory approaches to milk sharing are often inconsistent and underdeveloped. In public policy, milk sharing is ignored or occupies an uneasy position, fraught by what is deemed acceptable and safe. Milk sharing triggers social anxiety about bodily fluids, sexually transmitted disease and morality, fuelling a complex regulatory problem ‘beyond the state’, at the intersection of public and private domains and engaging a range of state or non-state actors. Part of the complexity of this ‘issue’ is its dichotomous nature: while informal milk sharing is framed as a regulatory ‘problem,’ milk banking is framed as a social good. Arguably, problematizing milk sharing needs to focus on how it affects breastfeeding.

However, the obscurity of milk sharing as a regulatory issue makes it difficult to measure and understand its scope. Statistics on the prevalence of different milk sharing practices, the volume of milk provided through these arrangements, and what is ‘surplus,’ ‘wasted’ and used for infants and other purposes are difficult to define and collect. At the highest levels of governance, this gap represents the gendered neglect in public policy making and economic frameworks of women’s labour and the value of their milk (209, 210).

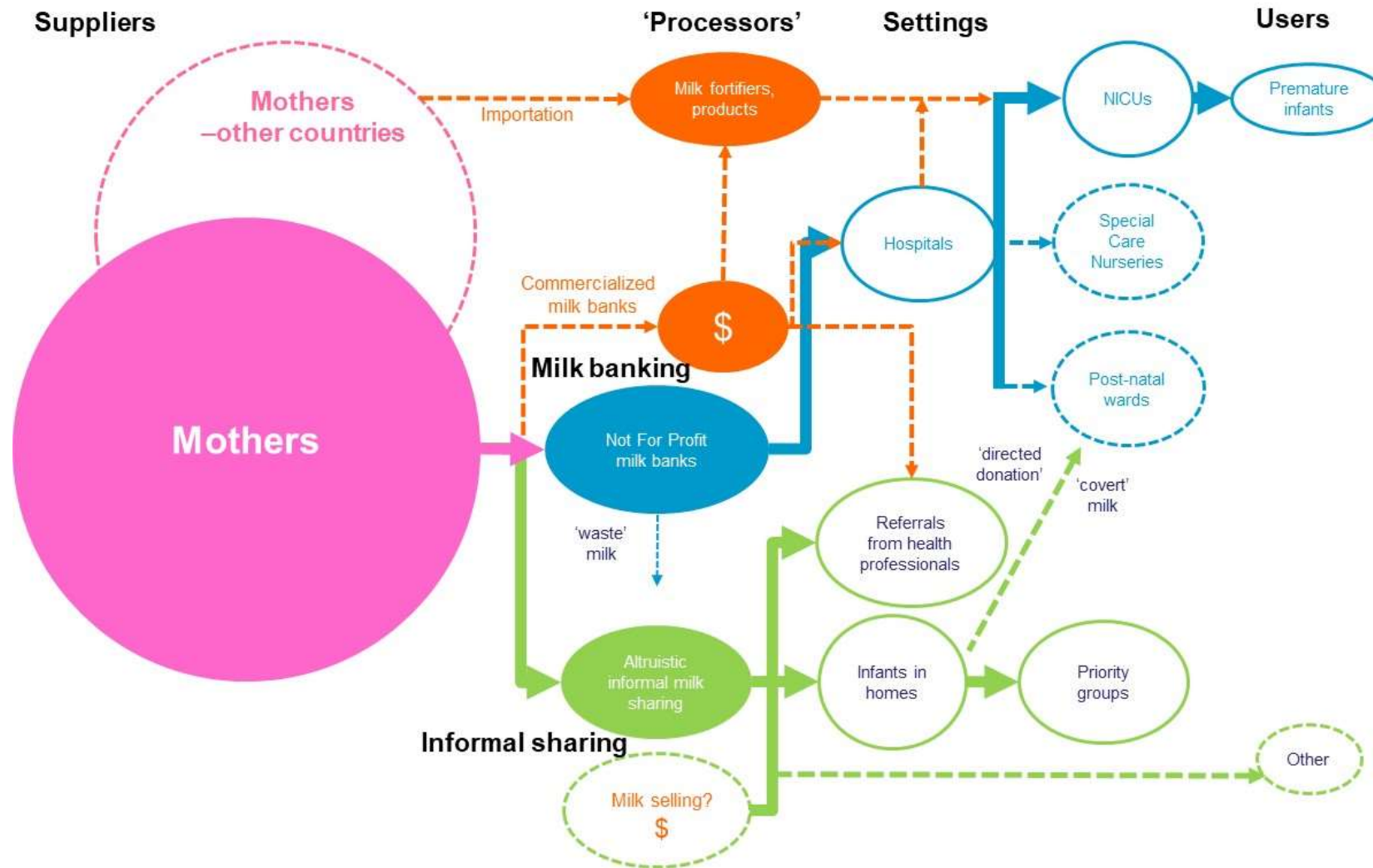


Figure 1 A map of the flow of milk from suppliers to users through various pathways for milk banking and informal milk sharing in Australia.

Yet, beyond the gaze of officialdom, alternative social structures around the exchange of milk create a rich field of human activity, in which everyday practices are themselves a form of regulation, dictated by social rules and biological and material constraints. At the micro-level of governance, milk sharing relies on the disruption of the mutual physiological feedback between a breastfeeding mother and infant (211).

Understanding milk sharing requires understanding local contexts: historic influences on current milk sharing practices and social, medical and commercial interests in milk. Understanding the power of these interests and their various regulatory mechanisms are key to disentangling the commercial and social determinants of milk sharing, breastfeeding and CMF use. Addressing this triangulated regulatory issue requires interdisciplinary and pluralistic approaches to regulation, and empirical research (212). The literature shows that studies of milk sharing require a detailed understanding of how breastfeeding works, its complex ecology and ‘politics.’ It also requires an understanding of the unique features of milk (and its various ‘supply chains’) compared to other donated human tissues, and the systems of knowledge that dictate the management of milk in health settings and its distribution in the freezers of suburbia. Who produces milk, controls it and gets it, may disrupt or reinforce the social and economic structures of breastfeeding. The literature shows substantial gaps in knowledge and theoretical approaches to these issues.

While Australian milk sharing practices resemble those in other high-income countries, their governance differs. Australian milk banks lack centralized regulation by the state, as in France, but also lacks governance by a national association, as in the USA. Australia’s long history of informal sharing without milk banking retained a firm grip on milk as a food, unlike regions where the dominance of milk banking led to the framing and regulation of donor milk as a medicine or human tissue (213-215). However, in common with many countries, the relationship between milk sharing sectors and breastfeeding is unclear in Australia. There is limited evidence of how different forms of milk sharing are currently practiced and contribute ‘on the ground’ to infant feeding decisions by mothers and their medical advisors (216). The attitudes of health professionals and NGOs are unclear and contribute to uncertainty about the safety of milk sharing and its role in breastfeeding. At higher levels of governance, it is not clear how informal milk sharing interacts with milk banking and emerging commercial sectors or how policy for milk sharing is developed across policy domains. These historical and contemporary differences from other countries make Australia an example of the heterogeneous governance of milk sharing, with unique characteristics that may offer insights into regulatory approaches elsewhere.

1.2 Research aim, objectives, questions, and relevance

Academic studies have approached different types of milk sharing from legalistic, public health nutrition or social sciences perspectives, highlighting the plurality of regulatory mechanisms but failing to align them with the sociocultural and political economic mechanisms that enable breastfeeding. However, there are few regulatory approaches that bridge the span of governance required to tackle this problem. This research set out to develop, empirically, an approach to regulation that linked macro-level societal ideas and organizational interests to micro-level embodied, physiological processes.

The research aims to develop a deep understanding of the ways that milk sharing is regulated in Australia through legal, policy and social mechanisms and their implications for infant feeding. The overarching research question is *'How does the regulatory regime for milk sharing shape breastfeeding in Australia?'* Australia provides ideal conditions for this research: both milk banking and informal milk sharing are practiced but breastfeeding is precarious and milk is exposed to emerging commercial interests. Specifically, the research aims to understand the regime of actors, institutions and ideas that regulate milk sharing, guided by the following objectives and sub-questions:

Objective 1: Understand how institutions frame milk sharing.

- i. What are the legal structures (laws and policies) that regulate milk and milk donation in Australia?

Objective 2: Understand the conditions under which milk sharing occurs.

- i. What factors shape the milk sharing behaviours of mothers in Australia?
- ii. What factors shape the behaviours of milk banks and other actors and institutions engaged with milk sharing in Australia?

Objective 3: Understand the regulatory regime of actors, ideas and institutions that shape the way milk is shared.

- i. What are the interests and power of actors and institutions in the regulatory regime for milk sharing?
- ii. What are the regulatory mechanisms used by actors and institutions engaged with milk sharing in Australia?

Objective 4: Understand how the regulation of milk sharing shapes breastfeeding.

- i. How do the actors, institutions and ideas that shape milk sharing, their interests, power and regulatory mechanisms shape breastfeeding?

The approach used in this research has potential application in other countries to ensure that milk sharing serves the interests of breastfeeding. More broadly, it offers a way to analyse how power is structured and circumvented, and pinpoint regulatory mechanisms that amplify public goods.

1.3 Outline of the dissertation

The following nine chapters describe how the research problem, questions and objectives were addressed as well presenting the findings. Chapter 2 reviews the academic literature to understand the complex legal, institutional and social mechanisms that regulate milk banking and informal milk sharing and their relationship to breastfeeding. The different disciplinary perspectives show the challenge of governance across milk sharing sectors and settings and understanding how institutions and ideas shape local conditions for milk sharing. The limited studies of milk sharing practices in Australia since the emergence of social media and re-establishment of milk banking, showed the need for empirical research on legal structures for milk sharing and their effects on multiple actor groups, grounded in the experiences of mothers.

Chapter 3 describes theoretical perspectives and models of regulation and governance appropriate to milk sharing, which were used to design the research and collect and interpret the data. Two theories were used to account for multicentric governance, in which power was directed in multiple directions 'beyond the state' by an array of actors with various degrees of agency. Burris' theory of *nodal governance* explained the alignment of actors, resources and regulatory mechanisms around specific societal ideas and interests in milk (217). This higher level of organization was combined with an analysis of governance at the level of individuals, using Honig et al and Petersen et al's behavioural model of *actor awareness, motivations, pathways and rewards (AMPR)* (218, 219). In combination, these 'top down' and 'bottom up' approaches provided insights into the institutional, social and material mechanisms that regulated milk sharing and their implications for breastfeeding.

Chapter 4 describes and explains the research design and methods used. The obscurity of milk sharing practices required a qualitative methodology that accommodated the social meaning and materiality of infant feeding within a critical realist world view. The research aimed to understand how institutions framed milk sharing and the conditions under which various forms of milk sharing occurred. The methods used were a document analysis of legal structures and in-depth interviews of

key informants: mothers, milk bank staff, health professionals and policy makers in six Australian states and territories.

Chapters 5 to 9 present the results of this research. Chapter 5 provides an analysis of the legal and policy structures concerned with milk sharing in Australia. It shows that siloed institutions around policy for nutrition, infection control and trade resulted in separate milk sharing sectors and incoherent ideas about the value, costs and risks of milk sharing. A legalistic focus on milk as a product and neglect of human rights and milk sharing processes resulted in failures to integrate milk sharing policy with breastfeeding policy and created the conditions for milk sharing in Australia to be largely self-governed. In this environment, regulation devolved to individuals in clinical settings and homes, leaving non-state actors to pursue personal or organizational interests, rather than public policy objectives for infant and young child feeding.

Chapters 6-9 provides a detailed analysis of actor awareness, motivations, pathways and rewards. Chapter 6 describes how the awareness of milk sharing by various actor groups is suppressed by social and legal mechanisms, while awareness was developed through personal experience and social media. Restricted awareness contributed to silos of knowledge and inconsistent understandings of risk and ethics. More importantly, the regulatory regime's lack of awareness restricted its capacity to govern, and for weak actors, including mothers, to participate in higher levels of governance.

Chapter 7 describes the diverse motivations of actors towards milk sharing. While actor groups agreed on the importance of an exclusive milk diet for infants, they diverged in their positions on risk relative to CMFs. Actor groups were also driven by specific motivations, which included human rights principles, concern for others, medical or narrow organizational objectives. The motivations of health professionals were unpredictable, depending on institutional settings. These motivations were shaped by broader world views about gender, individualism and systems of knowledge that intersected with lactation. Motivations showed how actors were aligned with these ideas and orientated towards milk sharing as a product or process.

Chapter 8 describes the pathways or options for action available to actors, in accordance with their motivations. These options were shaped by pragmatic resources and rules, modified by actor 'mindsets' that narrowed or created courses of action. As regulatory mechanisms, pathways provided actors with differing levels of legitimacy and autonomy, which shaped whether milk sharing was practiced through milk banks or informally, openly or covertly. The analysis showed that despite separate pathways for milk sharing sectors, they relied on common maternal resources, which put the social and economic conditions under which mothers breastfed at the centre of regulation.

Mothers determined the supply of milk, its safety, allocation and relational value linked to breastfeeding's sociocultural processes, while milk banks severed these links.

Chapter 9 describes actor rewards. Rewards were material and intangible, with infant health the most important reward to mothers, milk banks and health professionals in Australia's altruistic systems of milk sharing. In addition, social rewards were of critical importance to mothers. For other actors, these rewards provided weak signals, and, arguably, led to regulatory neglect, which created opportunities for commercial actors, to the detriment of breastfeeding.

Chapter 10 discusses the results, and provides conclusions and recommendations from the research, noting its limitations and contributions to scholarship. It synthesises the findings from the literature review, and studies of legal structures and actor behaviour, informed by the theory of nodal governance, to address the research questions. The research reconfigured the power of state and non-state actors around nodes of biocultural, medical, commercial and patriarchal power that explained the contests of legitimacy, resistance and objects of regulation in the current regulation of milk sharing. These insights form the basis of recommendations for governing milk sharing in ways that support breastfeeding and for further research on commercial interests in milk.

Chapter 2. Literature Review: the regulation of milk sharing

Chapter 2 provides an overview of what is known about the regulation of milk sharing and its effects on breastfeeding from the scholarly literature. A review of peer reviewed journals, books and government reports published from 2000 to 2023 was undertaken on donor milk, wet-nursing, milk banking and informal milk sharing and their regulation. Details of these electronic searches are provided in Appendix 1.

This chapter is structured around three disciplinary fields: regulation, public health nutrition and the social sciences generally, drawing on a structure used in a review of research in milk exchange (220). Sections 2 to 4 of this chapter examine the literature in each of these disciplines with a regulatory lens. Section 5 draws together these findings to show how they regulate milk as a product or process, concepts that help explain the implications of milk sharing's regulation for breastfeeding. Section 6 concludes with the research gaps and regulatory problems that require further theoretical and empirical investigation, and hence the rationale for my research.

As described in Chapter 1, the seminal policy for milk sharing is the WHO/UNICEF 2003 *Global Strategy for Infant and Young Child Feeding*. This policy recommends that infants are breastfed. However, when supplementation is required, the strategy specifies a 'hierarchy' of options that prioritize milk sharing before the use of CMFs ('breast-milk substitutes') (213):

'For those few health situations where infants cannot, or should not, be breastfed, the choice of the best alternative – expressed breast milk from an infant's own mother, breast milk from a healthy wet-nurse or a human-milk bank, or a breast-milk substitute fed with a cup, which is a safer method than a feeding bottle and teat – depends on individual circumstances' (7).

This hierarchy is reiterated in international policies for infant and young child feeding in emergencies and the COVID-19 pandemic (221-223), and widely cited in the literature as justification for various forms of milk sharing. However, when citing this hierarchy, the literature tended to emphasise donor milk over cross-feeding, and risk becoming untethered from breastfeeding, an issue that may reflect cultural and other influences on the research. A second issue identified from the literature is the lack of attention to milk sharing's governance. As shown in Chapter 1, concepts of regulation need to extend beyond formal institutions, to accommodate informal sharing and a range of actors and, most importantly, the bodies of mothers and infants, who regulate milk at the most intimate physiological

level. Bridging these levels of governance emerges as a major theoretical challenge in the regulation of milk sharing.

2.1 Regulatory literature: legalistic perspectives

The regulatory literature on milk sharing focused narrowly on two policy problems: access to milk and risk. Studies about access addressed barriers to the establishment of milk banks, while studies about risk attempted to restrict informal milk sharing. Frameworks for human rights and legal classifications for milk (sections 2.1.1 and 2.1.2) dictated the agencies and actors who governed milk and the contested roles of ethics and markets in the regulation of milk sharing (section 2.1.3). Understanding the ways that these frameworks shaped and linked the governance of milk sharing to breastfeeding are discussed (section 2.1.4).

2.1.1 Human rights frameworks

In a global study of milk banking, Lois Arnold, a director of the Human Milk Banking Association of North America (HMBANA) (213, 224), argued that access to donor milk was an extension of human rights to breastfeeding (225).¹² However, these principles were rarely upheld in public policy, as shown by a 2006 review of milk banking in Australia (73). Consequently, health and economic benefits, rather than human rights, were the basis of recommendations for milk banks in a 2007 Australian parliamentary inquiry (116). More recently, equitable access to PDHM for hospitals has driven the expansion of milk banking in Australia and globally (227-231).

2.1.2 Legal frameworks

Uncertainty about the legal classification of milk as a food, human tissue or therapeutic good was a barrier to establishing milk banks in Australia (11) and many other countries (88-90, 214, 215, 231-238). The European Commission was challenged by the heterogeneity of milk's legal classification across the EU, noting that 'at least 11 Member States currently do not regulate the activity while in others it is regulated under food, tissue and cell, or other frameworks' (239). These regulatory frameworks also had implications for models of governance: in Brazil and France, the regulation of milk as a human tissue promoted centralized governance by medical authorities while, at the other extreme, India's classification of milk as a food enabled the sale of milk and the expansion of milk banking within a free market (215, 240). However, a Canadian study of how donor milk was used in

¹² Human rights to breastfeeding are constituted through the 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' in the following United Nations treaties: 1967 International Covenant on Economic, Social and Cultural Rights; 1981 Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW); 1989 Convention on the Rights of the Child (Article 24), (226).

different settings showed the relevance of all three categories (human tissue, medicine and food) (232), in agreement with a seminal analysis by Cohen (89).

In policy and practice, milk banks and NICUs framed donor milk as a human tissue or therapeutic good (like blood), rather than a food. These medicalized approaches dominate, as shown in recent decisions by WHO to classify 'breast milk used to treat premature infants' as a '*medical product of human origin*' (MPOH) (237, 241-243) and the EC to apply guidelines for donated blood, tissue and cells to milk banks (234, 235, 244). Other countries are likely to follow this direction for milk banking, for example the UK (139), adding to the legal uncertainties around informal milk sharing.

Importantly, despite acknowledging that the regulation of donor milk 'remains open,' the EDQM chapter on human milk reiterates principles of tissue donation that prevent financial gain¹³ (244). However, preventing financial gain appears to counter commercial interests that were behind some submissions to the EC on the regulation of donor milk, and which indicate the complex role of donor milk in the political economy of infant feeding (130, 245-247).

Removed from the specialized requirements of milk banks, milk used in the community is handled routinely as a food, and legal frameworks for human tissue or therapeutic goods create a problematic, dichotomous framework for milk. Consequently, legal scholars described informal milk sharing as a legal 'grey area' in Ireland (248), the UK (142, 191) and Australia (195). These legal opinions emphasised milk sharing's potential risks to infant health and legal liability, citing alarmist media reports and a single US study of purchased contaminated milk (249, 250).

The implications of these studies show that classifying milk requires an understanding of local infant feeding policy and social contexts. In Australia, Bhatia et al argued that access to donor milk should be restricted to milk banks, regulated under uniform national laws for human tissue and a statutory authority, claiming that these institutions would ensure milk's safety and supply, and uphold societal solidarity and women's bodily autonomy (195). However, making informal milk sharing illegal neglects human rights to milk, costs, risk mitigation approaches and effects on breastfeeding, including cultural traditions of cross-feeding. Furthermore, it contributes to framing informal milk sharing as a 'black market' (125).

The challenge of finding a regulatory framework for milk that supports breastfeeding has preoccupied scholars in the USA, where women face multiple structural barriers to breastfeeding

¹³ 'The Oviedo Convention – the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (European Treaty Series, No. 164)' which 'specifically prohibits any financial gain from the body and its parts' (244).

(89, 251, 252). Fentiman recommended a free monetized market for milk to incentivize breastfeeding (251), while Cohen proposed segmenting the market for milk through laws for food, human tissue and therapeutic goods to serve infants with different vulnerabilities (89). This proposal legitimated different needs for milk but compounded its legal complexity and trade-offs between milk supply, cost and safety. Cohen also proposed a novel 'relational' categorization of milk to protect the mother-child breastfeeding relationship, concluding that equitable access to milk could only be achieved by structural reform of breastfeeding rather than 'fragmented and unstable' markets for milk.

In Western countries, these regulatory gaps have prompted policy and position statements by government authorities and NGOs, but their influence and legal status is unclear, but shows an ongoing discourse between health authorities, milk banking associations and social media groups for informal milk sharing (189). A review of 21 position statements from a range of international groups and countries, including Australia (220), showed the dichotomized approaches to milk sharing, as prohibitory or supportive of informed decision making. Policies from milk banking associations and regulators of food and human tissues framed milk exchange in terms of risk and were the most prohibitive of informal milk sharing, while breastfeeding and midwifery organizations focussed on access to milk, and provided pragmatic, evidence-based protocols. However, the review concluded that advising mothers to defer to health professionals was of limited value when many medical staff lacked adequate breastfeeding education (220) and a key structural weakness that contributed to regulatory failures, and resorting to legal waivers (253, 254). These structural gaps are examined further in the literature on public health nutrition and social sciences, reviewed in sections 3 and 4.

2.1.3 Ethical frameworks

The literature showed that medical ethics and bioethics were important regulatory mechanisms in milk sharing. However, missing in ethical debates about milk was recognition of corporate influence in policymaking for infant feeding (31, 47, 58, 255). In a seminal exploration of the ethical issues in milk donation, Shaw (256) identified tensions between individualistic, utilitarian and communitarian values, which arose from different philosophical and political economic frameworks. These philosophical frameworks may not be explicit in studies of milk sharing or the regulation of milk. Two branches of ethics are reviewed here which shape regulation: medical ethics and bioethics.

Medical ethics

Medical ethics is concerned with privacy and informed consent. Principles of donor and recipient privacy and anonymous donation are at odds in cultures that observe milk kinship, which are discussed further in the literature on the social sciences (257). The ethics of informed consent in

infant and young child feeding should require health professionals to include milk sharing options and compare their risks and benefits with CMFs (258).

Bioethics -the role of markets

Bioethics is concerned with human tissue supply, safety and end use and how these issues are shaped by markets. Medical norms for unpaid donation of human tissues are based on a seminal analysis of blood donation by Titmuss, who concluded that altruistic donation promoted safety, affordability and social solidarity (259). A later edition included a chapter on the history of milk donation, which showed the challenges to altruism of wet-nursing and paid donation to milk banks (260), which continued as current systems of compensation by some non-profit milk banks in Europe and commercial milk banks in the USA (84, 90, 141, 150, 261-264).

This utilitarian position on altruistic donation intersected with analyses of its symbolic and social meanings, informed by anthropological studies of 'gifts' that entailed reciprocity (265) or promoted social cohesion (Malinowski 1964 cited in (266)). Selling goods was thought to change or expunge these meanings, and ascribing a monetary value to human tissues was presented in the literature as taboo or tainting the meaning of the gift, framing donor payment as a moral dilemma (the 'gift/commodity dichotomy') (90, 267). However, studies of monetized 'free markets' for human tissues showed that while they often 'dispossessed' the donor, they did not remove relational meanings (90, 268). In contrast to milk, studies show that historical wet-nursing often involved multiple layers of dispossession: of the donor, her infant and status as a mother (67).

The 'gift/commodity dichotomy' was challenged by studies that showed that altruism and commodification coexisted (268). Feminist scholars argued that milk was already commodified through women's labour in producing it (267) but that this labour was undervalued and 'invisible' (182, 209). However, estimating the true value of milk is not straightforward (269). Labour costs are not covered in prices asked on US milk selling websites like 'Only The Breast' (180) and paid by for-profit companies (132), creating a 'highly capitalized and complex market environment' (194).

In Australia, paid donation was proposed by (270) but payment garners greatest support in the USA, where paid maternity leave is lacking (271, 272), highlighting the structural drivers of markets in milk. In the USA, Swanson argued for a semi-regulated market, teasing out legal concepts of civic and private property, and proposing that milk could be sold for public good, enabling women to be the 'subjects... rather than objects of commodification,' (90) (p. 246). Other authors support paid donation with a degree of regulation (271), or recognized that this could coexist with unpaid informal sharing (273).

Despite these proposals, the literature shows a lack of in-depth studies of mothers who are paid for milk. In Australia and the USA, altruistic milk donation has been described as a social norm (83, 274-279). While a few US surveys included mothers who used commercial exchanges through peers or for-profit milk banks (277, 280), mothers' views on compensation or profiting from milk are under-researched. In the USA, a survey by Palmquist and Doehler found that compensating donors (through travel, milk storage supplies and gifts) was 'somewhat important' to recipients (277). Another US study found that mothers were concerned about the motives of those who profited from milk and that selling milk limited access, with only a few mothers considered milk selling legitimate (280). Similarly, in a small Swiss study, one of five mothers considered compensation fair, but had refused to sell her milk to an agent for a German milk products company (281). Other research found that milk bank donors in Brazil stated that financial help would be welcome (282). Clearly, questions of payment and other ethical issues in milk sharing and infant feeding need to be informed by local economic and social contexts (283) and intersectional perspectives milk sharing (284) rather than dominated by Western views (285).

Ethics and gender

Analyses of bioethics with a feminist lens show that gender is leveraged in tissue donation (256) and altruistic milk sharing is critiqued as 'performance' of maternal identity (being a 'good' mother) (286). Maternal identity is also leveraged to keep donor milk affordable (287) and safe, relying on the motivations of donors to care for other infants ('bio-intimate economy of care') (288) and observe hygienic practices ('care work') (289). However, there is a fine line between leverage and exploitation, when milk sharing is structured by discrimination against women's reproductive services, for example, inadequate lactation support or paid maternity leave, as in the USA (15, 90, 252, 256, 269, 271, 290, 291). Gender discrimination also occurs in the ways that milk banks prioritise benefits for the community or shareholders before the needs of donors (292).

The ethics of international trade in milk

Trade in milk has introduced another set of ethical problems. The commercialization of milk, and its trade from low to high income countries, spurred the need for global ethical principles for the 'appropriate use of donor milk... to support breastfeeding,' proposed by the Oxford-PATH Human Milk Working Group *Call for equitable access to human milk for vulnerable infants* (293). These principles targeted four issues: equity in allocation and access to donor milk; the vulnerability of donors, recipients and breastfeeding; autonomy and human rights (293).

International trade in milk has also been framed as an extreme form of exploitative capitalism (240, 294). However, literature on milk has yet to consider legislation to prevent modern slavery, adopted by one milk bank in Australia (295).

2.1.4 Governance frameworks

Despite legal and ethical perspectives on milk, there was limited literature on its governance. At the global level, governance structures for milk banking are emerging, but these remain focused on clinical rather than broader food or breastfeeding policy objectives. However, strategies to address global mortality of children under 5 years caused by prematurity and low birthweight, framed by United Nations Sustainable Development Goals 2 and 3,¹⁴ have provided policy incentives for milk banking (297).

The literature on the governance of milk banking reflect this expansion in milk banking and the interests of milk bank associations in promoting access to PDHM for premature infants (298-303), and include guidelines (238, 304-306) and the need for policy and resources for milk banks, including in low income countries (214, 215, 227, 307). Initial concern that these associations promoted the 'unregulated expansion' of milk banking without sufficient 'evidence of benefit' (308), was superseded by evidence of the clinical and economic benefit of PDHM for premature infants, and its adoption as standard care by influential health authorities and professional associations (139, 203, 227, 297, 298, 309-316).

Despite efforts to protect milk banking through national legislation, as described in section 2.1.2, its governance in many countries devolved to the operational or facility level (307), and much of the literature on milk banking describes the need to harmonize standards for screening donors and processing milk (214, 215, 228-231, 233, 241, 243, 293, 300, 305). In the UK, France and Brazil, national governments issued milk banking guidelines (304, 306, 317), while elsewhere, NGOs took on this role, for example North America (91) and Europe (93), but in many countries, governance and the development of protocols devolved to state/territory governments or individual hospitals. As governing bodies, associations that were NGOs struggled to manage auditing and compliance (318), while governments like Brazil invested in sophisticated national quality assurance systems (94).

The activities of milk banking associations focused on advocacy for milk banking and responses to threats from pandemics and trade. Milk banks were also important voices warning of the risks and competition for supplies of milk from informal milk sharing (200-202, 205-207, 298, 319-321).

¹⁴ United Nations Sustainable Development Goals 2 ('zero hunger') and 3 ('good health and wellbeing') (296).

From 2016, the crises of international trade in milk, epidemics and pandemics (Zika and COVID-19¹⁵ viruses) saw milk banking associations form an umbrella organization, the Global Alliance of Milk Banks and Associations (GAMBA)(322), to coordinate information and research and make progress on consistent standards (228-231, 293, 323). Initial concerns that the COVID-19 virus was transmitted via milk had the potential to derail milk banking and breastfeeding, just as HIV had done. This concern was quickly disproved (324, 325).

These developments in the governance milk banking left unresolved the governance of informal milk sharing, which, like milk banks, were regulated mostly at the clinical level, for example, through protocols developed by the Academy of Breastfeeding Medicine (ABM) (204) and other groups. These are discussed further in the public health nutrition literature on safety (in section 2.2.3).

[How governance of milk sharing affects breastfeeding](#)

Overall, the literature paid limited attention to how various governance arrangements for milk sharing affected breastfeeding. Despite calls for the integration of milk banking and breastfeeding, it was not clear how this should be structured legally, ethically and institutionally. Breastfeeding advocates and policy makers were concerned that donor milk risked becoming a ‘substitute’ for breastfeeding policy and investment, at global (326), and clinical levels (307, 327, 328). This structural displacement added to concerns that the marketing of milk products and lactation equipment, including bottles and breast pumps, undermined breastfeeding and violated the WHO Code¹⁶ (130, 139, 329-331). These issues are re-visited at the end of this chapter (section 2.4).

2.2 Public health nutrition literature: institutional perspectives

The literature on public health nutrition described the regulation of milk sharing through the management of donor milk as a food and its acceptability, access and safety. These pragmatic concerns regulated milk in health settings, at policy and clinical levels, but also shaped milk sharing in the community.

2.2.1 Acceptability

The literature on infant nutrition shows that, despite WHO recommendations for supplementation to include milk sharing (7), ‘public health organizations may only value human milk under certain circumstances’ (332). This section probes these circumstances, showing that acceptability is highly contextualized.

¹⁵ SARS-COV2

¹⁶ WHO International Code of Marketing of Breastmilk Substitutes (53).

The acceptability of donor milk in health settings

PDHM is valued in NICUs for very premature and low birthweight infants¹⁷ who cannot be fed their mother's own milk, as demonstrated by the policies of health authorities outlined in section 2.1.4. These policies are based on clinical and economic evidence that use of PDHM rather than CMF halved rates of NEC (333) and possibly reduced other disorders associated with extreme prematurity, very low birthweight and congenital cardiac conditions (254)¹⁸ and was cost effective for NICUs (108, 335) and health systems in the long term (110). The economic benefits for families and communities have not been calculated.

However, the acceptability of PDHM was limited by slower rates of growth in infants fed PDHM compared to preterm CMFs, although these differences disappear with age (333). Consequently, several international policies recommended the use of fortifiers with PDHM but these policies did not distinguish between bovine- and human-derived fortifiers (139, 203, 297, 336, 337).

Evidence of the efficacy of human-derived fortifiers is mixed, and hampered by the limited number of small studies that compared human- and bovine-derived fortifiers when used with exclusive milk diets (of MOM or PDHM) (333, 338-346) and concerns about 'industry influence' on research (340). For example, a review by Magro and Sammut (347), who claimed the evidence for exclusive milk diets¹⁹ was 'incontrovertible,' cited research by (344) that was associated with Prolacta Bioscience, and this company funded a 'roundtable' which concluded that exclusive milk diets saved hospital costs of up to USD\$3.3 million annually (348). Overall, health authorities needed more evidence to recommend human-derived fortifiers, which were 100 times the cost of bovine-derived fortifiers (139).

While PDHM is now standard care in NICUs,²⁰ its clinical uptake has taken some time (220, 308). Studies in the USA and Iran showed that donor milk was not acceptable to all medical staff or recipient mothers in NICUs (349-354), but this could change with education and familiarity (353, 355). Similarly, a decade ago, not all Australian neonatologists supported the use of PDHM for preterm infants (356). A 2010 survey of health professionals in 25 Australian NICUs showed that only 79% agreed that PDHM was preferable to CMF and only 68% thought that milk banks were justified (357). Doctors were more uncertain than nurses and midwives about infection risks and potential

¹⁷ Typically, infants less than 32 weeks gestation and very low birthweight (<1500g).

¹⁸ Bronchopulmonary dysplasia, late-onset sepsis and severe retinopathy of prematurity (107, 334).

¹⁹ Mother's own milk (MOM), donor milk and human-derived fortifiers.

liability associated with PDHM (357). However, the acceptability of PDHM increased with increased access (358), as discussed in section 2.2.2.

Outside high level NICUs, in neonatal nurseries and post-natal wards, attitudes towards the use of PDHM is less understood, with few studies of PDHM use or medically-supervised milk sharing in these settings in Australia. A handful of hospitals (359) and a few lactation consultants (360) had protocols to use milk from a 'known' donor ('directed donation'). However, informal milk sharing occurred on post-natal wards, and cross-feeding was more common than acknowledged, and attitudes of health professionals ranged from acceptance to denial (80).

The acceptability of donor milk in community settings

The acceptability of informal milk sharing in the Australian community is difficult to assess. As outlined in Chapter 1, informal milk sharing was a private activity but supported by some doctors (62). However, there was limited local research after the emergence of Facebook pages dedicated to altruistic informal sharing ('Eats on Feets' and 'Human Milk for Human Babies') (188). Despite this, Australian researchers were prominent in early international studies of milk sharing via the internet (97, 274, 275, 361, 362). These studies were highly cited, giving the impression that milk sharing was well-researched in Australia, but only seven Australians were included in each of the samples of 23 and 138 mothers studied by Thorley and Gribble respectively.²¹

Following this research, there were three small qualitative studies of Australian mothers who used informal milk sharing. An in-depth study of 13 mothers with insufficient milk included nine Australians (363), a study of eight mothers who shared milk via social media in South Australia investigated attitudes towards safety (364) and, in the same state, a study of 21 mothers investigating attitudes towards donating to a proposed milk bank found that five had shared milk through friends, family or the internet (365). These investigations supported the view that a lack of access to milk banks fostered informal milk sharing (366). However, contextualizing this research was limited by a lack of quantitative data about the prevalence of milk sharing practices in Australia, a problem that occurs elsewhere.

The international literature on informal milk sharing was dominated by studies from the USA. In the USA, two prevalence studies showed high levels of awareness of milk banking or informal arrangements by mothers (77-94%) but lower levels of participation (4-19%), and few who had used commercial exchanges (1.3%) (280, 367).

²¹ Karleen Gribble, pers. comm.

Reviews of informal sharing in the community described 17 empirical studies of mothers, and their motivations and practices regarding acceptability, access and safety (220, 368). In general, mothers engaged in these practices were positive about their experiences, while mothers on postnatal wards who were previously unaware of donor milk were hesitant because of unfamiliarity, disgust, safety or concern about interference with the mother-infant relationship (369).

These studies showed that donor motivations included belief in the importance of breastfeeding and exclusive milk diets, the management of surplus milk and helping other mothers and premature infants (220, 370-372). However, their capacity to realize these goals was shaped by access to milk banks and supportive health professionals, and various philosophical positions, issues which are discussed in the next section. Recipient mothers also valued exclusive milk diets, and, if their infant was premature, health professionals and evidence supported this. Like mothers, health professionals were more likely to accept and support informal milk sharing if they had breastfeeding education or experience (373).

The literature on clinical nutrition increasingly accepted milk sharing for its positive effects on maternal mental health. Recipient mothers felt a sense of relief, validation of their infant feeding decisions and agency in securing or using donor milk (287, 328, 363, 371, 374-380) or managing grief after an infant's death (381, 382) (328, 383). However these benefits did not negate reports by some recipient mothers of mixed feelings, or stress, guilt, insecurity or societal disapproval and institutional stigmatization (354, 380, 383, 384).

2.2.2 Access

Access to donor milk is a central focus of regulation: improving access to PDHM justified the expansion of milk banking and its commercialization, and a lack of access to PDHM justified informal sharing.

In Australia, access to PDHM was highly restricted and inequitable for the first two decades of the 21st century and lagged other high income countries (385), as described in Chapter 1. However, access improved rapidly, and a recent survey showed that 77% of neonatal nurses worked in NICUs that used PDHM (358). PDHM is less available to regional NICUs (358) and not supplied to the Northern Territory (386). In addition, a study of Australian and New Zealand NICUs that used donor milk showed that seven of 18 facilities used unpasteurized milk from screened donors (387).

In the Australian community, public access to PDHM is extremely limited and health authorities, including milk banks, questioned the value and cost of PDHM over CMFs for healthy, full-term infants (329, 356, 366), and ignored the value of unpasteurized milk from screened donors. The supply of

donor milk was not, initially, a concern for milk banks (388) providing PDHM to eligible NICUs (a limited market).

The reasons for a lack of access to PDHM in Australia described in a 2014 government report (11) were similar to those in global studies of milk banking (213-215, 224, 227) and Europe (230, 231, 233, 281, 389). Common structural barriers to accessing PDHM were inadequate policy, funding, insurance coverage and health professional knowledge. A detailed analysis of policymaking for PDHM in the USA, showed the challenges of federal systems of government and the devolution of policy and funding to state levels, insufficient clinical evidence, NGO committees and a failure to implement existing policy (224). Despite these challenges, access to PDHM in the USA and other high income countries increased rapidly in the first decades of the 21st century. From 2007-17, the proportion of US NICUs with PDHM increased to 88% (390-392). This shift in institutional norms spurred interest in using PDHM for infants in less acute care nurseries and post-natal wards (393-402), extending to medically eligible infants the community in the UK (287).²²

These trends reflect a less rigid portrayal of milk sharing sectors and growing recognition of milk sharing as a spectrum of practices (241). Informal milk sharing is seen as a continuation of banked milk (409), based on a more informed and balanced appraisal of the value of unpasteurized milk (410). However this view is not held consistently in health settings, and earlier studies report institutional barriers, for example the need for covert use of milk sourced informally (411-414). In the community, the hidden use of informal milk sharing occurs, in part, because of limited access to services for medically supervised services to exchange unpasteurized milk like 'GETPUMPED!' in Florida in the USA (415), and 'Moedermelk' in the Netherlands, which facilitates contact between screened donors and recipients (97).

The literature also shows increased concern about equitable access to donor milk. In the USA, poor, black and Hispanic populations had less access to PDHM because of variation in policies for eligibility and reimbursement for donor milk in areas where these groups predominated (390, 395, 401, 416-420). Research in Europe also shows that administrative factors at the subnational level restricted access to milk banks (231). Inequities in access to PDHM also arose from discriminatory policies and attitudes of case workers towards surrogacy, foster or adoption arrangements (270, 273, 421, 422). For these families, tensions over access to donor milk promoted covert informal milk sharing, for fear of child removal (279), a fear also reported by biological mothers who shared milk informally (413).

²² This trend is a reversion to easier access in previous decades. In the USA, a 1986 report from HMBANA milk banks showed that they provided 23% of their PDHM to eligible infants and older children and adults, including those in the community (403-405), as did some in Europe (150, 181, 262, 406-408).

Concern about access to PDHM has also focussed attention on the supply of milk and donor perspectives, barriers and enablers. A global review of 28 studies of milk donation by (372) showed that common restriction on milk donation was a lack of time to pump milk, a factor which discriminated against women whose social and economic conditions did not support lactation in homes or workplaces (372).

Equitable access to milk banking has become a global issue (139). Over the last decade milk banking has expanded into low- and middle-income countries and more attention is being paid to scaling up this sector (92, 214, 227). In these countries, the importance of breastfeeding has brought greater scrutiny to how models of milk banking affect breastfeeding so that 'scaling up' milk banking does not undermine breastfeeding (92, 326). A preliminary analysis of milk banking governance, showed that 'process-oriented' models of milk banking better supported breastfeeding than 'product-oriented' models (92). This is exemplified in Brazil, where a focus on breastfeeding rather than milk promoted a distributed rather than a centralized model of milk banking, as centres of breastfeeding support, milk donation, research and health professional education (94). Centralized models of milk banking in other countries, for example France, do not provide breastfeeding support or PDHM to the public. In some countries, independent milk banks help fulfil this role (287).

2.2.3 Safety

Concepts of safety and risk in milk sharing are constructed socially and scientifically. In a continuation of historical perspectives, the risks of wet-nursing, the public health nutrition literature has a specific focus on the risk of disease transmission, especially through informal milk sharing arrangements. In health policy and legal systems, the framing of risk from milk also potentially frames mothers as 'toxic' (423-425). These frameworks 'preserve not only social systems but the common understanding of what threatens those social systems' (425). Accordingly, the conceptualization of risk in milk sharing needs to be locally specific, and take account of the cultural importance of breastfeeding to mothers, as well as infant health (285).

Unpasteurized milk potentially contains pathogenic bacteria and viruses, medicines, illicit drugs and environmental contaminants (426, 427). However, there are few cases of disease in infants attributed to milk for many of these hazards, with the important exceptions of HIV and Human T Lymphotropic Virus (HTLV) and, in premature infants, cytomegalovirus (CMV) (428). The safety of PDHM is widely accepted and confirmed by the paucity of adverse outcomes from banked milk (220, 429, 430). Recent Australian studies by Lifeblood Milk validated the safety of its PDHM: donors were excluded on caffeine and medicines rather than viruses of concern (431, 432). This encouraging result is partly because the milk bank's website requires prospective donors to screen themselves on

‘health and lifestyle issues,’ which mothers in earlier studies of informal sharing were also aware (62).

Attitudes to the safety may also shift with new research in milk science that replace earlier concepts of milk as a sterile product. Studies of the human biome recognize milk’s beneficial bacteria and components (433), but the effects of exclusive milk diets on the gut microbiome of premature infants are difficult to quantify (434). Actors must also weigh up the risks and benefits of milk sharing options relative to those of CMFs (435, 436), and construct ‘multiple orderings of safety’ (349). However, risk remained the defining regulatory issue for informal milk sharing, based on a single study of contaminated milk sold via the internet in the USA (249, 250, 437, 438), despite criticism that it misrepresented altruistic informal practices (439-441). A more recent study compared the level of microbial contamination in milk shared altruistically and found no difference between milk collected for informal networks, a non-profit milk bank and a mothers’ own use (442). In addition, Australian and international reviews found that there were no reported cases of adverse infant outcomes from using unpasteurized milk shared in altruistic informal arrangements in (220, 429, 430), but this lack of data may not be meaningful if milk sharing needs to be hidden.

Studies of mothers who shared milk informally showed they were generally aware of risks and exchanged milk in person, but inconsistent in their adherence to milk hygiene and donor screening (277, 361, 443). However, Australian studies described ‘informal screening’ by mothers who knew each other by (62, 97, 364), in agreement with a US study by Reyes-Foster et al (415), which identified ‘a variety of resources’ or strategies to manage risk, with Mumme et al (364) describing risk assessment as a ‘rational...as well as an emotional process.’ Research showed consistently that mothers assessed the risks of milk sharing relative to the risks of CMF for their infant, in Australia (62, 80, 97, 364) and internationally (168, 169, 266, 274, 275, 278, 279, 361, 362, 364, 414, 415, 435, 441, 443-450).

A concern for health authorities was the limited involvement of health professionals in decisions of mothers to share milk informally, as shown in studies in Australia (363, 364) and internationally (274, 361, 367, 445, 449, 451, 452). Despite some reports from mothers of supportive interactions with doctors, midwives and lactation consultants (62, 276, 412, 414, 448, 450, 453), others felt unsupported or the need for ‘secrecy and avoidance’ to avoid stigmatization (413, 414, 450). From the perspective of health professionals, involvement with milk sharing outside milk banks was limited by economic and professional risks from a suite of problems: legal liability, inadequate knowledge of breastfeeding and milk sharing options and ‘backlash from colleagues’ including in NICUs (281, 353, 357, 365, 412, 444, 454), and there were few published case studies of applying protocols for

informal milk sharing in the literature (181, 368, 412). For example, a recent article for Australian general practitioners on providing breastfeeding advice only mentioned milk banks (455).

2.3 Social sciences literature: women's perspectives

The social sciences literature described the regulation of milk sharing through practices and meanings. An extensive review of this literature on milk sharing by (220) confirmed that most studies were anthropological, in their focus on lived experience, showing how 'maternal experiences such as embodiment, sexuality and reproduction... are mediated within varying systems of human milk exchange' (456) (p.10). The majority of the studies were conducted in the USA (220, 278, 279) with limited research in Australia (270, 457), New Zealand (454, 458), and the UK (371), Sudan (266), and Italy (459). Many of these studies examined questions of importance to milk banking, about donor milk acceptability, access and safety and the institutional cultures of milk banks and NICUs (220, 349, 371, 377).

2.3.1 Practices as regulation

The regulation of milk sharing can be understood through its practices, which, like breastfeeding, are 'shaped by biology, cultural context and individual experiences' (460). This section summarizes studies of what donor and recipient mothers do in Australia and other countries, and what their experiences and cultural contexts tell us about milk sharing's regulation.

Australian studies of milk banking

The literature included one sociological study of milk banking in Australia. Zizzo interviewed 24 recipients and donors from the PREM milk bank in Perth (377). Most participants were mothers of premature infants, and predominantly middle class, white, educated, married and of high income, with two single mothers. None identified as Indigenous and 38% were born overseas. Zizzo interpreted their experiences of milk banking as participation in 'a network of power though a project of 'body work,' using theories from the French sociologist Michel Foucault. Constraints included logistic difficulties of providing milk for premature infants, and social and institutional constructions of bodily and maternal failure, within a 'panoptic' NICU nursery. However, providing and using donor milk transformed maternal failure into 'redemptive mothering' (377). In milk banking, the power of mothers was mediated by institutions. In contrast, grassroots forms of power operated in informal milk sharing networks, as outlined in the next section.

Australian studies of informal milk sharing

In the period before social media and milk banking emerged in Australia, informal milk sharing was investigated in two local studies (62, 80). A further two studies were undertaken after this period (363, 364).

In the earlier studies, Long described attitudes towards cross-feeding in a study of 46 mothers and 20 health professionals (mostly midwives) on a post-natal ward in 1999-2000 (80). Attitudes ranged from disgust to acceptance, but cross-feeding was practiced more commonly than openly acknowledged. Thorley also focused on cross-feeding in a study of 43 women in six Australian states and territories over the period 1978-2008 (62). The women in this study were white but included two same sex couples and grandmothers, one to a child of Indigenous heritage. A later study by Thorley included seven Australians in a sample of 23 women from eight countries,²³ who cross-fed or shared milk in the first decade of the 21st century (97). Thorley's research found that these practices were kept hidden, practiced by women in close, trusted relationships, breastfeeding groups or childcare arrangements, who observed norms for altruistic donation. The principal motivation of mothers in these arrangements was to avoid feeding CMF and manage breastfeeding problems, ranging from feeding a premature infant to returning to work.

Thorley's international sample of mothers provided insights into cultural influences on milk sharing, which included family traditions of cross-feeding, cultures in which families co-habited and allowing a baby to cry was shameful (97). Other reasons included a request by a midwife, providing a break for a new mother, and filling gaps in milk supply from various causes, ranging from cancer to adoption. Consent was often tacit and informal, and mothers used a range of screening practices, even when they knew each other. By asking mothers who they would not share milk with, Thorley elicited a range of criteria, including disparities in the age of infants to not 'liking' the donor. Similarly, asking mothers about who they would tell, showed that disclosing milk sharing was an indicator of social acceptance of milk sharing, with some mothers not disclosing their milk sharing activity to husbands or relatives when it transgressed a familial or social boundary. Thorley's studies reported the regulatory power of mothers' feelings and infant behaviour, for example the reaction of an infant to her mother after being cross-fed, an issue raised in a New Zealand study of 12 cross-feeding mothers (458).

The Australian studies of informal milk sharing conducted after 2010 focused on mothers' experiences of bodily autonomy. Mumme et al (364) found that donors who shared milk via social

²³ Mostly from the USA but including Canada, Colombia, Lebanon, India and Indonesia and the Netherlands

media felt a sense of autonomy over their bodies and milk, in defiance of authorities, while Smith (363) described how recipient mothers, struggling with lactation insufficiency, found donor milk 're-constitutive' and 'healing' of their sense of bodily brokenness and invasion ('cyborgification') from the technologies they used (breast pumps and supplementers²⁴). These deep feelings reflect the psychosocial conditions under which milk is shared and rarely surface in social media posts and internet blogs about milk sharing, analysed in the international literature (168, 169, 461, 462). Similarly, a 2018 Australian study of discussions on 15 closed Facebook groups hosted by the Australian Breastfeeding Association (ABA) showed that milk sharing ('wetnursing, donation of human milk') was a minor topic (463), but this may reflect judicious selection of forums by mothers, given ABA policy on informal milk sharing.

Overall, these Australian studies showed the autonomy of mothers to share milk independently, and the importance of local norms for altruistic donation, trusted relationships and groups in the regulation of milk sharing, with occasional involvement from a supportive health professional but the widespread need to keep informal milk sharing hidden.

Milk sharing practices in other countries

Social sciences studies of informal milk sharing in other countries, predominantly the USA (220, 368), showed that practices were similar to those in Australia. Reviews of donor motivations revealed common themes of altruism (providing help and hope for others) and not wasting surplus milk, factors noted across settings and cultures (220, 372). Irrespective of whether they used milk banks or informal milk sharing, recipient mothers were motivated by breastfeeding problems, due to infant or maternal medical conditions or inadequate support. Local variations in motivations around milk sharing reflected the prurience of Western cultures towards milk and concerns about potential HIV transmission. In countries with a high prevalence of HIV, for example South Africa, milk banking was driven by the need to protect breastfeeding and provide robust, low cost milk processing technologies (464). In-depth interviewing techniques provided insights into locally specific enablers of informal milk sharing, for example faith communities or supportive health professionals (278-280, 383, 414, 415, 441, 448, 451).

Importantly, in answer to warnings about the dangers of sharing milk online, the social sciences literature showed that mothers were flexible, and typically shared milk 'online and offline,' in exchanges that involved in-person contact and relationships at some point (277-279, 415, 441, 448).

²⁴ Feeding equipment that supplies a supplement while the infant feeds at the breast, typically through thin flexible tubing taped to the mother's breast and attached to a bottle or bag hung around her neck or pinned to her shoulder.

These personal exchanges influenced the assessment of risk in milk sharing and added to its social benefits, described by as a 'catalyst to friendship' (375) or the 'creation of community' (412, 461) and 'connection' (465).

However, studies in the USA and other countries showed that milk sharing was a practice of the privileged, other than in Brazil. Participants in altruistic milk sharing were well-resourced and overwhelmingly white, middle class, college-educated and married (372, 415, 444, 449, 465). An online survey of 867 US mothers who shared milk informally found that donors had more advantages than recipients ('higher income, education, and support for breastfeeding from spouse/partner, other family, employers, and pediatricians') (449). These observations have attracted criticism of milk sharing research designs that are insensitive to 'systemic racism, poverty, and homophobia/transphobia' and likely to perpetuate inequities in access to donor milk (284). A global review of research on milk bank donors showed similar problems (372), in common with breastfeeding research (466), and the need to refocus attention on structural rather than individual causes of inequitable infant feeding. For example, milk sharing behaviours of mothers were influenced by their access to health professionals and information sources knowledgeable about breastfeeding (451). However this support was less accessible for Black and Hispanic populations, as outlined in section 2.2.2. In light of these 'personal, cultural, and institutional factors,' McCloskey and Karandikar (414) reframed milk sharing as a socio-political response to structural barriers to breastfeeding, and called for health professionals to use empowering approaches rather than simplistic prohibitions or presentations of risks and benefits.

Communality and politics

These explanations of milk sharing's regulation as a political response to personal and structural factors raise questions about the effect of milk sharing's political power to 'up-regulate' infant feeding systems. Ideas of milk sharing as a form of exploitation are pervasive. For example, one anthropological interpretation of milk sharing as a form of collective, cooperative parenting ('allomaternal care') (467), emphasised that even this apparent form of power could be exploited by institutions:

'The capitalist institution of wet-nursing in large, stratified societies was weaponised to address a wide range of challenges associated with the enormous investment required to care for and feed infants in a rapidly modernising world... sustained largely by the exploitation and commodification of allomaternal lactation and care.' (467).

However, several in-depth studies of informal sharing reject ideas of exploitation, and mothers described a sense of social solidarity that went beyond helping others (278, 279, 461). This 'assertion

of collective values' and social cohesion uphold ethical concepts of altruistic donation as public goods (Titmuss (260) cited in Waldbly and Mitchell (268) p.14), in defiance of political economic systems that asserted the primacy of individualism and markets. These studies showed that milk sharing in close relationships promoted a sense of deep connection, with recipient mothers feeling cared for by the mother who cross-fed their child, and donors feeling 'honoured' to provide milk (62). Even milk bank recipient mothers felt connected to an 'imagined community of donors' (371, 468).

However, such solidarity did not bridge the divide between milk sharing sectors (356, 388, 469). Although early commentary suggested potential synergies or complementarity between informal sharing and milk banking (189, 208), the regulatory and public health nutrition literature outlined in this chapter portrayed milk banking and informal sharing as dissociated 'sectors' that operated in isolation (461). Few studies have probed these divisions. Research that investigated the reasons for donors using a specific form of milk sharing (274, 415, 444, 470) showed that some mothers shared milk through both sectors, or that their engagement with a sector was entirely pragmatic, arising from geographic, logistic or cost barriers to accessing milk banks, philosophical objections to milk banking or a preference to support someone they knew.

Understanding the political power of milk sharing sectors in infant feeding is a recent field of study. To some mothers, informal milk sharing was a political statement that validated the value of milk and said 'together, we will not be deceived, scared, placated or undermined into thinking otherwise' (461). Other researchers questioned its role as an 'activist movement' and the extent of its influence on infant feeding policy. For example, some US authors considered that altruistic exchanges engaged with the politics of infant feeding but did not overturn it, and milk sharing was a collective act but not a collective movement to change policy (276, 278, 279). Carter and Reyes Foster characterized milk sharing networks as systems of shared expertise and purpose ('biointimate communities of practice'), but did not consider them structures that changed societal power relations (276). Falls had a more radical interpretation of informal milk sharing's non-hierarchical structures ('heterarchies'), as inherently critical of breastfeeding authorities and capitalism (278). Wilson agreed with this position, noting that milk sharing interrupted the status quo and that 'all infant feeding practices in the contemporary West are political' (279). To Wilson, informal milk sharing represented a 'grassroots social movement' directed toward 'staving off regulation that limits breastfeeding' through narrow definitions of exclusive maternal breastfeeding (279).

In contrast, the politics of milk banks reinforced the power of medical institutions. An ethnographic study of milk banking and multiculturalism in Italy described the power imbalances in milk banking when confronted with milk:

‘Milk banks are places of power that respond to the logic of institutions (the hospital); the actors involved in the process, however, share a different degree of agency, and are not equals in the decision-making process’ (459).

Other studies have also questioned the politics of milk banking. Centralized, state-run models of milk banking run (for example, Norway, Scotland, France and Brazil) may be powerful actors in the ‘politics of breastfeeding’ but their policies and structures don’t always enhance breastfeeding protection and support for the wider community (89, 92, 371). Without an analysis of its governance, milk banking can appear inward-looking, shaped by priorities for medically fragile infants and acute hospital care, as shown in a study of milk banking in the UK (371).

2.3.2 Meanings as regulation

The literature shows that the regulation of milk sharing also occurs through ideas, social meanings and discourse –the ‘vocabularies, models and definitions’ used in communication (461).

‘Technologized’ and ‘biomedicalized’ discourses about breastfeeding and milk sharing regulate these activities by circumscribing ideas and meanings about how they work and what is normal or pathological (460, 471).

Historical and cross-cultural anthropological studies of milk sharing show the ‘polyphonic’ meanings of milk sharing (459, 472). For example, Cevese (citing Golden (87)), described how the meaning of milk in the USA changed over the 20th century from ‘commodified to sacralised’ as donor payment was replaced by altruistic donation, while the meaning of milk in North African society was anchored in kinship (459). In this study of modern milk banking in multicultural Italy, donor milk had a ‘moral connotation’ for Italian mothers but ‘connecting power’ for Moroccan mothers, while milk banks considered it a ‘public entity’ (459). These meanings shaped the motivations of Italian mothers to provide donor milk, immigrant mothers to refuse PDHM in NICUs and Italian doctors to avoid obtaining consent for its use.

While these cross-cultural insights may improve policies for milk sharing, a more urgent question is what they mean for breastfeeding (472), and how specific meanings or cultures ‘fit’ with breastfeeding’s biological and social processes (a ‘breastfeeding-friendly set of customs’) (472). Accordingly, milk sharing’s various meanings can be reappraised for compatibility with breastfeeding. The following sections examine four constructs that shaped the meanings of milk sharing (maternal identity, medicalization, deviance and kinship), and their implications for breastfeeding.

Motherhood and gendered identity

The literature on milk sharing has focused on Western societal constructions of motherhood that influenced the meaning of milk sharing (270, 377, 473) (279, 474). Constructs of 'good motherhood' vary between and within societies, and different types of milk sharing may represent idealized norms of motherhood, or transgress these norms, for example, by challenging a mother's identity as the sole provider for their infant (354), or liberating women from capitalism's individualistic framing of motherhood (189). Maternal identity is also manipulated by CMF marketing (15, 475, 476).

The meanings of milk sharing are mediated by the meanings of breastfeeding (13, 473). For example, some authors have concluded that breastfeeding is less important to maternal identity in France than the UK, highlighting competition between cultural values that supported breastfeeding ('intensive mothering' and a 'naturalist' approach to feeding on demand), and values that undermined breastfeeding (the importance of a sexualized body and the transmission of French food culture) (477, 478). In the USA, milk sharing as a response by privileged groups to expectations of intensive mothering and individualism was described as 'moral motherwork.' This term acknowledged that milk sharing may be ideal but inaccessible for social, economic and policy reasons (479). Similarly, Carroll was concerned that ideologies about motherhood ignored the structural factors and invisible maternal work that shaped concepts about 'altruism' and 'surplus' milk:

'The overuse of such terminology propagates the notion of an inherent motherly altruism and obfuscates donor motivations and practices that are mediated by social structures such as class and race, and by the identity work enacted by women in conversation with "intensive," "good," and "natural" motherhood ideologies' (289) (p. 175).

For example, the work of pumping milk adds to its cultural and personal meanings, making advice to 'dump' milk insulting (456). These complexities modify the portrayal of milk donation as a simple expression of maternal generosity (278, 279) and a 'gift of the self' (274, 280). Such portrayals are also problematic for recipient mothers, who must reframe or redeem their maternal identity through acts of obtaining or accepting donor milk as the 'next best' option for their child (279, 354, 363, 377). Similarly, donating milk after the death of an infant may 'redeem' the maternal identity and help manage grief (372, 382, 480-482). In contrast, a strong maternal identity may lead to a potential recipient mother refusing donor milk, even when health professionals recommended its use (459, 483).

The literature also described the complex meaning of milk production and exchange by parents whose family structures and gender identity were fluid (270, 273, 279, 461). Milk sharing by these families subvert the meanings of milk tied to essentialist gender norms for motherhood and expand

milk's meanings as expressions of care and social justice (279). In her study of breastfeeding strategies of US families with diverse identities and structures, including surrogacy and adoption, (279) described 'a less bounded world' of breastfeeding beyond that defined by the 'institutions of motherhood.' The message for institutions was that maternal identity, and the identities of donors and recipients were nuanced. Health professionals and breastfeeding organizations needed to provide information that did not stigmatize mothers and others who donated or sought milk and drive these practices further underground (279).

Medicalization

Medicalized discourses specifically pathologise (461). The literature on milk banking and public health nutrition shows the pervasive power of medicalized discourse, which defines milk as a medicine in NICUs and as 'a medical substance that requires scientific testing, surveillance and regulation' (461). Milk banking transformed milk into a safe product and distanced milk from the donor's body through anonymity (377, 483). An Australian study of 24 mothers' experiences of using a milk bank concluded that milk banks:

'Rely on disassociation and depersonalisation strategies in order to alleviate anxieties regarding the potential 'threat' of 'unnaturally' sharing a bodily fluid ...which has the consequence of fragmenting their bodies and disembodimenting their material roles' (457).

A study of US milk banks and NICUs showed how medicalization transformed milk by 'assembling' the 'safety-generating 'material labour' of HMB staff, the 'reproductive labour' of milk donors and the 'immaterial labour' of NICU clinicians' (349). These were discursive processes that contributed to concepts of safety, in addition to the material scientific approaches of managing donors and milk.

Conversely, informal milk sharing has been characterised as 'demedicalization,' defined as processes by which 'previously defined medical conditions come to be accepted as normal states of being' (461). Demedicalizing processes are political, and informal milk sharing practices and identities show 'the ways individuals exercise agency and seek empowerment despite hegemonic influences' and 'the everyday practices of resistance' (461) (p. 26). Yet, as studies of informal milk sharing showed, demedicalization was not an outright rejection of biomedicine, and mothers used biomedical evidence to navigate safety and consent (361, 364, 415, 461). In contrast, medical oversight was important to parents who were concerned about safety and unfamiliar with milk banking and informal milk sharing (369, 484).

Deviance

The previous themes of maternal identity and medicalization show how all forms of milk sharing in some way adhere or deviate from social or institutional norms. In the Western cultures that dominated the literature, milk sharing practices are framed as deviant because they ‘disrupt patrilineal exclusive mother-child relationships’ (485), and challenge the marginalization of ‘female reproductive biology...in the patriarchal dominated biomedical sciences’ (433).

Framing informal milk sharing, especially cross-feeding, as deviant kept it hidden, and separated from milk banking (279, 458). However, as the literature on acceptability showed (section 2.2.1), health professionals had a range of attitudes towards milk sharing that depended on settings, the level of breastfeeding knowledge and ‘breastfeeding friendly’ policies and cultures. The review of the regulatory literature also showed a recent trend for policymakers to view milk sharing as a spectrum of practices rather than isolated sectors. For example, a recent study described an Australian milk bank which informed donors about informal sharing, rather than waste milk that the milk bank could not accept (486). Similarly, when PDHM was not available in health settings, some health professionals facilitated a mother’s ‘subterranean’ use of unpasteurized milk, which required both parties to navigate medical and medico-legal rules and norms (409, 454). However, invisibility came at a price, and reinforced milk’s ambivalent status, whereas milk banks were ‘visible, approved, supported, acceptable, treasured facilities’ which enabled the gift of milk to be counted (454). In community settings, it was easier for health professionals to support individual mothers to share milk informally (448, 461).

Milk kinship

In some cultures and religions, including Islam, milk kinship is recognized and used proactively to create kinship status and strengthen social bonds, or prevent undesirable marriages (487). Milk kinship was important to Muslim mothers using informal milk sharing arrangements (375) and milk banks, and anonymity was a barrier to the use of milk banks in some countries and immigrant populations in Western societies (257, 266, 459, 487-493). Reviews of these practices have called for cultural sensitivity by health professionals in developing milk banking and processes of informed consent so that culture is not a barrier to accessing PDHM (220, 491).

In other cultures, milk’s meaning is tied to relationship. The secular use of kinship terms amongst ‘Anglo-Celtic, Christian Australian’ mothers who cross-fed their children was observed by Thorley (257), and in other studies of informal milk sharing (279, 375, 461). In the USA, Wilson observed that ‘milk’s real value comes from its intimacy’ and that milk sharing enacted a form of ‘intimate

citizenship' which promoted solidarity and humanity, perhaps articulating a broader, universal view of kinship (279).

In summary, the social sciences literature treats milk sharing, in particular informal sharing, as a sociocultural phenomenon, exotic or deviant to Western culture and health systems, despite its persistence in the community. This 'othering' reflects a temporary, modern loss of local and institutional cultures of milk sharing, with continued rediscovery of milk sharing by mothers in the community, facilitated by technologies and scientific knowledge about milk. There are clear cultural and technological similarities between milk sharing in Australia and the USA but their substantial institutional and other structural differences require local research.

The next section reviews how the social sciences and other disciplines discussed in this chapter frame connections between milk sharing and breastfeeding.

2.4 Effects of milk sharing on breastfeeding: product and process

The anthropologist Penny Van Esterik (211) identified the challenges that milk sharing presented to policy making and warned that 'product does not replace process' (472, 494) or the social practices of nurture (495). This warning has been echoed by others (460, 496), and the work of biocultural anthropologists who demand that evaluation of milk sharing also values the cultural and physiological processes of breastfeeding and maternal care (433, 497).

This view implies that a focus on breastmilk as a product separate to nurturing behaviour makes milk vulnerable to commodification. However, thinking about milk as a product has a long precedent in medical discourses of breastfeeding, which is promoted for the value of its components to infant health, not its value as an intersubjective experience and embodied biocultural process for the mother (460).

The review of the regulatory literature treated milk as product and various scholars struggled to find a framework for milk that supported breastfeeding. For example, reviews of interventions to protect, promote and support breastfeeding may omit milk banking and informal milk sharing (498), or consider them but remain unsure of their overall effect (499). In contrast, in Brazil, milk banking is conceptualized in a fundamentally different way to milk banking in the West, as a structural matter concerning the governance of infant feeding as whole, rather than the regulation of milk or its treatment as an 'intervention' (500, 501). In Brazil, a milk bank is defined as:

'A specialized, non-profit center, necessarily attached to a maternal and/or children's hospital, responsible for promoting and encouraging breastfeeding' (94).

Importantly, in this model, milk banks act as centres of expertise for health professional education on lactation management and research, ensuring that professionals and institutions ‘truly support breastfeeding’ (94) rather than pay lip service to it, and understand breastfeeding as biocultural (‘a nature-culture hybrid’) (502). Milk banks are ‘natural centres of care’ for all mothers (307) and provide breastfeeding support, individually and through groups, and this ‘integrated, process-focussed’ model of milk banking (92) contributed to Brazil’s increased rates of exclusive breastfeeding for infants under 4 months from 5% to 60%, from 1986 to 2019 (94).

The public health nutrition literature also shows that medical institutions treat milk as a product. Although there were calls for milk banking to be incorporated into breastfeeding policy (241, 307, 327, 328), the way to do this was unclear. Consequently, studies of the effects of milk banking on breastfeeding are inconclusive, as shown by reviews of PDHM use in the US in NICUs (10 studies) (503) and less acute hospital settings (seven studies) (470), hampered by inconsistent lactation support and infant feeding definitions, for example, ‘exclusive milk diets’ not prioritizing MOM over donor milk (504). These reviews found no evidence that PDHM displaced breastfeeding, while low quality evidence showed it increased rates of ‘any breastfeeding’ on hospital discharge by about 20% (503). Subsequent reviews have not changed these conclusions, but provide reassurance that PDHM does not displace breastfeeding in well-managed NICUs that provide lactation support (505). Australian studies showed mixed results (388, 506-508).

More recent studies have attempted to improve on this research by removing confounding effects from associations between acceptance of donor milk and a positive attitude towards breastfeeding. This was done by studying cohorts of mothers who intended to breastfeed but subsequently needed to use supplements. A US study in a neonatal nursery showed that supplementation with PDHM rather than CMF doubled the odds of any breastfeeding at 6 months old (399). Another, small study of PDHM and CMF supplementation in a neonatal nursery showed no difference in their effects on breastfeeding at one month (509). Other research emphasises that these benefits may not be realized if there are institutional and social barriers to breastfeeding (510). The issue centres on who is responsible for providing lactation support to recipient mothers. To address this, global authorities have called for health facilities using PDHM to be BFHI-accredited (241),²⁵ a requirement that should surely apply to all maternity and paediatric hospitals.

²⁵ The BFHI program implements ‘Ten Steps to Successful Breastfeeding,’ consisting of: hospital policies; staff competency; antenatal care; care right after birth; support for mothers with breastfeeding; supplementing; rooming-in; responsive feeding; the use of bottles, teats and pacifiers and referring mothers to community resources for breastfeeding support on discharge from hospital (54).

In the community, the effects of milk sharing on breastfeeding are under-researched. Two US studies concluded that informal milk sharing increased the duration of breastfeeding by recipient mothers (451, 461), but it is difficult for observational studies to disentangle associations between mothers' use of donor milk and their motivation to breastfeed. The social sciences literature better shows how different types of milk sharing reinforce or disrupt concepts of breastfeeding as a product or a process.

Figure 2 maps these dichotomized ideas, systems of knowledge and policies, as identified in the literature. These relational processes are supported by infant feeding and social policies that recognize breastfeeding as a right and enable mothers and infants to remain in proximity through maternity leave, workplace-based childcare and flexible work arrangements (511-513). Arguably, relational processes are retained and valued in cross-feeding and informal milk sharing, as identified in qualitative studies in the social sciences literature.

In contrast, the commodification and loss of milk's relational value undermines breastfeeding as a relational process (211, 460). Underpinning commodification are Western philosophical dualisms of mind and body, which treat breastfeeding as mechanistic and milk as separate from bodies, from which added value is created through various products: expressed milk (164), donor milk, milk products and CMFs. These products, and their marketing, risk displacing breastfeeding in practice and policy or diverting milk from infant feeding systems. However, approaches to milk science and research that promote commercialization or outcomes that undermine breastfeeding may be curtailed by governance structures for research. Recently, a translational science framework has been applied to research on milk that aims to 'support safe and efficacious infant feeding practices,' based on a multidisciplinary, ecological model of lactation that 'encompasses sociocultural, political-economic, geographic, cultural, ethical, and legal factors' (514).

Whether these frameworks can incorporate the relational processes integral to breastfeeding and resist the antecedent constructs of commodification remains to be seen. Commodification is supported by structural factors, specifically the policies that make breastfeeding difficult to perform in public and in workplaces, and the need to express milk to maintain lactation, initiating the cascade of surplus milk production wastage and deficits, all of which are leveraged by milk banking or milk selling. Anonymized milk donation and selling milk enable milk to be used in ways that threaten breastfeeding. Labour in milk sharing is also commodified, when milk is sold or wet-nursing occurs, and the latter commodifies the relationship in breastfeeding as well as the labour of lactation and infant care.

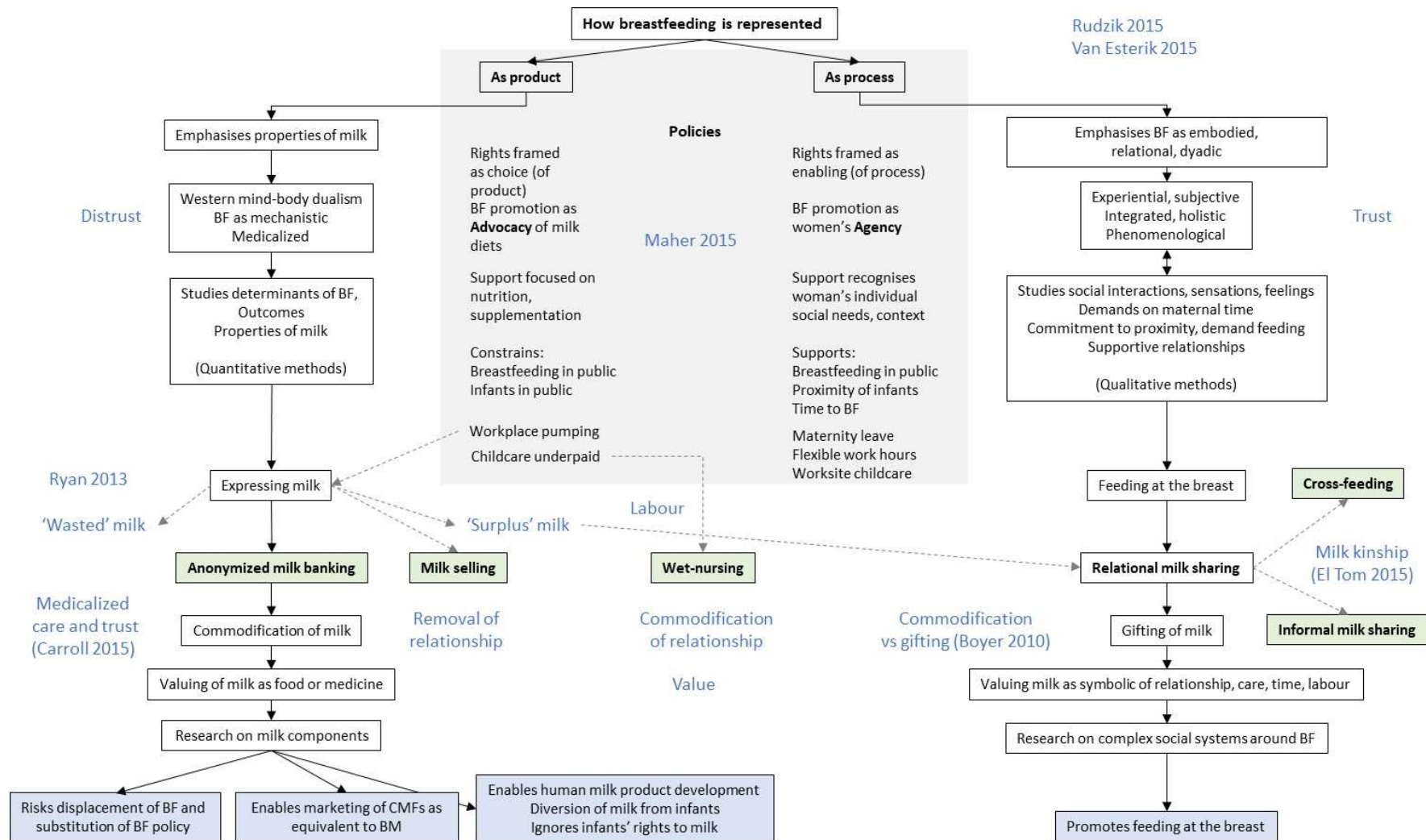


Figure 2 A proposed causal pathway showing how the regulation of different types of milk sharing shapes breastfeeding by reinforcing a product or process.

Clearly, these ideas and outcomes are shaped by local policies, norms and practices, which need investigation. However, the model helps sharpen focus on how these regulatory mechanisms in milk sharing emphasise process over product in breastfeeding, pointing to some of the theoretical issues and methodological questions discussed in the following Chapters 3 and 4. As noted by Van Esterik (211) and Maher (511), regulatory inquiry about infant feeding centred on ‘the conditions in which women nurture their children,’ has far reaching implications:

‘Solving the problem of universal access to human milk requires supporting and valuing the providers of that milk. Policies and practices that accomplish these objectives might go a long way to addressing other problems of the modern world’ (211) (p. xxiii)

2.5 Summary of literature review

2.5.1 What is known from the literature about the regulation of milk sharing

This chapter reviewed the literature concerning regulation and governance of infant feeding, with a focus on milk sharing. It drew on the historical overview provided in Chapter 1, which showed the persistence of informal practices without the hegemonic influence of a milk banking sector, until the first decade of the 21st century, when milk banking was established. This history showed that the regulation of milk sharing was emergent, with ongoing tensions between regulation by the state and beyond the state, and dynamic shifts in social, medical, economic conditions and technological developments, and the need for an interdisciplinary perspective on milk sharing’s regulation.

The literature relevant to the regulation of milk sharing spanned three disciplines: regulatory studies, public health nutrition and the social sciences. However, it was difficult to synthesize the various legal, medical, ethical, economic, sociological and feminist perspectives presented in the literature into a coherent picture of governance. The review showed that milk sharing tended to be studied as separate sectors and settings, with descriptions of various practices that focused on non-state actors: principally mothers, with few studies of health professionals and milk bank staff and no empirical research of the range of state actors involved in milk sharing’s regulation.

Research was dominated by US studies of milk banking and informal sharing, which were framed as separate sectors. Institutional approaches to different types of milk sharing were not clear, tended to emphasise product over process and were not integrated with breastfeeding. The ambivalence and needs of health professionals were not well understood.

Studies across fields revealed overlapping concerns about rights and risk and the need to bridge siloed governance structures and ideas. However, the dominance of studies from the USA restricted

an understanding of milk sharing to medicalized, neoliberal models of infant feeding and care, which tended to focus on individual, rather than institutional, societal and system level causes of various problems.

The limited literature from other countries, showed that research was focused almost exclusively on milk banking. Consequently, concepts of 'regulation' were based on institutional rather than social perspectives, leaving informal sharing persistently framed as 'unregulated' and risky (212). However, international and US surveys and studies in the social sciences showed that mothers managed risk in nuanced ways, which included milk's symbolic and relational meanings, and an evaluation of risks relative to those of CMFs. The meanings of milk sharing included the value of milk and breastfeeding to maternal identity, a key factor in understanding how the regulation of milk sharing was linked to breastfeeding. The importance of breastfeeding also shaped how milk sharing was positioned in policy and clinical practice, which varied between countries. These findings showed that the 'scale' and scope' of milk sharing included its emotional register and communality, which were as important to its governance as specific policies and practices.

Other insights into the links between the regulation of milk sharing and breastfeeding came from cross-cultural research. These perspectives showed that regulatory frameworks based on products, rather than bio-sociocultural processes related to breastfeeding, promoted governance in which milk sharing sectors competed for acceptability, access and safety disconnected from breastfeeding (92). However, regulatory models based on processes were rare, and their origins had deep ideological roots in human rights that rather than commerce.

The literature showed that the regulation of milk sharing needed to weld the symbolic with the pragmatic, but this was a challenge to public policy. Invariably, the literature showed the need for structural reform or strengthening of breastfeeding policy (89), without which market-based approaches to milk exchange proliferate, as in the USA. However, the literature also showed the need to develop governance that specifically addressed commercial interests in milk, which operate as a separate driver of milk sharing, as in India. Without these reforms, donor milk risked being a 'quick fix' for institutional failures to invest in breastfeeding, as described in Chapter 1.

2.5.2 Gaps in the literature

The review shows the limitations of the literature on the regulation of milk sharing, and the need to understand its regulation and governance from the perspectives of a wide range of state and non-state actors. The review identified gaps in understanding how the legal and social regulation of milk intersected across milk sharing sectors in Australia. This included gaps in the literature on how regulatory mechanisms operated across levels of government and community settings. More

specifically, there were gaps in understanding how legal, institutional and social structures and rules regulated milk sharing as a product or process.

The review also identified a larger gap in the literature about milk sharing's regulation, which stemmed from its portrayal of two-way contests between milk sharing and breastfeeding, or milk sharing and CMF, rather than the three-way contest between milk sharing, breastfeeding and CMFs, as described in Chapter 1. Arguably, this triangulated competition applies at various levels of governance, from practices to policy. This framework helps understand the 'regulatory conditions' under which milk sharing displaces or enhances breastfeeding or use of CMFs.

In addition, Australia's multicultural society requires models of governance that accommodate cultural diversity in milk sharing practices and address the dynamic national and international trends in milk banking and informal milk sharing. These models need to manage new actors, technologies, social and commercial factors so that the governance of milk sharing serves the interests of Australian mothers and infants.

The most important missing piece of the regulatory puzzle is to move beyond the boundaries of scholarly disciplines and develop theoretical and methodological approaches to this research, which spans sectors and settings, and shed light on the ways that milk sharing affects breastfeeding. These approaches are discussed next, in chapters 3 and 4.

2.6 Conclusion of literature review

The complexities of modern milk sharing and its development over the last two decades in Australia show that an interdisciplinary approach is required to understand its governance and complex relationship with breastfeeding. This review of the literature found the need for approaches that accommodate the multiplicity of actors, ideas and forms and levels of governance involved. Consequently, a deeper dive is needed into this complexity, to understand the local terrain, and identify the specific actors, institutions and ideas that frame the regulation of milk sharing in Australia. Public policy makers need to understand this complexity, and the shifting public health and commercial interests around milk, so that its regulation enables breastfeeding to flourish rather than threaten it. The way to do this in Australia is not yet clear. Understanding the regulation of milk sharing and its effects on breastfeeding requires empirical study centred on mothers, and the institutional, socioeconomic and socio-political and cultural spaces they inhabit.

Chapter 3. Theoretical perspectives

Chapter 3 describes theoretical approaches that accommodate multidisciplinary perspectives of governance and power, which are necessary to investigate the regulation of milk sharing and address the overarching research question, *‘How does the regulation of milk sharing shape breastfeeding?’* This question makes several demands on theory: at the macro-level, it must engage with the ‘politics of breastfeeding’ and, at the micro-level, with the practices of milk sharing and the biological and psychosocial aspects of lactation (515). Accordingly, I used a hybrid theoretical framework to guide my research, based on two regulatory theories: nodal governance (217), which addressed macro-level factors, and an adaptation of behavioural theory (218, 219), to accommodate the factors that shaped ‘what actors did’ at the micro-level.

3.1 Regulatory meaning and concepts

In this thesis, regulation is defined in broad terms, as ‘steering the flow of events’ (3) and draws on pluralistic models of regulation as a ‘web of control’ (516), exercised through a ‘regulatory regime’ of actors, institutions and ideas (4). A key question in regulatory theory is the extent to which behaviour is caused by individual agency and structural factors. To address this problem, Braithwaite and Drahos advise that studies of regulation should aim to uncover the broader principles (‘prescriptions that guide conduct’) and mechanisms (‘tools that actors use to achieve their goals’) that underpin an activity (516) (p. 9).

Among these principles are political ideologies that allocate responsibility for behaviour to individuals and ignore the role of the state and its institutions in shaping human agency, as noted in analyses of breastfeeding (515, 517-519). This thesis interrogates ideas of informal milk sharing and private social spaces as independent of the state and ‘unregulatable,’ against evidence that state and non-state actors influence the conditions that enable women to breastfeed (517), and shape demand for milk as well as its supply. This interplay of structure and agency was noted by Kauffman in a study of grassroots governance, which emphasised that ‘governance is not merely a process resulting from structure; it contains agency... the purposive efforts by both state and non-state actors to “steer” society towards the pursuit of particular goals’ (520).

In this tussle ‘to steer society and affect policy,’ actors and institutions use a wide variety of regulatory mechanisms or tools that include ‘force, persuasion, economic pressure, and norm creation’ (520). In milk sharing, these regulatory mechanisms include legal, social and biological ‘rules,’ and the structures through which these rules operate. In biophysical systems, these rules

include positive feedback mechanisms, which are as important as inhibition (521). Similarly, positive feedback in social systems are important mechanisms that may become ends in themselves, for example social cohesion and cooperation. These and other mechanisms or explanations of regulation raise questions about the nature of reality and how this is known, which shape what is attended to – and measured. These ontological and epistemological issues are examined in more detail at the end of this chapter and inform the research methods described in chapter 4 on Methodology.

3.1.1 Actors, institutions and ‘actants’

The central regulatory questions of ‘who governs?’ and ‘how they govern’ require ‘empirical, context specific research’ (522) p. 165. This question of ‘who governs?’ is an open one. The literature on milk sharing described a range of state and non-state actors. Informal milk sharing occurs in social groups with limited consultation with health professionals, and arrangements remain hidden through use of the internet. Thus, informal milk sharing is largely ‘self-regulated,’ in the sense that it operates according to social rules determined by non-state actors. Central to this regime were the women who produced and sought milk, and their infants, as drivers of nurture and lactation.

Milk banks were the second obvious actor group involved in the regulation of milk sharing, with health professionals being a third actor group. The fourth actor group were policy makers in a range of positions in state institutions, health services in the public and private sectors and non-government organizations. The regulatory roles of these actors and their institutions required investigation, including the nature, direction and extent of their power, and the role, if any, of commercial influence. A further complexity for milk sharing was that, in addition to institutions, whose power was exercised hierarchically, informal milk sharing involved non-hierarchical structures for the distribution of milk by peers.

From the literature, the relationships between these actors were typically examined in single settings, for example, NICUs. Including all forms of milk sharing practiced in Australia showed the limitations of defining regulation through an actor or institutional position. Within actor groups and institutions, there appeared to be a spectrum of roles and positions and it was important to understand their motivations and the factors that shaped actor agency.

Things, as well as actors, may have regulatory power. The characterization of ‘actants’ uses a concept from Latour (523), which has been incorporated into regulatory theory, to engage the ‘social world’ with the ‘natural world’ and hard sciences (522, 524). In milk sharing, actants include milk and technology (for example social media and breast pumps), which shape the interests or capabilities of actors. Milk has agentic properties through its ‘vitality,’ as a source of nutrients, hormones, immunological, cellular and other living components, which interact with the environments and

physiologies of those who produce and consume milk (433). However, as noted earlier, the public health nutrition literature tended to focus overly on milk. My research aims to avoid such fetishization of things, and to understand how ‘the law of things remain bound up with the law of persons’ (525) and how the ‘rules’ around milk sharing affect the complex, embodied behaviour of breastfeeding.

3.2 Analytical frameworks and alignment with research questions

This section outlines the specific theories applied to the regulation of milk sharing, which accommodate governance that is pluralistic and multicentric in nature, involving state and non-state actors operating at various levels of governance. These theoretical approaches enabled the research questions to be investigated (Table 2) using the analytical methods described in the chapter 4 (Table 3).

The question ‘*How is milk sharing regulated in Australia?*’ was investigated using the theories of nodal governance by Burris et al (217, 526, 527), to describe pluralistic and multicentric models of regulation, in which power is decentralized and held by a range of actors and institutions, and exercised through a mix of legal and social rules and other factors. At the outset, nodes of power were assumed to be arranged around the shared interests of key actor groups.

The mechanisms of regulation (the ‘how’) were investigated in depth through three sub-questions. The first sub-question, ‘*How do institutions frame milk sharing?*’ established the laws and policies that state and non-state organizations applied to milk sharing using a document analysis and inquiries to government agencies, as the basis for exploring the extent of their influence.

The second sub-question asked ‘*What are the conditions under which milk sharing occurred?*’ and used the behavioural theories of Petersen et al and Honig et al (218, 219) to investigate actor awareness, motivations, pathways and rewards and how actor agency to share milk was shaped by structural factors, including state and non-state institutions. This analysis examined the ways actor agency and structures for milk sharing intersected with those for breastfeeding. The third sub-question, ‘*How does the regulatory regime of actors, ideas and institutions shape the way milk was shared?*’ synthesised the analyses of nodal governance, legal structures and actor behaviour to provide a description of the overall ‘regulatory regime’ for milk sharing and its operation.

Understanding this regime was the foundation for answering the overarching research question, ‘*How does the regulation of milk sharing shape breastfeeding?*’ by enabling analysis of how the distribution of power, regulatory mechanisms and levels of governance involved in milk sharing supported or undermined breastfeeding.

Table 2 Theoretical basis of analysis and alignment with research questions.

Research questions	Theoretical basis	Theories	Theoretical constructs	Analytical methods
1. <i>How is milk sharing regulated in Australia?</i>	Pluralistic, multicentric governance, including 'beyond the state.' Power distributed in various forms and hierarchical and non-hierarchical directions.	Burris' (2004) theory of nodal governance.	Nodes of power. Nodal interfaces.	Identification of state and non-state actor groups and organisations with shared interests.
(a) How do institutions frame milk sharing?	The power of the state through legal structures and their meanings, to understand what shapes actor agency.	Maxwell et al's theory of critical realism.	Reality as complex. Incorporates ontological positivity with epidemiological constructivism. Legal power of actors. The legal definitions and social meanings of donor milk.	Document analysis of legal structures. Letters to government agencies.
(b) What are the conditions under which milk sharing occurred?	Actor groups and their agency.	Honig et al and Petersen et al's (2015) theory of actor and organizational behaviour (AMPR)	Actor and organizational awareness, motivations, pathways and rewards	Key informant interviews of actor groups and organizations.
(c) How does the regulatory regime of actors, institutions and ideas shape the way milk was shared?	Linking regulatory systems and levels of governance.	Maxwell et al's theory of critical realism. Layder's adaptive theory.	Iterative and flexible methodological approach of adaptive theory (Layder 1998) to qualitative research to investigate connections between macro and micro levels of the regulatory regime.	Synthesis of analyses of legal structures, actor behaviour and nodal governance.
2. <i>How does the regulation of milk sharing shape breastfeeding?</i>	Linking the regulation of milk sharing to the physical, sociocultural, legal and commercial factors that shape breastfeeding.	Burris' (2004) theory of nodal governance. Honig and Petersen et al's (2015) theory of actor and organizational behaviour (AMPR). Maxwell et al's theory of critical realism. Layder's (1998) adaptive theory.	Iterative and flexible methodological approach of adaptive theory (Layder 1998) to qualitative research to investigate connections between the governance of milk sharing and breastfeeding.	Synthesis of governance structures and meanings.

3.3 Theories of decentralized power: nodal governance

To understand how milk sharing was governed, and what this meant for breastfeeding, my thesis draws on theories of nodal governance (217, 522, 526, 527). The array of state and non-state actors and institutions involved, and the various ways that power was distributed, indicated that the regulation of milk sharing was polycentric, arranged around multiple 'sites of capacity, knowledge and resources' or nodes (522) (p. 165). Nodes are defined as 'actors within a network' which include entities that are not 'formally constituted or legally recognized,' for example groups who share milk (526). Nodes may be coordinated in larger clusters as 'superstructural nodes,' as the 'product of two or more networks which are tied together... to concentrate resources and technologies for the purpose of achieving a common goal' (528) (p. 404).

3.3.1 Nodes and superstructural nodes

The four elements of nodes are mentalities ('ways of thinking'), technologies ('sets of methods for exerting influence'), resources ('to support the operation of the node') and institutions ('structures that enable the directed mobilization of resources, mentalities and technologies over time') (526). Understanding nodes of power and their mentalities, technologies, resources and institutions requires empirical research, guided by eight dimensions: who makes the rules, the nature of rules, the focus of governance, who executes governance (through modes, processes and technologies) and 'mentalities' of governance (529). Mentalities, 'the mental frameworks that shape the way we think about the world,' are considered to be the most significant dimension in shaping methods of governance and may be explicit or implicit (529). For example, mentalities that govern various nodes in milk sharing may reflect explicit principles about feminism or bioethics or be inferred from actions, for example not disclosing milk sharing.

The investigation of nodes may require investigation of sub-nodes, or smaller localized networks of actors and entities within a node, but nodal governance approaches have been criticised for being too localized, and ignoring the vertical, cross-cutting structures that shape behaviour (Cook 2010 in (522)). However, localized nodes contribute to the overall outcomes or 'generative' properties of nodal governance (217). These outcomes may be broad systems of control or empowerment, social harms or public goods, including just outcomes (530). In my research, the outcome of interest is breastfeeding, and nodal governance theory is applied to understand how the configurations of power around milk sharing affect breastfeeding. A nodal governance approach offers insights into the ways that the governance of milk banking and informal milk sharing interact with each other and systems of infant feeding more widely. It provides a framework to assess whether milk sharing is a project of liberation of mothers, (414) or displacement of breastfeeding or CMFs.

3.3.2 Co-production of nodes: interfaces and influence

Mapping nodes of power brings attention to the points of interaction between nodes ('interfaces'), where critical differences between values, interests and 'modes of rationality' or 'logics' become apparent (531). An interface may be based on localized discontinuities in beliefs and cultures and also higher-level or global differences in 'political processes and dynamics of power,' which can take several forms: discursive, resource transfers, organizational and legal power (531).

An important concept in nodal governance is that nodes are defined by these social and political interfaces, and co-constructed through interactions (531). These interactions are characterised by the array of power relationships and motivational postures between actors described earlier in this chapter. Nodal governance provides a dynamic model of these relationships, and scope to study how actors sidestep authority through various modes of governance or by shifting interfaces or forums for interaction. This flexibility makes nodal governance an appropriate theoretical framework to study the self-regulated governance of milk banking and informal milk sharing in Australia.

3.3.3 Nature and direction of power between nodes

The literature showed that in the regulation of milk sharing, power flowed in multiple directions, depending on which milk sharing sector was examined. Hierarchical systems of control in medical institutions suggested that power in milk banking was arranged vertically, but this was at odds with this sector's self-regulatory model of governance in Australia. In contrast, power in informal milk sharing appeared to be non-hierarchical, and flow horizontally through social structures of families, 'peers' and social media, described in the literature as 'heterarchies' (278), or 'bio-communities of practice' (276).

The levels of governance at which nodes operated also required further investigation. Previous studies had focused on sub-national levels of governance, but an interest in governance at national and international levels was emerging. In addition, emerging commercial interests in milk and established commercial interests in CMFs showed that business interests shaped milk sharing in complex ways. Other commercial interests that supported milk diets included health insurers and manufacturers of breast pumps and lactation aids who shaped the cost of producing milk by women. The ways that power, governance and interests were arranged and shaped the regulation of milk sharing needed detailed research.

3.3.4 A provisional map of nodal governance of milk sharing

To guide further theoretical exploration of governance for my research, a provisional map of the sites of power or nodes involved in milk sharing in Australia was assembled (Figure 3). This map assumed that nodes of governance consisted of the principal actors and institutions identified in the literature

(532): mothers, milk banks, health providers and policy makers. The configuration of these groups reflected the disciplinary perspectives described in the literature review, which typically studied actors in isolation of each other and the legal frameworks in which they operated.

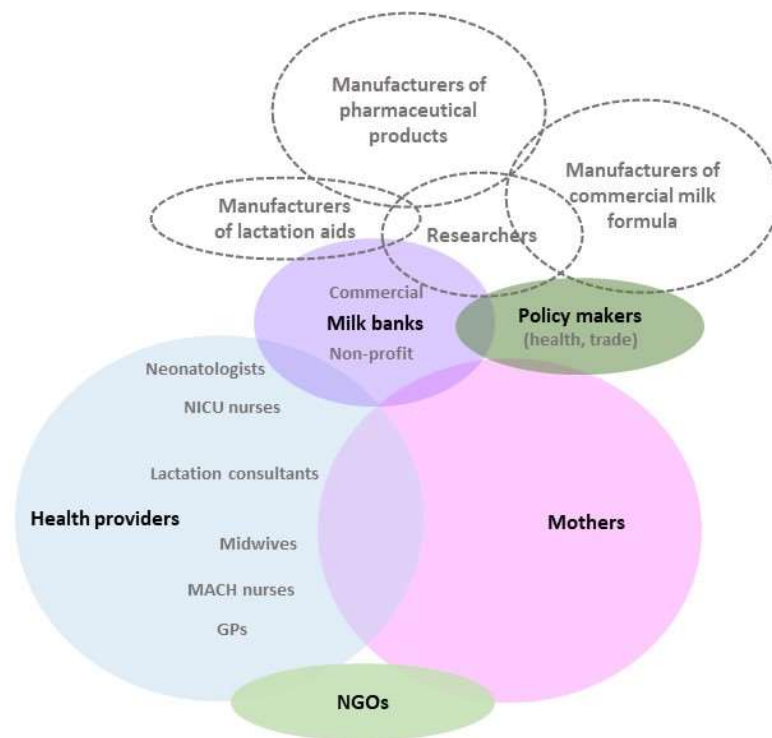


Figure 3 A provisional map of the governance of milk sharing through 'nodes' conceptualized as actor groups.

These primary nodes contained sub-nodes. For example, milk banks contained non-profit and for-profit models, health providers included sub-groups of health professionals, and policy makers concerned with various objectives, for example health and trade. Less understood were the roles of other actors with indirect links to milk sharing (NGOs, researchers, manufacturers of lactation aids, manufacturers of CMF and, potentially, manufacturers of biopharmaceutical products), indicated by the dotted lines in Figure 3. Concepts of nodal governance were central to my research and informed the empirical investigation of the conditions that promoted and supported nodes. This research required 'thick' descriptive studies of the central node, consisting of mothers and their milk sharing practices in Australia.

The next section describes the theories used to link nodal governance at the macro-level with governance at these lower levels, which included individual actor behaviours and the micro-level physiological processes of lactation.

3.4 Theories of actor behaviour: awareness, motivations, pathways and rewards -the 'AMPR' framework

To investigate lower levels of governance within nodes, this research required a theoretical framework to help explain the agency of the actors and organizations that constituted each node. In addition, this framework needed to accommodate the structural and individual factors that shaped agency across various settings and levels of governance, and the range of contexts under which milk sharing occurs. Accordingly, an open theory of actor behaviour —the AMPR²⁶ framework— of Honig et al and Petersen et al (218, 219) was used. The AMPR framework was developed to explain environmentally-responsible behaviour by corporations, in terms of their awareness, motivations, pathways, and rewards (218, 219). AMPR principles have been applied in studies of change towards a social good (533, 534).

The open behavioural framework of AMPR offered a framework to accommodate the wide range of factors that regulated of milk sharing described in the literature, and to build theory empirically, based on the perspectives of the actors involved, rather than impose theoretical constructs of regulation and power on these actors. A danger was that these open-ended theoretical frameworks of actor behaviour and nodal governance were merely descriptive, leading to a rudderless analysis of power and regulation. However, the analysis in this thesis is focused on how the regulatory structures of milk sharing shape breastfeeding. Anchoring the analysis on breastfeeding added complexity, and engaged with various theories of breastfeeding, ranging from constructivist theories, for example, of breastfeeding as 'natural,' to positivist theories that included 'ecological' models of the sociological, institutional and political economic factors that shaped breastfeeding (517).

A further theoretical requirement was the need to accommodate milk sharing as a social good and harm. For example, the literature showed that health institutions viewed milk banking as a social good and informal milk sharing as a potential harm. There was also the added complexity of how alternatives to these options, CMFs, were viewed in various contexts.

A generalized explanation of behaviour, consisting of awareness, motivations, pathways and rewards, accords with a theories of social learning and planned behaviour (535). The theory of planned behaviour hypothesizes that behaviour is predicted by intention and has been widely applied to the design of health interventions that target individuals. For example, the intention to breastfeed is a major predictor of breastfeeding duration (536). However, the theory of planned

²⁶ The AMPR framework may also be referred to as the RAMP framework. AMPR is used in accordance with Petersen et al and Honig et al (218, 219) and represents the logical sequence of behavioural elements.

behaviour has been critiqued, and, on its own, explains less than 50% of behaviour. An 'extended theory of planned behaviour' acknowledges that social influences also shape individual agency, and the importance of (1) moral norms, (2) self-identity and (3) in-group altruism (537, 538). In addition, agency in the collective sphere (539) provides access to collective power or alliances with groups with shared knowledge and interests ('epistemic communities') (516). This form of agency is used in milk sharing to harness other types of power, for example social capital and trust, and tap into feelings of connectedness ('bio-intimacy' and 'biological citizenship'), which are recognized as important regulators of human tissue donation (291).

In studies of breastfeeding and milk sharing, attention has been paid to actor awareness and motivations and also to structural, socio-economic factors. However, little work has been done to combine these factors with rewards and pathways to promote or inhibit specific types of milk sharing. As discussed in the literature review, these concepts, in isolation, have been offered as explanations of different types of milk sharing, for example 'wanting to help' (275, 278) is an explanation of motivation and 'not having a local milk bank' is a rationale for a pathway (274, 444). However, these concepts have not been integrated, or used to examine how milk sharing and its structures are socially maintained and reproduced. Finally, milk sharing has been investigated as an end in itself, as a complaint or deviant behaviour (279), but not as a signifier of barriers or agency in achieving breastfeeding.

With these issues in mind, AMPR concepts were operationalized in my research loosely, according to the principles of Honig et al and Petersen et al (218, 219). Motivations are defined as the 'personal and operational drivers that encourage an individual or organisation to respond' (219). These drivers include 'psychological and institutional factors', for example an individual's values or an organization's culture, and capture motivations that are 'intrinsic (broadly captured in personal norms) and extrinsic (e.g. risk, reward, reputation)' (218, 219). Motivations are distinguished from rewards by time, with motivations preceding action and rewards following action. However, these factors remain closely linked, when rewards reinforce or weaken motivations through incentives (218). At the time of this research, principles of altruistic donation and not-for-profit milk banking in Australia removed most financial incentives to donate milk (discussed further in the chapter on Rewards).

In this thesis, theories of nodal governance guide consideration of configuration of power, but the operation of power is identified within the analysis of agency and structure (540). AMPR provided a consistent analytical framework across nodes of actor groups and organizations to investigate what

shaped their actions or stance towards milk sharing. In particular, pathways showed how individuals navigated structural factors, and connected macro and micro levels of regulation.

3.4.1 The nature and direction of regulating actor behaviour

Just as theories of nodal governance are not prescriptive about the nature and direction of power, AMPR is not prescriptive about the nature and direction of actor behaviour. The AMPR theory is flexible in its definitions of awareness, motivations, pathways and rewards, and the specificity of these elements for various actors, settings and types of milk sharing. However, the AMPR model is limited in its conceptualization of ‘rewards,’ or the factors that provide positive reinforcement of a behaviour. This means that the AMPR framework ignored the negative factors that inhibited behaviour or caused avoidance. In applying AMPR to milk sharing, it was unclear whether the concept of rewards could accommodate the negative social consequences and other penalties for violating various norms for breastfeeding and CMF feeding experienced by women who shared milk.

In addition, the theories of nodal governance and behaviour used in this thesis make few assumptions about compliance. Compliance is an important construct in regulatory studies, and requires a desired set of behaviours and an authority that prescribes and monitors these behaviours (541). However, a multicentric model of regulation acknowledges that multiple authorities exist, and that compliance becomes complex. For example, mothers supplying milk banks can be viewed as ‘compliant’ because they do so under medical supervision and meet other criteria of health authorities, while mothers who share milk informally, and health professionals who help them, are ‘non-compliant.’ An important part of investigating the regulation of milk sharing is understanding who the various authorities in milk sharing are, and which actors adopt postures of ‘critical deference’ or defiance to them (541). These ‘motivational postures’ explain alternative pathways to compliance, which must be found when compliant ways are blocked, for example when milk banks are inaccessible. The literature also shows that compliance may shift as rules change, for example the expansion of medical criteria to use PDHM outside NICUs (241, 409, 410).

To investigate compliance in any context, Val Braithwaite proposes eight principles that start with the need to ‘*systematically gather data on patterns of non-compliance from different sources and initiate regulatory conversations among different actors in the regulatory space around what these patterns mean and the risks they pose*’ (541). The literature shows these data and conversations are lacking for milk sharing in Australia and require an analysis of the legal and social rules that structure compliance. This includes understanding how health professionals and policy makers understand various forms of milk sharing, the formation of institutional norms (542) and their integration with societal norms.

In addition, nodal governance and behavioural theories make no assumptions about the role of markets in milk's production and exchange and the socioeconomic conditions in which these activities occur. The literature sketched out milk sharing's regulation as a 'hybrid' of social norms and state control, market competition and industry self-regulation, with communities and NGOs responding to various institutional anachronisms, market failures and inequities (543): such hybrids are particularly subject to bureaucratic inefficiency, externalities, rent-seeking, a lack of accountability or transparency and exploitation. Accordingly, markets alone were unlikely to explain the regulation of milk sharing and its effects on breastfeeding, but the research was informed by market interests and mechanisms.

3.5 Linking levels of governance: integrating nodal governance and AMPR

Theories that link levels of governance are scarce. One assumption in my theoretical framework is that the behaviours of actors and organizations aggregate until they reach a critical mass or encounter countervailing or synergistic forces, at the boundary of their influence, which define the node. Nodal governance is not prescriptive about the level of governance at which these points of pressure occur.

The AMPR framework works from the other direction and takes a 'bottom up' approach to understand how levels of governance intersect, by combining psychological and non-psychological ('structural') factors affect behaviour (218, 219). These non-psychological factors include legal structures and political economic factors that actors may not perceive.

To cover this potential gap, my research includes an analysis of laws and policies that shape milk sharing. The political economic factors that structure the behaviour of actors are harder to reach, and require quantitative data on milk sharing and infant feeding practices that are missing or inadequate in Australia. The risk of missing the deeper workings of power is of particular concern for studies of regulation at the international level. For example, Sell states that 'unit-level constructivist analyses ...tend to underplay power considerations. Preferences and norms are crucial, but they are not the whole story' (544) p. 5. In uncovering 'the whole story,' processes of governance at the international level may seem removed from suburban decisions about milk sharing. However, as outlined in Chapters 1 and 2, public policy and corporate decisions reach from the international and national level to shape infant feeding options available to individual mothers, through politico-economic mechanisms that favour CMFs (31).

Milk sharing raises questions about where power is exercised and the systems and levels of governance are involved. Sociologists recognize that health institutions and women's bodies are sites

of struggle for power in capitalist, medical and patriarchal systems (545). The theoretical frameworks of nodal governance and AMPR allowed actors to describe these struggles and systems.

3.6 Theories that inform research methods for milk sharing

In combination, nodal governance and the AMPR framework make few philosophical assumptions, and accommodate the constructivist and positivist worldviews presented in the literature on milk sharing. Regulatory research of milk sharing must acknowledge the competing positions of these worldviews about ontology ('the nature of reality'), and epistemology ('what counts as knowledge and how knowledge claims are justified') (546). Ideas were clearly important drivers of milk sharing, for example norms of motherhood, 'optimal' nutrition, altruism and milk's symbolic value. These ideas supported the constructivist position that reality is understood through subjective meanings, 'formed through interaction with others and through historical and cultural norms that operate in individuals' lives' (546) (p.24). In contrast, the public health literature on milk sharing was based on positivist sciences, that were primarily 'reductionistic, logical, empirical, cause-and-effect oriented and deterministic based on a priori theories,' but acknowledged that cause and effect were probabilistic ('post-positivist') (546) (p. 24), for example assessments of risk and interventions based on behavioural theory.

However, the literature on milk sharing showed that constructivist and post-positivist world views often intersected. For example, the theory of planned behaviour acknowledges the influence of non-material attitudes and beliefs as real and causative (535). Similarly, the social sciences literature acknowledged material enablers and constraints of milk sharing practices, for example economic conditions. This engagement with post-positivist and constructivist worldviews is a feature of other studies of milk and its regulation (89, 547, 548). For example, a study of milk and cow's milk by Asdal analysed how their systems of classification and institutional arrangements were shaped by their physical and symbolic attributes, including competing 'bacteriological, nutritional and economic' ideas (548).

Critical realism is a worldview developed by Maxwell and other theorists that combines ontological realism (that existence occurs independently of the human mind) with epistemological constructivism (that knowledge of the world is 'mediated by our conceptual 'lens') (549). Critical realism differs in ontology from positivism by claiming that reality includes what cannot be empirically known. Critical realism acknowledges that 'what the practices, institutions, rules, roles or relationships are depends on what they mean in society to its members' (550) p.30. Recognition of the importance of meanings is central to critical realism's embrace of complexity and focus on 'the role of both agency and structural factors in influencing human behaviour' (551). Maxwell's

application of critical realism (552) uses qualitative research methods to explain processes, an approach consistent with studies of regulation that aim to understand regulatory mechanisms (516), as discussed in Chapter 4.

The hidden nature of milk sharing makes it difficult to conduct research and the use of prior theory tentative. Layder's adaptive theory acknowledges the messiness of research in practice and the need for multiple strategies, in which a temporal sequence of activities is blurred by the fact that 'theorizing and data analysis go hand in hand' (540) (p. 28). This interplay between prior and emergent theory provides an approach to qualitative research which acknowledge the use of conceptual models prior to data collection and methods that reveal, through descriptions of the settings and contexts of behaviour, the structural factors which provide 'more inclusive and powerful explanations of social life' and balance 'behavioural typologies' that are the focus of grounded theory approaches to qualitative research (540) (p. 78).

3.7 Conclusion to theory

Empirical research was required to test assumptions about the separate regulation of milk sharing sectors, investigate the actors involved in milk sharing, how their power was distributed and exercised through various regulatory mechanisms. Bringing together theories of regulation that handled macro-and micro-level forms of power, from nodes of power arranged around actor and institutional interests to the biological level of individuals, provided a framework to understand how the regulation of milk sharing shaped breastfeeding (Table 2).

These theories informed the investigation of limits of state and non-state power in milk sharing, the ways that actors and institutions framed different forms of milk sharing and the other factors that shaped actor agency across settings and levels of governance. The next chapter describes the methodology and specific methods used to investigate nodal governance and actor behaviour and their regulatory mechanisms.

Chapter 4. Methodology

4.1 Research aims and questions

The aim of this research is to understand how the regulation of milk sharing affects breastfeeding in Australia. This chapter describes the study design and methods used to answer the research questions and sub-questions:

1. *How is milk sharing regulated in Australia?*
 - (a) *How do institutions frame milk sharing?*
 - (b) *What are the conditions under which milk sharing occurred?*
 - (c) *How does the regulatory regime of actors, institutions and ideas shape the way milk was shared?*
2. *How does the regulation of milk sharing shape breastfeeding?*

The methods used to investigate these questions described in Table 3 are based on the theories relevant to milk sharing, described in chapter 3. In brief, critical realism is the philosophical approach used to accommodate post-positivist and constructivist positions of milk sharing's materiality and social meaning, which are necessary for a broad understanding of its regulation (552-555). Two theories of governance were used: nodal governance (526) provided a model of regulation beyond the state, and the AMPR behavioural model of actor awareness, motivations, pathways and rewards provided a model of actor agency (218, 219).

This chapter describes the research design including the research settings, data sources, concepts and methods of data collection and analysis, and the measures to meet ethical requirements and ensure rigor (556) (Table 3).

Table 3 Research questions, settings, data sources, concepts and methods for data generation.

Research sub-question	Setting	Data sources	Concepts	Methods
1. How is milk sharing regulated in Australia?			Nodal governance. Actor behaviour.	
(a) How do institutions frame milk sharing?	Institutions	Legal structures: - Laws, policies and guidelines related to milk and milk sharing in Australia (and overseas, as relevant) from: - Written responses from government Departments of Health (federal and State/Territory) - Publicly available academic literature, government web pages, grey literature, NGO position statements and guidelines. - Non-public clinical guidelines.	Governance by the state. Legal responsibilities and policy advice that applied to milk and different types of milk sharing. Jurisdictional variation in the application of laws and policies to different types of milk sharing. Milk sharing sectors.	Document analysis: - Letters to Departments of Health. - Review and analysis of laws and policies in each Australian jurisdiction.
	Institutions	Policy makers from: - Departments of Health -Australian Government and State/Territory - Other relevant government agencies - Non-government organizations. - Administrators of social media pages for milk sharing in Australia	Policy makers' interpretations of law and policy. Policy makers' awareness, motivations, pathways and rewards related to policy around milk sharing.	In-depth interviews. Triangulation with data from interviews of other actors and document analysis.
(b) What are the conditions under which milk sharing occurred?	Community	Australian mothers who shared milk or cross-fed through milk banks and/or informal arrangements in health and community settings. Mothers' demographic and socioeconomic characteristics.	Non-state power. Mothers' awareness, motivations, pathways, rewards related to different types of milk sharing. Structures shape agency: Mother's social and economic resources, including maternity leave.	In-depth interviews. Online survey of mothers interviewed.
	Health	Milk bank managers and staff.	Milk bank staff awareness, motivations, pathways, rewards related to different types of milk sharing	In-depth interviews.
	Health	Health professionals concerned with lactation (midwives, lactation consultants and doctors)	Health professionals' awareness, motivations, pathways, rewards related to different types of milk sharing	In-depth interviews.
(c) How does the regulatory regime of actors institutions and ideas shape the way milk was shared?		Legal structures. Actor groups engaged with milk sharing.	Nodes of power and nodal interfaces in the governance of milk sharing. Structures that shape actor agency. Institutional and social norms for different types of milk sharing.	Comparison of awareness, motivations, pathways, rewards between actor groups. Analysis of nodes of power in milk sharing. Analysis of regulatory principles for milk sharing revealed by the analysis of nodal governance and actor behaviour.
2. How does the regulation of milk sharing shape breastfeeding?		Legal structures. Actor groups engaged with milk sharing and their breastfeeding experiences.	How the institutional framing and the conditions of milk sharing affect breastfeeding protection, promotion and support. The regulation of milk sharing is connected to the determinants of infant feeding.	Document analysis. In-depth interviews. Academic literature.

4.2 Research design

The broad conceptualization of regulation in this study meant that the research sought information from multiple sources to provide richness and context to accounts of milk sharing and its governance by state and non-state actors. The first part of my study investigated the ways that institutions framed milk sharing. This was undertaken through an analysis of legal structures (laws, policies and guidelines), institutional arrangements and ideas related to milk donation. The aim was to understand how these documents represented and framed milk banking and informal milk sharing and their relationships with breastfeeding. These documents showed the objectives, types of evidence, policy making processes and information on milk sharing practices available to other policy makers, health professionals and the public.

The second part of the study investigated the conditions under which various forms of milk sharing occurred by investigating four actor groups (mothers, milk banks, health professionals and policy makers) with direct experience of milk banks or informal milk sharing or cross-feeding arrangements or administrative or policy roles related to these activities (Table 4). The aim here was to provide an understanding of a wide range of milk sharing practices in health and community settings in Australia and the institutional, social and other factors that shaped actor behaviours and attitudes. The hidden nature of milk sharing, in particular informal practices, meant that data from different actor groups were needed to build a picture of the institutional and social norms around milk sharing, their relationship to breastfeeding, and the legal, conceptual and pragmatic challenges actors faced. Participants in all actor groups were recruited purposively and opportunistically through snowball techniques (through their social and professional networks).

The research approach was to centre the study on the production and distribution of milk, by starting with mothers and milk banks. Information provided by these two actor groups prompted investigation of health professionals and policy makers as important intermediaries of policy and practice. Each actor group was used to triangulate data obtained from the other actor groups. The perspectives of each actor group provided insights into the nature and direction of power in milk sharing, needed to flesh out the model of nodal governance, and its relationships to the wider governance of infant feeding.

The findings were synthesised to understand the operation of the regulatory regime for milk sharing, its nodes of power and their reach and implications for breastfeeding. The research design was informed by theory of nodal governance and its eight dimensions, as described in Chapter 3 on theory, but did not assume that this theory provided a sufficient explanation of governance. The research design left open the question of how higher and lower levels of governance were linked,

and subject to the empirical evidence from the studies of actor groups. In the final analysis, the proposed map of nodal governance presented in the previous chapter (Figure 3, Chapter 3), was revised, because it was not supported by the data and integrated analysis of the legal structures and four actor groups studied. The revised map is presented in the Discussion (Figure 11, Chapter 10).

4.3 Research methods and sources

This section describes the selection of documents for the analysis of legal structures and the selection of participants to interview in the different actor groups.

4.3.1 Policy and legal structures for milk sharing

In Australia and many other countries, uncertainty about the legal structures that applied to milk sharing made its analysis an iterative process. The absence of law and policy are as important as their presence, and several approaches were needed to define and understand these gaps within Australia's federal system of government.

The analysis of legal structures that governed milk,²⁷ milk banking and informal milk sharing started with institutions with responsibilities for infant feeding, and a federal Department of Health report on the regulation of milk banking (11). Over the course of the study, other institutions and policy domains were identified at various levels of government.

Documents were obtained for the period following the re-establishment of milk banking in Australia (2006-2019), from three sources: (1) publicly available legislation, policies and guidelines on the web sites of government and non-government organizations, including non-profit entities and for-profit companies; (2) inquiries to Departments of Health in each Australian jurisdiction (federal and State/Territory), and (3) actors from the second study, in particular policy makers in state agencies, health professionals and non-government organizations, who provided policies during interviews.

A sub-set of documents was selected for more detailed analysis from jurisdictions and levels of government with specific policy for milk, donor milk or milk sharing in policy domains for infant feeding, milk banking and infection control (listed at the end of Chapter 5). These documents did not enable an analysis of the history of policy development for donor milk, as previous versions of policies were often not available from the web pages of organizations.

²⁷ In this thesis, 'milk' refers to human milk unless stated otherwise.

4.3.2 Interviews: participants and recruitment

The actor groups selected for interview represented a mix of state and non-state actors identified in the literature. State actors were government regulatory authorities and public sector health services. Non-state actors were mothers who shared milk, milk banks, health professionals working in the private sector and professional and consumer associations that represented these actors. The selection of actors aimed to include as many jurisdictions in Australia with and without milk banks as possible, within the limited scope of a PhD. In addition, the sensitivity of infant feeding issues and the time demands on busy mothers, milk banks and clinicians, required me to travel to participants. The number of interviews conducted in each actor group was determined by data saturation (no new information was identified). Table 4 summarises the numbers of participants in each actor group.

Table 4 Numbers of participants in each of four actor groups, and their principal role or type of organization

Actor Group	No. participants interviewed	Total number of participants in each actor group
Mothers	48	48
Milk banks (5)	8	8
Health professionals		19
<i>Midwives</i>	7	
<i>Lactation consultants</i>	5	
<i>Doctors</i>	3	
<i>Nurses</i>	4	
Policy makers		20
<i>Government agencies</i>	15	
<i>Health services</i>	2	
<i>Non-government organizations</i>	3	
Total		95

Mothers

The investigation of mothers aimed to identify the factors that influenced how milk was shared in Australia and the ideas and biological, legal, economic and social factors that determined these infant feeding options at the time. Mothers were donors or recipients of shared milk or cross-feeding through milk banks or informal arrangements.

I used a sampling strategy to purposively select women with diverse milk sharing practices from across Australia. Mothers were recruited who spoke English, resided in Australia and had provided or received donor milk through milk banks, informal sharing or cross-feeding arrangements from 1 April 2011 to 2016 (Appendix 7. Demographic data from the study of mothers and Appendix 8. Milk sharing practices). This date was chosen to cover the period in which Facebook pages for milk sharing first became available in Australia.

Mothers were recruited using methods appropriate for populations that are difficult to access. The study was initially publicised in July 2016 by the Australian Breastfeeding Association in a national online forum for breastfeeding research available and a website I established for the study 'Sharing Human Milk in Australia' (www.sharinghumanmilkinaustralia.info). Mothers spread information about the study, including via social media. Inquiries were received from a mix of metropolitan and regional locations in all Australian States and Territories, except South Australia. Clusters of respondents located in some areas were associated with local milk sharing networks, donor-recipient pairs, and the clients of health professionals and groups focused on infant feeding issues, parenting and other topics.

As I live in the ACT, an initial sample of women in the ACT was interviewed for convenience, to refine the focus of the research and interview methods. Preliminary analysis of this sample was followed by selection of health professionals and policy makers with roles related to the use of PDHM in the Territory health service. This helped me understand regional relationships between milk banks and the wider milk sharing community.

A total of 48 mothers who shared milk were interviewed in six states and territories from 12 July 2016 to 19 January 2017 from the ACT, Victoria, Western Australia, Queensland, NSW and the Northern Territory. Of these mothers, six were from regional areas, the rest from capital cities.

Milk banks

The empirical study of milk banks aimed to understand the legal, financial and social conditions under which milk banks operated and their influence on infant feeding options and other types of milk sharing in Australia. Milk banks operated within the public and charitable sectors but commercial milk banks and products emerged during the period of my research. All four of Australia's established milk banks were contacted and participated in the study from November 2016 to January 2017, and two new milk banks were added between February 2017 and February 2019 (Lifeblood Milk and the Australian Breast Milk Bank) (Table 1, page 8). Interviews were conducted with milk bank directors, managers and staff who had knowledge of milk bank operations and the policy, legal, financial and social frameworks under which it was established. The final analysis included data from eight participants who represented five milk banks located Victoria, Queensland, Western Australia and NSW (Table 4, page 65). The withdrawal of one milk bank for commercial reasons highlights the difficulty of researching political economic influences in milk sharing. The investigation of milk banking was informed by data collected from three institutional clients of milk banks (health services in the ACT, SA and NSW), who were included in the policy maker or health professional actor groups.

Health professionals

The study of health professionals selected midwives, lactation consultants and doctors with expertise in lactation and breastfeeding support. In Australia, midwives are typically employed by maternity hospitals to provide antenatal and perinatal care and education, including on breastfeeding, in post-natal wards and home visits in the first few weeks postpartum when breastfeeding is being established. Less commonly, midwives provide these services in private practice. In 2015 there were 32,651 midwives registered in Australia (557). The Australian College of Midwives (ACM) had about 4500 members but not all of these were practising (558).

Lactation consultants are International Board Certified Lactation Consultants (IBCLCs) who provide high level expertise when breastfeeding difficulties are encountered. In 2018 there were 2,059 IBCLCs in Australia (559). Most are midwives or doctors employed in public and private sector hospitals and private practice.

To recruit health professionals, I sent emails to the Board of Directors of Lactation Consultants of Australia and New Zealand (LCANZ) and the Australian College of Midwives (ACM) to request assistance, used snowball techniques and my personal networks, and advertised the study in the quarterly magazine *Australian Midwifery News* and a national newsletter emailed to ACM members. To be eligible, midwives, lactation consultants and doctors needed to be registered in Australia and have clinical, administrative or teaching roles that concerned lactation or someone in their professional care who shared milk after 1 April 2011. A total of 19 health professionals were interviewed between 2017 and 2019 (seven midwives, five lactation consultants, three doctors and four nurses) located in the ACT, NSW, Victoria and Tasmania employed in public and private hospital NICUs, special care nurseries, post-natal wards, clinics and homes.

Policy makers

The study of policy makers aimed to investigate how government and non-government organisations and institutional factors shaped the regulation of milk sharing. Organizations were selected purposively that had responsibilities for policy and regulation concerning infant feeding, population health, infectious disease control, risk management, food and therapeutic goods. There were nine government agencies and health services at federal and state/territory levels and three NGOs that represented health professionals (LCANZ and ACM) and breastfeeding mothers (the Australian Breastfeeding Association) (Table 5). Policy makers were recruited using direct inquiries to organizations and opportunistic, snowball techniques. A total of 20 participants were interviewed from 18 November 2016 to April 2019 in the ACT, Victoria, NSW and South Australia. This aspect of the study was informed by data collected from interviews with two mothers who were also

administrators of social media pages dedicated to milk sharing ('Eats on Feets' and 'Human Milk for Human Babies') and who explained their policies and operation.

Table 5 Policy makers interviewed in government agencies at the federal and state/territory level and non-government organizations.

Policy makers	Number of participants interviewed
Federal government agencies: <i>Department of Health and Aged Care</i> <i>National Health and Medical Research Council</i> <i>Food Standards Australia New Zealand</i> <i>Therapeutic Goods Administration</i> <i>Department of Agriculture and Water Resources</i>	11
State/territory government agencies: <i>Department of Health</i> <i>Health services</i> <i>Food Authority</i> <i>State insurer</i>	6
Non-government organizations	3
Total	20

4.4 Data collection and analysis

4.4.1 Data collection

Documents for the study of legal structures

Documents collected for the study of legal structures for milk sharing were Australian federal and state/territory legislation and regulations related to food, human tissue, therapeutic goods, workplace safety, importation permits, parliamentary inquiries and government reports from relevant agencies. I also obtained policies, standards, guidelines, position statements and parental advice from health services, milk banks, non-government organizations and social media sites. International sources were used where relevant, and included WHO infant feeding policies and overseas milk banking associations. These documents were current over 2014-16, with any subsequent changes noted, and obtained through online searches of legal databases, the web pages of parliaments, government agencies and NGOs, and Google, using terms for 'human milk,' 'breastmilk,' 'milk donation,' 'milk banking' and 'wet-nursing.' These documents provided evidence of the regulatory roles of various authorities and actors, their awareness of milk banking and informal milk sharing and relationships to infant feeding policy and other policy domains.

To understand how legislation was interpreted, a letter was sent in September 2016 to the Department of Health in each jurisdiction (federal, state and territory), asking which laws applied to

different milk sharing arrangements in six hypothetical scenarios (Appendix 3. Study of legal structures). These scenarios represented milk sharing with different levels of medical supervision in hospital and community settings, and presented to policy makers the range of circumstances in which milk was shared and the 'grey areas' for mothers and health professionals. Replies were received from all jurisdictions from 2016 to 2018.

Key informant interviews

Interviews were conducted to collect qualitative data from four actor groups about their knowledge, experiences, attitudes and practices associated with milk sharing. The use of in-depth, face-to-face interviewing techniques allowed exploration of the settings and contextual factors that affected each participant's awareness, motivations, pathways and rewards with respect to milk sharing (218, 219). This technique enabled me to discuss the specific settings, circumstances or meanings surrounding milk sharing in a manner that was sensitive to the emotional or legal vulnerability of mothers and health professionals, and enabled participants in official positions to describe their personal experiences and opinions. Some mothers had multiple roles as donors, recipients or both over more than one lactation, and it took time to trace key events and complex social and institutional arrangements.

Interviews were conducted in accordance with accepted practices for qualitative data collection (546, 560). All participants were provided with an information sheet and provided consent prior to the interview (Appendix 2. Ethics approval). Individual interviews were conducted in person with all mothers, and other actor groups, except for five group interviews of two to four participants in milk bank, health professional and policy maker actor groups (a total of 16 participants), at their request, and three interviews of participants in remote locations were conducted online via video link (one mother and one policy maker) or phone (one policy maker). Interviews were scheduled for one hour but were often longer (mean=94 minutes, range=36-197 minutes), with a total of 127 hours of interviews audio recorded. Interviews took place in homes, workplaces or other locations and at times of day convenient to the participant to maximize their availability. Access to mothers was improved by conducting interviews in their homes and accommodating their family and work responsibilities. Interviews with mothers were often interrupted by infants and young children, and others phoning or arriving at the door to exchange milk. Mothers showed me media reports, social media posts and phone messages about milk sharing, photos of their children at various stages in their milk sharing story and opened their freezers to display stocks of donor milk. I made notes of this rich material but did not use images, in order to preserve participant anonymity.

I prepared semi-structured interview schedules that covered each AMPR domain (Appendix 6. Interview questions) and used them in a flexible way to allow specific topics to be explored in detail. I was also mindful that the AMPR concepts may not provide sufficient explanation of milk sharing, and I listened for and pursued topics that appeared to be outside this framework. During interviews, I used the concepts introduced by the participant in order to avoid biasing the participant's responses.

For milk banks, health professionals and policy makers, interviews were conducted according to a tailored schedule of questions that was emailed to participants prior to the interview. Questions were based on the literature, analysis of legal structures, and documentation on milk bank websites and data collected from interviews with mothers. In the interview I asked about the participants' parenting and professional roles, qualifications, training, experience of different types of milk sharing, and their role and that of their organization in infant feeding. I asked participants to describe relevant policies and legal instruments, operations, governance, funding, knowledge of the supply, demand and distribution of milk and probed their attitudes towards informal milk sharing and the effects of different types of milk sharing on breastfeeding, safety, ethics and emerging issues, including payment for milk and milk sharing services.

Interviews were recorded on a small portable digital audio recorder to obtain an accurate account and I took handwritten notes during the interviews. Three participants from actor groups other than mothers did not give permission for audio recording and, in addition, a fourth did not permit notes to be taken during the interview. Within 48 hours of each interview, I recorded field notes to aid interpretation of the data, for example, distractions in the interview, the participant's demeanour and topics that appeared to be sensitive, and my reactions to them, to better understand how my values and biases (axiological assumptions) affected the research (546). The audio recording of each study participant was given a unique identifying code and transcribed by me or a private transcription company. I proofread all transcriptions against the recordings and de-identified all individuals and locations mentioned in the interviews. Each interview transcript was read before each cycle of coding commenced and read a minimum of four times.

Mothers' demographic data

Demographic data were collected from study participants who shared milk to describe their socioeconomic characteristics and understand the limitations of my research. Data were collected via a 12-item self-completion questionnaire designed in Survey Monkey (© 1999-2018 SurveyMonkey) on the participant's postcode, age, marital status, number of children, education, employment status prior to milk sharing, parental leave, number of children under 15 years of age and adults in the household, income, country of birth, language and membership of ABA (Appendix 7. Demographic

data from the study of mothers). The survey was tested with two adults not involved in the research, piloted with the first 13 participants and took approximately five minutes to complete.

Ethical considerations

The Australian National University ANU Human Research Ethics Committee and the Australian Breastfeeding Association (ABA) approved this research (Protocol: 2016/036) (Appendix 2. Ethics approval). ABA helped advertise the study of mothers a public forum on its website but did not fund the study or provide information about ABA members (ABA Research Approval Number: 2016-9). My role as an ABA breastfeeding counsellor was disclosed in discussions with participants, by word of mouth or social media. My background as an ABA breastfeeding counsellor gave me skills to discuss infant feeding issues that helped establish trust with mothers who shared milk. All participants were advised before the interview that they could pause, discontinue or withdraw from the research or if distressed, to contact support services.

4.4.2 Data analysis

Document analysis

I first analysed the legal classification and interpretation of policies of about milk and milk sharing in each jurisdiction by tabulating and comparing the replies to letters sent to Departments of Health (Appendix 1.2.4.1). I then examined the ways in which these legal and other instruments shaped milk sharing in Australia from the highest level of governance to the lowest, at the level of health facilities and advice to parents. Legal definitions and restrictions on access, end use, consent, safety, advertising, sale and compensation for milk sharing were compared with those for other infant feeding methods (breastfeeding and CMFs). The overall analysis of legal structures integrated data from the document analysis and interviews of actor groups.

Coding and analysis of interview data

The behavioural theory that underpins AMPR is well developed, but the application of AMPR in regulatory research is limited. For each actor group, interview data was provisionally coded using the AMPR framework (561), prior to exploration of meanings within these categories. This framework was used as a loose conceptual tool to organize data and consider the contexts for AMPR categories, in addition to the components of categories, and was not prescriptive about the relative importance of AMPR categories. Coding of AMPR categories was undertaken in stages (pre-coding, provisional coding and coding around core and satellite concepts) (540), and was consistent with ‘topic’ and ‘eclectic’ methods of coding qualitative data described by (561). Within each AMPR coding category, meaning was constructed from this data in an exploratory manner (560), using memos to link the analysis to pre-existing and developing concepts and theory.

All interview data were analysed using NVivo 12 Pro software (©QSR International Pty Ltd) that handled data categorization, coding, memos and manipulation in several forms and linked qualitative and quantitative data from interviews and the demographic survey of mothers. Mothers were categorized as donors, recipients or both and their milk sharing practices and relationships characterised (Appendix 8. Milk sharing practices). To analyse connections, I created narrative summaries of each account that focused on the functional aspects of interactions and processes and how they were organized (552) p. 117. These categorical and connecting strategies were used to develop more rounded explanations of milk sharing and its regulation.

4.5 Limitations

In common with most qualitative research, my research aim, study design and sampling methods are not intended to be generalizable to the wider population. I was interested in the diversity of experiences and positions concerning milk sharing, how participants interpreted their experience, and the factors they attributed to milk sharing practices and breastfeeding outcomes (Appendix 8. Milk sharing practices of mothers studied).

The qualitative methods and research design that I used have several limitations. I used snowball techniques to recruit actors with knowledge and experience of milk sharing and this risked bias in the results towards those with favourable attitudes towards milk sharing and altruistic donation. These attitudes were also a product of contemporary norms, which may change. Attempts to recruit actors with commercial interests in milk sharing were restricted to commercial milk banks and not successful. Initial advertising for mothers through ABA may have resulted in over-representation of mothers associated with this organization (26 of 45 participants were current or past members of ABA), which may have introduced positive or negative subject bias (Appendix 7. Demographic data from the study of mothers). Recruitment through social media sites for altruistic milk sharing may have excluded mothers who were compensated for milk donation or had limited access to the internet. However, in 2017, 97% of households with children under 15 years had the internet (562), and snowball methods also recruited women who shared milk outside social media networks.

My study underrepresented population groups exposed to milk banking through admission of infants to NICUs (about 8% of the population) (563, 564). Groups more likely to give birth to premature and low birthweight infants include teenage mothers and groups with low health status, including Aboriginal or Torres Strait Islander (ATSI) women (565).

Purposive sampling of ATSI and culturally and linguistically diverse (CALD) communities was outside the scope of this study, despite the importance of these groups to a full understanding of milk sharing in Australia. Demographic data showed that 22% (8/37) of participants were born in a

country other than Australia, in line with national statistics showing that 28% of the Australian population was born overseas (566). Of these, most were from Anglophone countries, including in Asia, which was broadly consistent with Australia's immigrant population profile. However, none were from the Middle East, South America or Africa, where various forms of milk sharing are well recognized (257, 567) (Appendix 7. Demographic data from the study of mothers).

Participants in my study of mothers were well-resourced, which is consistent with population-based studies that show positive associations between breastfeeding and higher levels of education and income (35). Most women in the study (81%) were employed during pregnancy, a finding that was consistent with a national data (568). Most participants lived in a capital city with a partner (married or in a defacto relationship) and had an average of 1.88 children, which is consistent with national fertility rates (569). In contrast, in 2017 about half of Australia's children aged 0-4 years old lived outside capital cities (570).

There is debate about the ways in which the validity and accuracy of qualitative studies can be demonstrated without subjecting interpretative processes to standards appropriate to positivist ontologies. I have adopted an approach by Maxwell (552) that describes validity in terms of the three types of claims made at successive stages of the qualitative research process: descriptive, interpretative and theoretical. Maxwell added two further types of validity: generalizability and evaluative validity. Maxwell (571) also considered two principal threats to validity to be researcher bias ('ways in which data collection or analysis are distorted by the researcher's theory, values, or preconceptions') and participant reactivity ('the effect of the researcher on the individuals studied'). I describe how I addressed these types of validity below.

Descriptive validity: Descriptive validity is the factual accuracy of the researcher's account (552) (pp 135), which I addressed by audio recording interviews, transcribing and coding the full interview and using verbatim quotations to illustrate what was said. I also made notes of my observations of events and behaviours in the interview and retained copies of documents and records of their date of retrieval and source in bibliographic software (EndNote™ X8). Descriptive validity can be affected by omission and there were parts of the regulatory regime that I missed or over-emphasised. To address these gaps, I used multiple sources to obtain descriptions of the regime, spent an extended period (2016-19) in the field observing developments in infant feeding policy and practice and asked participants to reflect on these in the five years to the present.

Descriptive validity also requires reliable research methods. To address reliability, I applied consistent methods to interview actor groups, provide background information and obtain consent. However, the course of the interview and follow-up questions varied according to the participants'

experiences. (Appendix 1.3). I triangulated my findings by using different types of data (interviews and documents) about interpretations of law and policy, and multiple sources, for example donor and recipient pairs who exchanged milk, or policy makers from different agencies or administrative levels.

Interpretive validity: Maxwell emphasised that it is not data that are valid but the inferences or conclusions drawn from them (552)(pp 134). The researcher is attempting to understand the meaning of objects, events and behaviours and interpret the participant's 'intention, cognition, affect, belief and evaluation.' To address interpretive validity, I used face-to-face interviews in a setting chosen by participants so that they were relaxed and to observe their facial expressions and other behaviour to interpret meaning. During data collection and analysis I noted emotional expression and used the participants' 'own words and concepts' (552) pp 138. According to critical realists, the perspectives of actors are respected but a social phenomenon need not be centred on that perspective (552) and my research studied the perspectives of a range of individuals and actors, which enabled comparison, triangulation and negative case analysis.

Theoretical validity: Theoretical validity refers to 'an account's function as an explanation' of phenomena and 'making sense of things' in general, which requires a degree of abstraction (552) pp 138-140. This requires valid concepts to be applied to phenomena (construct validity) and valid configurations of relationships between these concepts (which includes causal validity). To improve the validity of explanations my research involved intensive, long-term involvement and collecting rich data (572) p 43.

Generalizability: Generalizability in qualitative research refers to the ability of theory generated from the research to explain a process that can be applied beyond the direct study and to different situations. As discussed at the start of this section, I recognized that my research design and the purposive selection of participants limited its generalizability. My research aimed to understand diverse milk sharing practices and positions on milk sharing, and how participants interpreted their experience, including their accounts of causation. Maxwell also notes that interviewing was a method of data collection with limited internal generalizability, when it failed to elicit a participant's full perspective on an issue (573). This problem is addressed through the relationship between the researcher and participant, and, in my research, I endeavoured to build respectful relationships and trust with participants through open communication and transparency about my background.

Evaluative validity: I addressed researcher bias and participant reactivity by asking open questions, using terms that were, as far as possible, neutral and free of my values and evaluations (Appendix 6. Interview questions), and making field notes as part of reflexive practice, to raise my awareness of

issues that were emotive and contentious for me or participants and affected our subjective interpretations (573, 574).

4.6 Conclusions to methodology

This chapter explained my research design and methodology to investigate the ways in which the regulation of milk sharing shaped breastfeeding in Australia. I investigated how institutions frame milk sharing and the conditions under which milk sharing occurred in interlinked, empirical studies of documents and four key actor groups: women who shared milk, milk banks, policy makers and health professionals associated with lactation. I used multiple strategies to analyse qualitative data from these studies to explore the rewards, awareness, motivations and pathways (RAMP) to share milk for key actors and organizations.

Findings from the studies of documents and each actor group are presented in the following chapters. The next chapter reviews and analyses the legal structures for milk as a product and milk sharing as a process.

Chapter 5. Results: Legal structures for milk sharing

Chapter 5 is the first results chapter. It describes the laws and policies which affect the exchange of milk, as a product, and acts of milk sharing in Australia. Exchanges of milk may be affected by the legal regulation of property, contracts, intellectual property, consumer protection, food, human tissue and therapeutic goods. Jurisdictions vary in their legal classification of milk as a food, human tissue or therapeutic good and these frameworks are the focus of the laws examined here (Table 6). Government policies applicable to shared milk are concerned with infant nutrition and infection control (Table 7), with an emphasis on milk banks. The policies of non-government organizations (NGOs) on milk sharing include the position statements of key actor groups and policies of milk banks that operate outside hospitals. Policies that indirectly affect the supply and demand for shared milk are described briefly and international policies for milk sharing are referred to when cited in Australian policy.

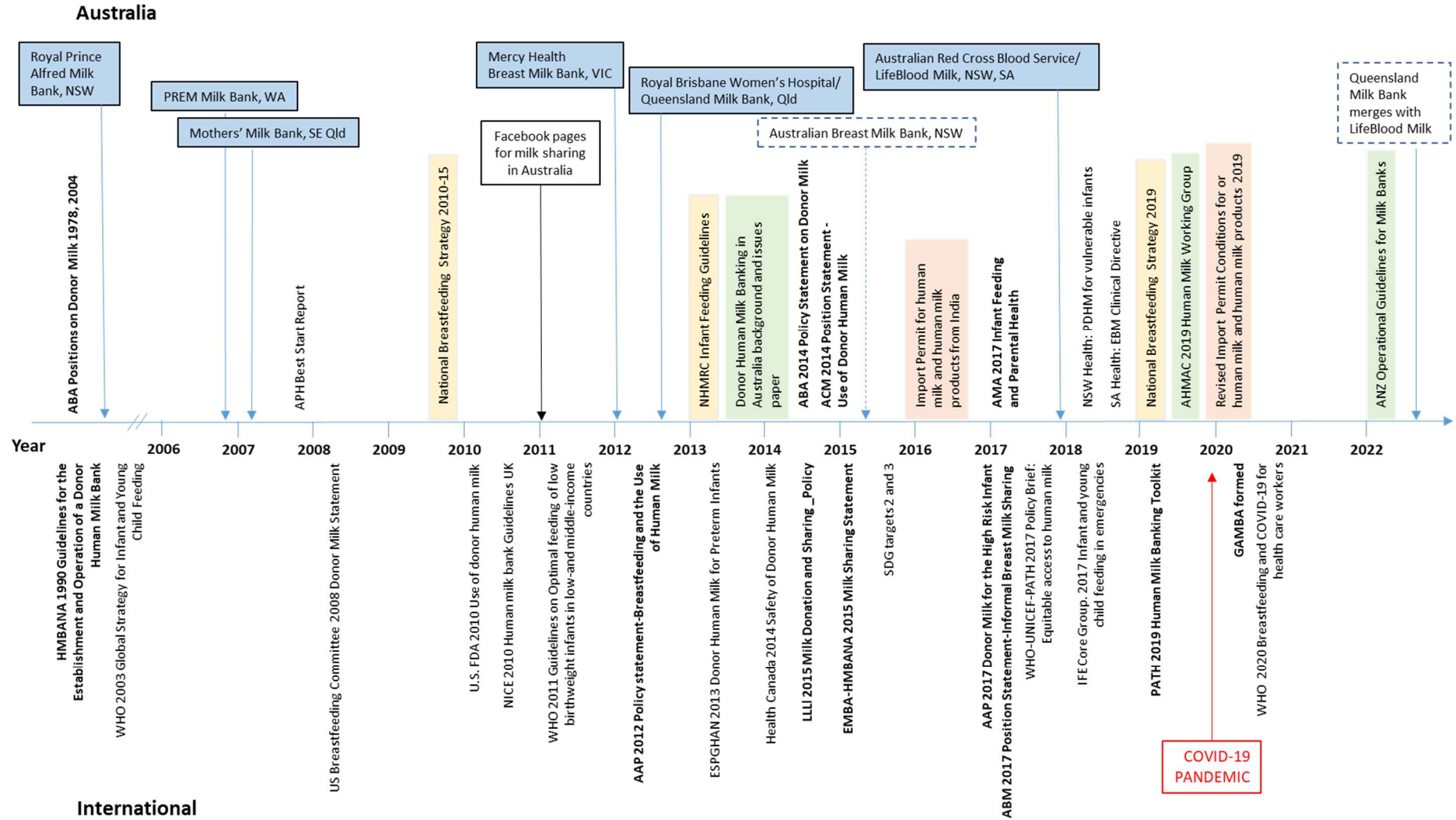
5.1 Policy Context

The policy context for milk sharing is the three-way competition between public health and commercial interests in breastfeeding, CMFs and milk, as outlined in chapter 1. This competition is structured by the policies and policy making environments that enable breastfeeding and CMF feeding, which provide the background to policies developed by government agencies and NGOs for shared milk in Australia and internationally from 2000, as shown in Figure 4.

In 2007, an Australian federal parliamentary inquiry into breastfeeding recommended a national system of publicly funded milk banks operating within ‘*a national regulatory and quality framework*’ (Recommendation 8) (116). The *Australian National Breastfeeding Strategy 2010-15* that followed the inquiry did not include policy for milk banking, but committed to ‘*consider the evidence, quality assurance and regulatory issues*’ for milk banks (575, 576).

Next page:

Figure 4 Timeline of key Australian and international policy documents for milk sharing 2006-2022, showing commencement of Australia’s six milk banks (blue boxes) and publication of national infant feeding policies (coloured bars) and NGO position statements (bold text).



Accordingly, the Australian Government Department of Health published a background paper, *Donor Human Milk Banking in Australia*, that rejected federal responsibility for the regulation of milk banks and concluded that their establishment, management and funding were ‘*a matter for consideration by local hospital networks, subject to local priorities.*’ Self-regulation was also justified as a means of fostering innovation and research in milk banking (11).

From 2007, milk banking expanded slowly in Australia and, despite calls for a national milk bank network, standards and a national strategy (73, 96, 116, 577), Australian milk banks were left to adopt operating principles from the PREM Bank in Perth (96) and international guidelines. Informal milk sharing received little policy attention, but made regulatory questions about milk more complex. The Commonwealth 2014 background paper noted the warnings from overseas health authorities (200, 320) about milk sharing via social media and concerns about health risks, selling milk, therapeutic claims and potential capture by milk bank standards of ‘*feeding mothers’ own milk in hospital or child care settings, wet nursing, and informal milk sharing in the community*’ (11, 578).

In 2019, a revised National Breastfeeding Strategy was published (579) after review and public consultation. As part of the review process, stakeholders requested expansion of milk banks to provide donor milk in NICUs, post-natal wards and the community (580, 581). During this period of review, the Australian Government’s stance on self-regulation of milk banking and sharing was challenged by the potential importation of milk from India and a human-origin milk fortifier product from the USA (127, 143). In 2017, FSANZ provided advice on disease risks from imported milk and assessed 30 potential hazards (427), and later the Department of Agriculture, Water and Environment issued an import permit. In response, the Australian Health Ministers' Advisory Council²⁸ established a National Working Group on Human Milk (579, 583) to provide advice on:

- ‘*The regulation and importation of human milk and human milk products in Australia and New Zealand.*
- *The complexity of the topic including ethical and social implications, safety and quality standards, regulation and legislation, research and therapeutic use.*
- *Consideration of human milk and human milk products in the context of Australian jurisdictional Human Tissue Acts.*
- *The benefits of national standards to apply to operating human milk banks.*’ (584).

The Working Group was instructed to consider the local supply of milk and align its work with the principles of the Australian Breastfeeding Strategy, to ‘*support, promote and protect infant health outcomes and optimise maternal breastfeeding*’ (584). At the time of writing, the Working Group had

²⁸ Restructured in 2020 as a National Cabinet Reform Committee (NCRC) for Health (582).

not published its report and it is unclear whether it considered Australian human milk products developed by the Australian Breast Milk Bank, that were proposed in 2020 (pressure-treated freeze dried milk and a human-derived fortifier).²⁹ In Australia, bovine-based fortifier products were included in FSANZ Food Standards, while human-derived fortifiers, if used in Australia, required regulation in ways that did not unintentionally capture mothers' own expressed milk (11).

Australian policies for milk sharing are potentially influenced by international developments in the governance of milk banking (Figure 4). However, as described in the literature review (Chapter 2), these mechanisms of influence are medicalized, not transparent, ignore the informal milk sharing sector and limit the participation of mothers to 'consumer representation,' when they are, in fact, producers. It remains to be seen whether Australian regulators fall in with global trends, set by WHO and the EU, and classify banked milk and milk products as 'medical products of human origin' (234, 235, 237, 241, 243, 244, 585).

5.2 Laws and legal regulations for milk sharing

5.2.1 Human Rights

Access to donor milk is derived from international human rights to health that support breastfeeding³⁰ (213, 586).³¹ Australia has ratified these conventions, and is obligated under international law to implement them nationally.³² In Australia, the right to breastfeed is implemented in 2011 amendments to the federal *Sex Discrimination Act* 1984 (Cth), and State and Territory laws, that prohibit discrimination against women who breastfeed or express milk.³³ These laws do not refer to milk sharing.

5.2.2 Food

In Australia, at the federal level, milk is classified as a food (11, 575), defined as: '*any substance or thing of a kind used, capable of being used, or represented as being for use, for human consumption (whether it is live, raw, prepared or partly prepared)*' in the *Food Standards Australia New Zealand Act* 1991 (FSANZ Act).³⁴ The legislation excludes products recognised as therapeutic goods and gives

²⁹ Pers. comm. (Marea Ryan, Mothers Milk Bank Charity, 11 November 2019).

³⁰ Universal Declaration of Human Rights, the 1967 International Covenant on Economic, Social and Cultural Rights and the 1981 Convention on the Elimination of all Forms of Discrimination Against Women (CEDAW) and the Convention on the Rights of the Child.

³¹ Article 24 of the 1989 Convention of the Rights of the Child recognizes a child's right to '*the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health*' and requires governments to educate their populations about the advantages of breastfeeding and '*ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of child health and nutrition, the advantages of breastfeeding...*' (1989 Convention of the Rights of the Child. CI 24 (e)).

³² (587).

³³ Sex Discrimination Act 1984 (S.7AA).

³⁴ Food Standards Australia New Zealand Act 1991 S.5(1)(a))

the Minister of Health discretion to declare a substance to be a food.^{35 36} This definition of food is consistent in State and Territory Food Acts and aligns with that in Codex Alimentarius (Codex),³⁷ the international system of food standards developed by FAO and WHO (Codex Alimentarius) and recognized by the World Trade Organization.

Milk is subject to three Commonwealth laws that concern food: the *Biosecurity Act* 2015, the *Imported Food Control Act* 1992 and the *Export Control Act* 1982, administered by the Australian Government Department of Agriculture and Water Resources, in consultation with the Australian Government Department of Health. Importation of donor milk is restricted. A personal consignment of expressed milk that is not accompanied by an infant requires a declaration that “*the milk has not been sourced from donors and/or a commercial enterprise.*”³⁸ Import conditions for commercial consignments of milk (ten or more litres) must be negotiated with the Department.

The FSANZ Act gives effect to national standards for food safety and quality (the FSANZ Code). The statutory authority, Food Standards Australia New Zealand (FSANZ), develops food standards jointly with New Zealand, to meet objectives for public health, informed choice by consumers and trade (590). Currently, there are no food standards for milk, PDHM or fortifier products.³⁹ Development of these standards would need to consider New Zealand policy and regulations, which classify milk as a human tissue (591, 592). However, several precedents for milk have been established in FSANZ and Codex standards. Milk is used as a reference for the composition of CMFs and existing standards cover dairy-based fortifier products. In practice, food standards are used in policy for milk (11, 96, 593).

Food standards are enforced through state and territory Food Acts^{40,41} but may only apply to food that is sold. The definition of ‘sell’ includes barter and ‘*dispose of by any method for valuable consideration.*’⁴² In some jurisdictions, the altruistic donation of milk is not considered to fit this definition (Table 6). However, Food Acts also allow the declaration of special regulations for foods

³⁵ Food Standards Australia New Zealand Act 1991 S.5.(2)).

³⁶ Food Standards Australia New Zealand Act 1991 S.6.(1).

³⁷ Food is defined in Codex Alimentarius (Codex) as: ‘any substance, whether processed, semi-processed or raw, which is intended for human consumption,... but does not include... substances used only as drugs’ (588).

³⁸ Australian Biosecurity Import Conditions (BICON) (589) Accessed 16 September 2019.

³⁹ Here referring only to human milk and human-origin fortifier products. Fortifiers are supplements of energy, protein and minerals added to milk and PDHM to increase the growth of very preterm infants. Fortifiers are manufactured from either milk or cows’ milk, although until recently fortifiers were only cows’ milk based.

⁴⁰ In Australia, food standards have force in law and it is ‘a criminal offence ...to supply food which does not comply with relevant food standards’ (594) and ANZ Standard 3.1.1 - Interpretation and Application (Australia Only) (595).

⁴¹ FSANZ Standard 3.1.1. states that the objective of food standards is ‘to ensure that only safe and suitable food is sold in Australia’ (595).

⁴² Australia New Zealand Food Standards Code - Standard 3.1.1 - Interpretation and Application (595).

that are not sold, for example Food Safety Schemes for high risk foods or for vulnerable persons.⁴³ In some states, milk is covered under these provisions. For example, NSW classifies milk as a food and expressed breastmilk (EBM) is included in the *Children's Services Voluntary Food Safety Program* (598).

Food regulation may provide a common framework for shared milk and CMFs, in which to manage the commodification and competition between these products to ensure protection of breastfeeding, for example through full implementation of WHO recommendations on the marketing of breastmilk substitutes (599). However, donor milk and milk sharing receive limited attention in global food systems.

5.2.3 Human Tissue

In State and Territory *Human Tissue Acts* or *Transplantation and Anatomy Acts* (HTAs), milk may fit the definition of human tissue as '*a substance extracted from the human body*' (11). However large sections of HTAs are irrelevant because milk is consumed rather than transplanted, a reason for excluding milk banks from a national coalition of tissue banks⁴⁴ (11). Some bodily fluids and tissues are excluded from HTAs, for example, blood and blood products (which are regulated at the federal level) and some States have separate Acts for reproductive tissues.⁴⁵ Shared milk differs from these tissues because it does not require invasive medical procedures. The complexity of these issues prompted calls for a review of HTAs, but it was unclear whether milk was included in its scope (600).

Overall, HTAs aim to prevent risks of infectious disease transmission and exploitation. HTAs require a medical authority or a licenced third party to obtain informed consent from the donor and recipient and to preserve their anonymity. HTAs prohibit selling, buying or advertising human tissue. However alternative legislation enables the operation of commercial services and supply of some tissues.⁴⁶ It is not clear how HTAs might apply to acts of cross-feeding or wet-nursing, where the service of breastfeeding is provided, rather than milk as a product.

5.2.4 Therapeutic Goods

The *Therapeutic Goods Act* 1989 (Cth), administered by the Therapeutic Goods Authority (TGA), is national legislation that could apply to milk and milk products. Under this Act, 'therapeutic' is defined

⁴³ NSW Food Act 2003, Part 8, Division 2. S.102 (596) and NSW Food Regulation 2015 (597). Food safety programs are based on the Codex HACCP system and guidelines, or Standard 3.2.1 of the FSANZ Food Standards Code (595).

⁴⁴ The Australasian Tissue and Bio-therapeutics Forum (11).

⁴⁵ For (sperm or ova) and embryos, for example, the Assisted Reproductive Treatment Act 2008 (Vic) and Assisted Reproductive Technology Act 2007 (NSW).

⁴⁶ For example, in Victoria, human spermatozoa or ova cannot be purchased under the Human Tissue Act 1982 (Vic) S.39(2), but compensation of donors of sperm or ova for 'reasonable expenses' is permitted under the Prohibition of Human Cloning for Reproduction Act 2008 (Vic)

as ‘preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury’ or ‘influencing, inhibiting or modifying a physiological process.’ Where the functions of therapeutic goods and foods overlap, their legal classification is complex. The TGA developed a guide that suggests that milk should be classified as a food unless it is ‘*represented to be for therapeutic use*’ (601). Therapeutic goods are typically sold and have established frameworks for international trade.

In the past, the TGA advised that milk should not be classified as a therapeutic good (11). However the *Therapeutic Goods Act* 1989 (Cth) regulates blood and bloods products and sets out requirements for donor eligibility that are relevant to shared milk.⁴⁷ This provision excludes donors of human tissues or blood for six months after tattooing and body piercing or who are known or suspected to be infected with HIV, HTLV I and II and Hepatitis B and C, or exposed to prions, for example through medical treatment or residence in the UK between 1980 and 1996. Classifying milk or milk products as therapeutic goods enables tight control of manufacturing and supply to consumers, advertising, and the option to require prescription. For example, the PREM Milk Bank in Perth was advised that they could not supply PDHM to other hospitals under the *Therapeutic Goods Act*⁴⁸ (602). Similarly, the Lifeblood Milk facilities for processing milk must comply with TGA regulations (593).

5.2.5 Legal interpretations by Australian States and Territories

In 2016, as part of this study, Departments of Health in each Australian jurisdiction provided written comments on their interpretation of the legal classification of milk, as a food and/or human tissue, and any legal regulation of milk sharing practices (Table 6). There was wide variation in these departmental interpretations and opinions about the legality of selling milk.

Some states were clear in their application of both food and human tissue legislation (VIC, Qld, SA) or neither (WA). The Victorian authority stated that the application of the state's HTA meant that the hospital in which the milk bank is located ‘*is not able to cost recover for the collection, testing, processing, delivery or storage of the donated breastmilk.*’ South Australian authorities clarified that classification of milk as human tissue ‘*may vary with end use and level of processing.*’ In some jurisdictions, food legislation applied only if milk was sold (SA, ACT), while in others, supply to a hospital was included as a form of sale (TAS). In NSW and NT, the legal classification of milk was uncertain, and reference was made to local health policy.

⁴⁷ Section 10 of the Act in Therapeutic Goods Order No. 88 2013- Standards for donor selection, testing and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products.

⁴⁸ Therapeutic Goods Act (Therapeutic Goods (Excluded Goods) Order No. 1 2011)

Table 6 Legal instruments applied to shared milk in Australian jurisdictions, as advised by State or Territory Departments of Health in September 2016
(various state and territory Food Acts and Human Tissue/Transplantation and Anatomy Acts and the Commonwealth Therapeutic Goods Act 1989).

Jurisdiction	Legislation			Breastmilk bank in this jurisdiction?	Comments by each jurisdiction on the legal instruments applied to milk
	Food Act	Human Tissue Act	Therapeutic Goods Act		
WA	No	No	No	PREM Breastmilk Bank at King Edward Memorial Hospital, Perth	<i>'There are none.'</i> The breastmilk bank <i>'has been operating for the past 10 years within existing legislative frameworks.'</i> With regard to informal sharing of breastmilk, <i>'These practices are uncontrolled and currently unsupported by evidence of benefit.'</i>
VIC	Yes	Yes	No	Mercy Health Breastmilk Bank, Melbourne	<i>'The HTA restricts the unauthorized buying and selling of human tissue and any advertising relating to these activities.'</i> <i>'No remuneration is given to donors and there is no cost to the recipient.'</i> <i>'As breastmilk is considered a food, the Food Act requires the hospital to have a food safety program, a food safety supervisor and an annual audit by a third party auditor as well as an annual assessment by local council.'</i>
Qld	Yes	Yes?	?	Royal Brisbane and Women's Hospital (RBWH) Milk Bank, Brisbane	<i>'...human milk may fit the definition of human tissue under ...the Transplantation and Anatomy Act 1979. ... although I am not aware of any judicial interpretation. The Act prohibits the buying or selling of tissue. It is considered that making or receiving any payment in exchange for the provision of tissue, even on a cost recovery basis, may breach these prohibitions. The Act also prohibits advertising to buy tissue...However the Minister for Health and Ambulance Services may approve the buying of tissue by reason of special circumstance and the Minister may also approve advertisement regarding the buying of tissue.'</i>
NSW	Yes	?	?	Sydney Local Health District (LHD)	<i>'The provision of breast milk to babies from non-birth mothers in NSW health facilities can occur where quality and safety processes for the management, storage and provision of donated breast milk have been approved by the Chief Executive of the Local Health District.'</i>
ACT	Yes, if sold	No	No	No (sourced from Mothers' Breastmilk Bank, south east Qld)	<i>'While the broad definition of 'food' under the Food Act 2001 could potentially encompass breastmilk, the Food Act primarily relates to the sale of food. The sharing of breastmilk, either through breastmilk banks or informally through the community, would not be considered as a 'sale' and therefore not within the scope of the Food Act. If breastmilk were to be sold commercially in the ACT (for example, donor banks selling breastmilk product, known as breastmilk banks), then the normal regulatory aspects of the Food Act may apply.'</i>

Chapter 5 Results - Legal structures

Jurisdiction	Legislation			Breastmilk bank in this jurisdiction?	Comments by each jurisdiction on the legal instruments applied to milk
SA	Yes, if sold	Yes	?	No (none procured interstate)	<i>'If it were procured as part of a contract, or sold, the Food Act would apply...'</i> In the South Australia Transplantation and Anatomy Act 1983: <i>'...the definition of tissue includes an organ, or part, of a human body or a substance extracted from, or from a part of, the human body. Part 7 of the Act also prohibits trading in tissue except in specific circumstances. Breastmilk could be captured under this definition.'</i> <i>'...there are case by case situations, usually for preterm infants, where donor breastmilk is negotiated under medical supervision between a mother and a donor, usually known to her.'</i>
NT	No	Yes?	No	No	<i>'We would abide by Australian law that payment for any breastmilk goes against the law.'</i> <i>'Breastfeeding policy includes donor breastmilk but this is implemented at the level of the local hospital. ...In addition, protocols for hospital infection control apply for cases of accidental cross-feeding or use of another mother's breastmilk.'</i>
TAS	Yes, if sold	Yes	Yes?	No (sourced from the Royal Brisbane Women's Hospital (RBWH) Milk Bank)	<i>'Food, human tissue and therapeutic good legislation could all regulate the supply of human milk in Tasmania.'</i> <i>'Section 27(1) of Human Tissue Act creates an offence for entering into a contract or arrangement for valuable consideration around the sale or supply of tissue from a body. 'Tissue' is defined to include a substance from a part of the human body. Subsection (2) provides exceptions to ss(1) where:</i> <i>- The tissue has been subjected to processing or treatment; and</i> <i>- The sale or supply is made for use, in accordance with the directions of a medical practitioner, for therapeutic or scientific purposes.'</i> PDHM use at the Royal Hobart Hospital is subject to a Tasmanian Health Service internal guideline, Pasteurised Donor Human Milk for very Preterm Infants, <i>'to provide a pathway for the management of PDHM from a milk bank'</i> and <i>'...use beyond those parameters is a clinical decision of the treating doctor.'</i> <i>The Food Act would only apply to breastmilk that is sold, and the PHDM is not sold to patients, it is prescribed by doctors. The PHBM is purchased from the Royal Brisbane Women's Hospital.'</i>

One jurisdiction also considered the Therapeutic Goods Act relevant (TAS). No jurisdiction provided written comment on legislation that applied to informal milk sharing practices, cross-feeding or wet-nursing. The implications of this uncertainty were not clear from the document analysis, and required insights from actors on the ground, which is provided in the analysis of actor pathways (Chapter 8).

5.3 Government policies for milk sharing

Milk sharing is included in public policy for infant nutrition and infection control at federal, state/territory and local levels of government. At the federal level, overarching frameworks aim to harmonize policy across jurisdictions. At the State and Territory level, governments regulate shared milk through policy for milk banks, neonatal intensive care units (NICUs), maternity care and child health. Gaps in policy at this level are filled by local guidelines for milk sharing in health districts, hospitals and the community. The legal status of these policies varies, and employers determine which directives and guidelines are mandatory or discretionary for health workers. Guidance is also issued to the general public in websites and brochures.

5.3.1 Infant feeding policy

Donor milk appears in infant feeding policies for breastfeeding and supplementation, for healthy and unwell, hospitalized infants.

Federal Government

Federal policies for shared milk focus almost entirely on milk banking (575, 579). The 2019 revised National Breastfeeding Strategy (ANBS) recognizes the role of federal government in overcoming barriers to milk banking, and includes, in its evaluation criteria, *'expansion of milk banks'* and standards within *'a national ethics and regulatory framework for human milk and human milk banking,'* subject to the findings of the National Working Group on Human Milk (583, 584). However, regulatory and funding models to achieve these objectives were not clear, apart from the ad hoc federal budget announcements for milk banking mentioned at the start of this thesis.

Milk sharing is included in policy objectives for *'exclusive breastfeeding,'* where this includes milk *'from a wet nurse or breast milk donor'* (10, 579, 603).⁴⁹ This definition of exclusive breastfeeding is consistent with international policy (7, 54). However, policy emphasis on the biological breastfeeding relationship excludes milk sharing in references to *'maternal'* breastfeeding, *'own mother's milk'* and use of possessive pronouns (575, 579). In contrast, Australian BFHI policy defined *'exclusive*

⁴⁹ The previous Strategy did not include donor milk in its definition of exclusive breastfeeding (575).

breastfeeding' and 'breastmilk' as including donor milk⁵⁰ (604),⁵¹ out of step with updated international BFHI policy, which defined breastmilk more narrowly, as milk from an infant's '*own mother or from a human milk bank*' (54).

The importance of exclusive breastfeeding is reiterated in Australia's national dietary guidelines, the NHMRC *Infant Feeding Guidelines for Health Workers* (10). To limit the use of CMFs, these guidelines provide instructions on milk expression, storage and transport in homes and workplaces, which are included in national policy frameworks for health, workplace relations, parental leave⁵² and childcare (579).

Supplementation is necessary when a mother cannot produce sufficient milk. The NHMRC guidelines recommend supplementation with donor milk from milk banks, preferably pasteurized, for very low birthweight (<1500g), preterm (<32 weeks) or hypoglycaemic infants and warn of '*dangers from sharing milk from unknown sources*' (10). For full-term infants, the guidelines state that CMF is '*the only suitable and safe alternative*' to breastfeeding (10). Clinical decisions about supplementation require informed parental consent and health workers are advised to outline the benefits and harms of breastfeeding and CMFs. In the guidelines' model consent form, donor milk is not included (10). In contrast, WHO/UNICEF recommendations prioritize milk from a healthy donor before CMFs (7, 222),⁵³ and the use of cross-feeding in emergencies (605). Consequently, informed decision-making in infant feeding regulates milk sharing through the omission of options for shared milk or exposure of parents and health professionals to CMF marketing (606).⁵⁴ The use of milk for research also requires donor consent (143, 271, 608)

In policy, the medical criteria for supplementation with CMF (clinical indications) are limited to very rare metabolic conditions of infants and several maternal conditions⁵⁵ in NHMRC guidelines and

⁵⁰ The WHO/UNICEF Baby-friendly Hospital Initiative (BFHI) Step 6 states: 'Do not provide breastfed newborns any food or fluids other than breast milk, unless medically indicated.' BFHI programs require hospitals to teach mothers to express and manage their milk safely.

⁵¹ BFHI defines 'exclusive breastfeeding' as including milk '*expressed or from a wet nurse or breast milk donor*' and breastmilk as '*mother's expressed milk or donor milk*' (604).

⁵² The Sex Discrimination Act 1984 (Cth); the Fair Work Act 2009 (Cth) and National Employment Standards for Flexible Working Arrangements and Parental leave; the Australian Government's Paid Parental Leave (PPL) scheme (2011).

⁵³ WHO Global Strategy for Infant and Young Child Feeding states that 'For those few health situations where infants cannot, or should not, be breastfed, the choice of the best alternative – expressed breast milk from an infant's own mother, breast milk from a healthy wet-nurse or a human-milk bank, or a breast-milk substitute fed with a cup, which is a safer method than a feeding bottle and teat – depends on individual circumstances.' (7) p.10

⁵⁴ In Australia, the WHO International Code of Marketing of Breast-milk Substitutes and subsequent World Health Assembly resolutions (53) are not legislated but implemented in an industry self-regulated Code of Practice, the Marketing in Australia of Infant Formula Agreement (607).

⁵⁵ Breastfeeding is not advised when a mother is severely ill or using medications that induce drowsiness (sedatives, opiates) or treatments containing iodine, radioactive or chemotherapeutic agents, or infected with diseases transmitted via contact with skin or milk. Exclusive formula feeding is advised only for maternal HIV infection and very rare metabolic disorders of infants (10).

WHO policy (10, 609). Maternal infections potentially transmitted through milk should be treated to enable breastfeeding, with exceptions for HIV, which is discussed further in section 5.3.2 on Infection Control.

Federal policies on infant feeding are disseminated in advice for parents on government websites and State health policies and services (610). The website *Raising Children Network* mentions milk banks for premature infants (611). In contrast, *Pregnancy, Birth and Baby* recognizes diverse milk sharing practices (*'When the baby isn't able to receive their mother's own milk, human breast milk expressed by another woman is a very good alternative, especially for sick or premature babies,'*) and contexts, (*'when a baby is born via a surrogate, is adopted or fostered, or is the child of same-sex parents'*). This website warns of safety risks in a balanced way, stating: *'There have been very few cases of adverse events in babies being given donor breast milk,'* and outlining risk management by milk banks and in informal arrangements. For example, *'milk from private networks, ...is not properly processed or pasteurised,'* but social media networks *'typically provide guidelines about screening donors and storing and transporting breast milk safely'* (612).

State/Territory and local levels of government

State and Territory policies mention donor milk in clinical guidelines for breastfeeding, supplementary feeding and neonatal medical conditions. In line with national policy, these policies support exclusive maternal breastfeeding and legitimize PDHM but vary in their approach to informal milk sharing. For example, a 2018 NSW policy for breastfeeding recognizes that informal milk sharing occurs and makes provision for its management at the local level:

'NSW Health organisations ensure all breastfed infants in their care receive breast milk from their birth mother except where there is access to a milk bank approved by the Chief Executive. Local arrangements should be made for special circumstances, including but not limited to, adoption, same sex couples, foster carers and surrogacy' (610).

In contrast, a South Australian perinatal practice guideline on breastfeeding refers to donor milk only in terms of risk:

'Increased risk of gastro-intestinal infection, due to poor hygiene practices or the use of incorrectly prepared/stored/collected artificial formula or donor expressed breastmilk' (613).

States and Territories also differ in their definitions of exclusive breastfeeding, which include donor milk in NSW (610) but not South Australia (614). Most States and Territories have adopted BFHI principles that include donor milk in definitions of breast milk but few Australian hospitals are BFHI accredited (55, 610, 614-619).

Local policies for medically supervised informal milk sharing have been developed where access to PDHM is restricted. In Victoria and Tasmania, a few individual hospitals and health districts have directed donation policies for the use of unpasteurized milk from a screened, known donor (620, 621). These policies address the needs of the local community and manage legal liability. A protocol from northern Tasmania refers to human rights principles (*'The provision of human milk is a birth right of all babies'*) and requires staff to *'acknowledge and respect parents lifestyle and parenting choices and include support for parents who are lesbian, gay, bisexual, transgender, queer/questioning or intersex as well as those receiving a baby via a surrogate birth...'* (621). In practice, the use of directed donation is restricted to a local hospital or service and by requirements that staff do not publicize it as an option (621).

Individual hospitals also establish clinical indications for supplementation that may include donor milk (609, 622-626). In postnatal wards, NICUs and maternal and child health services, standards and thresholds for infant weight are significant policy documents that prompt advice to supplement infants (627).

Informal milk sharing

Some state-level infant feeding policies acknowledge that informal milk sharing practices occur (620). In other jurisdictions, informal milk sharing is omitted in policy or declared to be out of scope (628) or excluded by referring only to maternal breastfeeding or mother's own milk (610).

Policies that recognize informal sharing take different approaches to safety, that shape perceptions of risks from milk. They may prohibit its use or provide guidance on its safe handling or defer to local policy. For example, SA Health employees *'must not proceed to store or administer donor EBM if there is doubt the EBM derives from the infant's birth mother'* (629). In contrast, *Victorian Breastfeeding Guidelines for Health Professionals*, provide some direction:

'Informal breastmilk sharing networks exist in Victoria and it is important that health professionals are aware if they are being used. If a woman indicates that she intends to use unscreened, unpasteurised donated breastmilk the health professional should recommend that the woman consider potential risks of unscreened breastmilk and consider asking for the donor to be screened for the infections listed above' (617).

Milk banks and pasteurized donor human milk (PDHM)

Australian milk banks operate as autonomous entities, and their governance varies according to oversight by affiliated hospitals and legislative frameworks in each State or Territory. For example, the Victorian Government placed stringent requirements on the Mercy Health Breastmilk Bank to

comply with the *Human Tissue Act* 1982 (Vic), the *Food Act* 1984 (Vic) and the *Blood Donation Statement items from the Public Health and Wellbeing Act* 2008 (Vic) and other requirements of the state's health ministry and state government insurer which, until 2019, restricted milk donors to women who had given birth at that hospital (630, 631). Other jurisdictions were less restrictive.

All Australian milk banks supplied pasteurized milk but some state policies allowed other milk processing activities and allocation, for example by prescription (11, 593, 629). Criteria for donor eligibility are consistent nationally: milk bank web sites inform prospective donors of requirements to provide their history of cancer, smoking, caffeine consumption, residence in the United Kingdom between 1980 and 1996, and undergo blood testing for blood borne viruses (HIV, Hepatitis B and C), HTLV and syphilis. No Australian milk banks test donors routinely for CMV (632-637).

Government policies for PDHM restrict its use to NICUs for feeding very premature infants vulnerable to NEC and a limited number of medical and surgical conditions when a mother's milk is not available (593). Information for parents about access to PDHM also varies and may influence community expectations about access to donor milk. In the ACT and NSW, a 2018 fact sheet describes PDHM for NICUs (637), but donor milk is not mentioned in a general guide to breastfeeding for ACT parents (615). In small jurisdictions, for example the Northern Territory and Tasmania, public information on PDHM is scarce. Several factors influence access to PDHM. In NSW, state-wide policy for PDHM was introduced when a milk bank of sufficient scale could supply all eligible NICUs and the principle of equity of access to PDHM was adopted (593). In other jurisdictions, policies for PDHM occur in the state's few facilities that provide high level care for very premature infants.

Australian milk bank websites inform donors and recipients about safety and anonymous, altruistic donation, stating that they do not pay donors and cite a range of international health authorities and milk banking association guidelines to justify their requirements⁵⁶ (577, 608, 634, 640). Standards increasingly refer to recognized frameworks for standards: International Organization for Standardization (ISO); food safety Hazard Analysis and Critical Control Point (HACCP) and Good Manufacturing Practice (GMP) (91, 238, 304), an approach spearheaded by the PREM bank in Perth in their 2007 guidelines (96). In 2022, national guidelines were published, *Operational Guidelines for Milk Banks in Australia and New Zealand* (641).

⁵⁶ For example, WHO (608, 638). The Mercy Health Breastmilk Bank web pages reference the WHO, American Academy of Paediatrics (AAP) and ESPGHAN (631). The Mothers' Milk Bank Charity recipient consent form (639), refers to the guidelines of the Human Milk Banking Association of North America (HMBANA) 2015. NSW policy (593) refers to the UK National Institute for Health and Care Excellence guidelines (304).

In their focus on the safety of milk, milk bank guidelines must attend to the safety of donors and breastfeeding. For example, milk banks emphasise the vulnerability of premature infants to justify donor testing (and potential rejection), without creating anxiety about the safety of a mother's milk for her own infant (*'If you don't meet our criteria, be reassured that your own breast milk is the best possible nutrition for your own baby'*) (632) (642).

However, operational standards do not provide a governance structure for the milk banking sector. Importantly, the 2022 national milk banking guidelines are mandatory, and include principles to support breastfeeding, but also provide scope for milk product development through its definition of a milk bank:

- '(a) Collaborate with government and community stakeholders in the support of breastfeeding.*
- (b) Raise, when appropriate, the opportunity of donation of excess milk.*
- (c) Inform, enrol, obtain informed consent and screen potential donors.*
- (d) Facilitate the donation and collection of donated human milk.*
- (e) Process, store and distribute DHM and HDMP in accordance with relevant jurisdictional and national legislation.*
- (f) Engage in DHM and/or HMDP product development, process validations, and collaboration in academic research programs.'* (641).

These guidelines also helped clarify legislation that applied to milk in some jurisdictions (641). Human Tissue Acts applied to milk in the ACT, Tas, Vic, WA and NT, while Food Acts applied in SA and Tas. This list omits Qld and NSW. This was a change from the information provided in the first stages of my research, in which Human Tissue Acts applied in Qld and Food Acts applied in NSW, ACT, SA and VIC (Table 6). These changes show a trend towards the classification of milk away from food and towards human tissue, in line with international developments.

5.3.2 Infection control policy

Policy for prevention of infection via milk is focused on four policy areas: maternity care; management of expressed milk; accidental feeding of expressed milk to the wrong infant and occupational exposure. Few of these policies refer directly to donor milk but, arguably, influence the perceptions and management of risk associated with milk sharing.

Federal Government

Medical supervision of pregnancy reduces mother-to-child transmission of infections via milk. National clinical guidelines for antenatal care (*'Pregnancy Guidelines'*) recommend ten antenatal visits for uncomplicated first pregnancies and seven for subsequent pregnancies. (643). The Pregnancy Guidelines list milk as a potential source of HIV, Hepatitis B, Hepatitis C, syphilis and

Cytomegalovirus (CMV), and recommend routine antenatal testing for these infections, except CMV. CMV testing is advised only for women exposed to groups of young children, for example childcare workers (643, 644).

Pregnant women who test positive for infections potentially transmitted via milk are advised about breastfeeding management (643). Breastfeeding is contraindicated for HIV infection if replacement feeding is *'acceptable, feasible, affordable, sustainable and safe,'* (10, 579, 643). For other infections potentially transmitted via milk, treatment and temporary avoidance of breastfeeding is advised, with recommendations that distinguish risks for types of hepatitis virus: *'women with hepatitis B ... can breastfeed without risk of transmission to the baby'* and there is *'no evidence that breastfeeding is associated with an increased risk of hepatitis C transmission to the newborn ...unless the nipples are cracked and/or bleeding'* (10, 643).⁵⁷

HTLV has the potential to be transmitted via breastfeeding but it is very rare in the general population and not included in routine antenatal screening (643). Donors of human tissue and blood are tested for HTLV but the value of mandatory testing has been questioned given its low prevalence (645). However, in some Central Australian Indigenous communities, high rates of HTLV have resulted in mixed recommendations, from no change to breastfeeding practices (646, 647), to advice that women infected with HTLV-1 avoid or restrict breastfeeding (629, 648) or freeze milk (649).

In health facilities and services, national policy frameworks to prevent infection aim to reduce the exposure of patients and health workers to *'all body substances, secretions and excretions'* (650).⁵⁸ These frameworks do not mention milk specifically but are applied to milk (629).

Breastfeeding and EBM are acknowledged as measures to prevent infection in national policies for nutrition and infection control in childcare services (652-654). However, policies for infection control in childcare list milk as a potential source of HIV, Hepatitis B and CMV (653) and warn of accidentally feeding milk to the wrong child (579). In childcare nutrition policies, such events must be reported as *'accidental exposure to a body fluid'* and two staff members must check the labels on bottles of milk before feeding (654, 655).

In medical settings, exposure to milk as a source of blood-borne viruses is included in policies for occupational health, mostly at the State and Territory level (629). These policies are based on sharps

⁵⁷ However, these recommendations assume the mother is feeding her biological infant, and complex interactions between immunological development during gestation and the mothers and infant's shared environment, make premature infants more vulnerable to exposure to some viruses in unpasteurized donor milk.

⁵⁸ Milk is mentioned as a route of transmission of arthropod-borne viruses e.g. West Nile Virus (651).

injuries and the risks from exposure to milk is ‘unknown’ (656). However, in the period following exposure to an HIV risk, workers are advised not to donate milk, blood or other tissues (656).

State/Territory and Localized Government

In line with national policy, most State and Territory policies for infant feeding recommend that HIV positive women do not breastfeed. However, a recent South Australian policy makes provision for breastfeeding if HIV medications are taken (629) and in 2021 further guidance was published by a collaboration between the Victorian government and an NGO for HIV positive women (657)⁵⁹ For other infections, jurisdictions vary from national policy and list between three and 21 microbial agents potentially transmitted via milk.⁶⁰ In contrast to national policy, some omit Hepatitis B and include Hepatitis C in these lists (620) and local policies may warn of the infectivity of milk (626).

The risk of infection from specific milk sharing practices also appeared in some policies, for example warnings that *‘purchasing breast milk from the internet from unknown donors should be actively discouraged’* (620). SA Health requires staff to warn parents of *‘the infectious risks associated with administering unpasteurised human donor milk or wet nursing’* but advise that this risk is small (629).

The accidental administration of milk in health settings triggers a serious response (629). The *ACT Expressed Breast Milk Incident Guide*, requires medical staff to immediately notify the Infection Control and Prevention Unit and inform and counsel both the ‘source’ and recipient mother (660). In NSW, a similar protocol includes a mother inadvertently breastfeeding *‘a baby other than her own’* and lists 21 infectious agents potentially transmitted via milk, while stating that *‘only a small number of these agents have been shown to be transmitted’* (659).

In line with national policy for blood and tissue donation, milk banks managed the risk of transmitting prions associated with ‘mad cow’ disease (Bovine spongiform encephalopathy or BSE)⁶¹ by excluding milk donors who had resided in the UK between 1980 and 1996 (661). However, the extremely low risk of infection was noted and this restriction was removed a few years later.

Risks of transmitting bacterial infections via milk are of less concern than viruses (621) and managed through routine food safety measures for homes and workplaces (10, 662-664). NHMRC *Infant*

⁵⁹ Victorian policy states: *‘Breastfeeding is NOT recommended in women with HIV due to the risk of viral transmission through breast milk. Formula feeds are preferred’* (658). South Australian policy advises against breastfeeding by HIV positive women but makes allowance for women and infants receiving antivirals (629).

⁶⁰ One Victorian guideline on breastfeeding neonates lists three viral infections of concern (HIV, Hepatitis C and CMV) (620), while another lists five (617). A South Australian policy lists nine diseases, including tuberculosis and HTLV (629) and a NSW policy lists 21 (659). SA Health lists Cytomegalovirus (CMV), Hepatitis B virus, Hepatitis C virus, Herpes simplex virus 1, Human immunodeficiency virus (HIV), Human T lymphotropic virus (HTLV) types 1 and 2, Tuberculosis, recently acquired Syphilis, Varicella-zoster (chickenpox and shingles) (629).

⁶¹ Creutzfeldt-Jakob disease (vCJD) in humans

Feeding Guidelines refer to a protocol from the Academy of Breastfeeding Medicine which states that EBM ‘does not require special handling ...required for other bodily fluids such as blood. It can be stored in a workplace refrigerator where other workers store food, although it should be labelled with name and date’ (665). Some milk banks required higher standards of hygiene, while other protocols recommended routine measures⁶² (617). In other health settings, policy for EBM management treats milk as a bodily fluid. A South Australian policy for and a brochure for parents recommends that ‘When at home, large volumes of unused EBM (i.e. greater than 10mls), should be discarded via the sewage system’ (666). The associated Clinical Directive advises that, in hospitals, unused milk should be discarded in a toilet or managed as clinical waste.⁶³

5.4 Non-Government Organization (NGO) policies on milk sharing

In the absence of consistent national policy, NGOs published position statements on milk sharing for midwives, doctors and breastfeeding women. Organizations that represent lactation consultants, paediatricians, obstetricians and general practitioners did not include donor milk or milk sharing in their policies.

5.4.1 Non-profit organizations

The **Australian Breastfeeding Association (ABA)** is Australia’s ‘leading authority on breastfeeding’ that provides information and support to breastfeeding women and health professionals.⁶⁴ ABA policies had covered milk banking since at least the 1970s and its 2004 Breastfeeding Leadership Plan included advocacy for developing a human milk bank network in Australia, as part of a package of health service measures to support breastfeeding (73, 668). ABA’s 2014 *Position Statement on Donor Milk*, aimed to manage the legal and business risks of informal milk sharing to the Association, and stated that it ‘does not directly facilitate private milk sharing by making its resources available to link private donors and recipients, and accepts no responsibility for expressed breastmilk donated by its members.’ The statement refers to unspecified risks of informal milk sharing but did not provide advice on their management. ABA supports not-for-profit milk banks, citing a 1979 WHO/UNICEF

⁶²Promoting Breastfeeding: Victorian Breastfeeding Guidelines provide guidance on informal milk sharing: ‘Breastmilk from screened or unscreened donors and unpasteurised donor breastmilk presents a risk of transmission of infectious agents to babies, therefore the use of unscreened, unpasteurised human breastmilk is not recommended. Unpasteurised and unscreened donor human breastmilk can expose the baby to infections such as HIV1 or 2, hepatitis B or C, human T cell lymphotropic virus (HTLV) type 1 or 2, or syphilis. It should also be recognised that infant formula carries some risk for all babies, which must be balanced against the risks of unscreened, unpasteurised donor human milk’ (617).

⁶³ ‘All women and their family administering EBM to their infant should discard small amounts (i.e. less than 10mls) of unused EBM via the sewage system, but large volumes (i.e. greater than 10mls) of unused EBM should be discarded as clinical waste when in a health facility. It is important that unused EBM is not discarded in any wash basin that has been identified for hand washing’ (629).

⁶⁴ (667).

Declaration,⁶⁵ and provides links on its website to Australian milk banks and social media pages dedicated to altruistic milk sharing (669).

The **Australian College of Midwives (ACM)** represents midwives and administers the BFHI program in Australia. Their comprehensive 2014 *Position Statement on the use of Donor Human Milk* applies principles of informed decision-making and risk management for the use of milk banks and informal milk sharing arrangements. It states that '*Women using ...nonregulated sources of donor human milk, need to be well informed about potential risks, and how to mitigate the risk to make a safe choice.*' For milk exchanges mediated by the internet or social media, '*caution is needed to ensure safety and honesty for both sides*' (670).

The position statement provides guidance for health professionals on procedures for donor screening and testing and milk processing, based on UK guidelines (304) and (96). In addition, the statement includes protocols for unpasteurized milk in milk banks, hospitals and the community in a culturally sensitive way, referring to NHMRC Infant Feeding Guidelines and ABA recommendations (670).

The **Australian Medical Association (AMA)** 2017 position on *Infant Feeding and Parental Health* supported 'hospital-based' milk banks for premature and underweight infants, and advised that sharing '*unpasteurized and untested milk ...without medical oversight*' poses '*significant risks*' and that parents should be educated about potential harms as part of informed decision-making, without providing guidance to medical practitioners on management of these risks or access to milk banks (671).

The **Lactation Consultants of Australia and New Zealand (LCANZ)** is the peak body for lactation professionals (IBCLCs) in Australia and its region⁶⁶ (672). IBCLCs are '*obligated to practice within the laws of the geopolitical region and setting in which the IBCLC works*' (673), and, accordingly, ILCA and LCANZ do not provide guidance on milk sharing.⁶⁷ However lactation consultants encounter several forms of milk sharing through their work and professional education.

⁶⁵ '*Where it is not possible for the biological mother to breastfeed, the first alternative, if available, should be the use of human milk from other sources. Human milk banks should be made available in appropriate situations*' (1979 WHO/UNICEF Declaration), cited in (669)

⁶⁶ LCANZ operates under the aegis of the International Consultants Association (ILCA), which accredits lactation consultants as International Board Certified Lactation Consultants (IBCLCs).

⁶⁷ LCANZ has no policies for any form of milk sharing but shares information to its members on milk banking in Australia and New Zealand. IBCLC guidance documents produced by ILCA include a standard of practice, clinical competencies, a code of professional conduct, a scope of practice, the WHO Code (674) and a Position Paper on the Role and Impact of the IBCLC (675). Only one of these documents mentions milk sharing -an ILCA Position Paper Infant and Young Child Feeding in Emergencies, which refers to wet nursing (676).

The breastfeeding policies of the **Paediatrics and Child Health Division of the Royal Australasian College of Physicians (RACP)** and the **Royal Australian College of General Practitioners' (RACGP)** support the NHMRC Infant Feeding Guidelines and BFHI but do not mention donor milk, milk banking or sharing (677, 678). The **Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)** has no statements or guidelines on infant feeding.

The **Mothers' Milk Bank Charity (MMBC)** provides PDHM to NICUs and private individuals in Northern New South Wales, Southeast Queensland region, Northern Queensland, ACT, Sydney, Melbourne and Hobart (577). MMBC is Australia's only community-based milk bank and operates as a private not-for-profit company that aims to *'increase the proportion of Australian infants exclusively breastmilk feeding in the first six months of life.'* The MMBC has greater latitude than hospital-associated milk banks in allocating PDHM (632, 639).

MMBC refers to policies from WHO, UNICEF and the Australian government and guidelines from the Human Milk Banking Association of North America (679). To cover its costs, the milk bank asks recipients of PDHM for a donation (639, 680).

Lifeblood Milk, is a section of the Australian Red Cross Blood Service (ARCBS), a not-for-profit incorporated entity that supplies blood and blood products under the governance of the National Blood Authority, a statutory agency within the Australian Government health portfolio (681, 682). The milk bank is financed through the Australian government and public health system (683, 684).

As a blood bank, its legitimacy in milk banking relies on adherence to *'international standards'* and history of safe blood supply (*'The Milk Bank adheres to the similar rigorous safety processes as all biological products used by the Blood Service – one of the world's safest suppliers of blood'*) (638).

5.4.2 For-profit organizations

The **Australian Breast Milk Bank (ABMB)** is a private for-profit company established in 2015 in NSW to develop a commercial shelf-stable milk product using 'non-heat pasteurisation' (147). In 2019, the ABMB and Mother's Milk Bank Charity co-sponsored support for Indigenous mothers with diabetes and announced *'we are now able to provide processed donor breast milk, with a shelf life with no expiry date. This health prevention initiative supports any mother with diabetes in pregnancy by providing donor milk "Just in Case" before and then after birth and is scheduled for release in January 2020'* (680). However, the ABMB did not proceed, as discussed in Chapter 1.

5.4.3 Social media

Eats on Feets (EOF) enables informal milk sharing arrangements via Facebook pages for five Australian states (New South Wales, Queensland, Tasmania, Victoria and Western Australia). The

organization's main website hosts a *Resource for Informed Breast Milk Sharing* (www.eatsonfeets.org) (685), the '*Four Pillars of Safe Breast Milk Sharing*,' that provides detailed procedures for informed choice, donor screening, safe handling and home pasteurization (686). Donor screening includes criteria for self-exclusion, similar to milk banks, based on a donor's health, lifestyle, social and other issues.

Human Milk for Human Babies (HM4HB) separated from EOF around 2011 and has public Facebook pages in all Australian States and Territories. The public pages of HM4HB provide little information on safe milk sharing and no links to EOF resources. More detailed information on safety may be available on the group's closed, moderated pages. The Victorian HM4HB page became a closed group in 2015. To ensure safety by direct screening and respect between donors and recipients, third party arrangements are not supported and its public page states '*We respect the right of families to make informed choices and we expect our members to take full responsibility for those choices. It is up to the participants to get to know each other, to ask questions, and to continue talking and engaging directly with one another until a relationship of trust is established*' (687).

5.5 Summary of analysis of legal structures

5.5.1 How legal structures regulated milk sharing

This chapter showed that Australian jurisdictions had inconsistent approaches to the legal classification milk as a food, human tissue or therapeutic good, creating a fragmented, confusing and costly regime for the regulation and governance of milk sharing. This legal structure left the role of milk sharing in infant nutrition unresolved, and framed milk as a hazardous bodily fluid, and conflicting perceptions of milk that shape social and institutional norms, for example between health and childcare settings. Policies created tensions between public health objectives for exclusive breastfeeding and exclusive milk diets, and avoiding exposure to infection via milk.

Policies for supplementation restricted milk sharing to the use of PDHM for eligible infants in NICUs and warned of the risks of sharing milk informally. However, access to PDHM was hindered by legal barriers to establishing milk banks, while legal liability restricted access to medically supervised milk sharing and the involvement of NGOs that supported breastfeeding. A handful of localized protocols provided guidance to health professionals on sharing unpasteurized milk, while parents had to resort to guidance on social media pages.

Legal structures offered little scope to address ethical and political questions of who should bear the cost of producing shared milk and control it: laws required the altruistic donation of milk and milk banks were left as an underfunded, self-governing sector. Policies focused on milk as a product and few recognized cross-feeding or the culturally diverse, relational or environmental aspects of milk

sharing. Policies did not recognize the potential contribution of milk sharing to infant feeding or food security, especially in emergencies, or protect milk from commercialization. The net effect of this legal and policy regime was to limit the use of PDHM and dis-endorse or obscure other types of milk sharing and uses of milk.

5.5.2 How legal structures for milk sharing affected breastfeeding

Australian milk banking lacked governance structures and policies that integrated all forms of milk sharing with breastfeeding. Policies framed milk sharing as a problem that threatened rather than supported breastfeeding, and limited its potential to displace CMFs. Concerns that donor milk may displace breastfeeding made the provision of lactation support an important but discretionary part of policy for PDHM use in health settings, but this requirement added to its costs, and did not apply to the use of CMFs. Similarly, restrictions on advertising, accessing and paying for human tissue, disadvantaged milk sharing, while CMFs were highly promoted, accessible and profitable. Overall, legal structures for milk sharing created an untidy mix of over-regulation and policy neglect around milk sharing, which diminished its role in protecting, promoting and supporting breastfeeding, and made donor milk less competitive with CMFs.

These tensions, and milk sharing's role in infant feeding and risk, were left to institutions and society to resolve, with uncertain effects on norms regarding donor milk in health, work, childcare and community settings. However, this document analysis does not show the effect of these laws and policies in practice. A full understanding of how legal structures shaped rewards, awareness, motivations and pathways to share milk must be obtained from the perspectives of actors on the ground, which is the focus of the analysis in subsequent chapters.

Table 7 Key Australian policy documents analysed.

No.	Author	Year	Title	Govt /NGO	Level of government*
Infant feeding					
1	Parliament of the Commonwealth of Australia, House of Representatives Standing Committee on Health and Ageing	2007	The Best Start Report on the inquiry into the health benefits of breastfeeding	Govt	Cth
2	Australian Health Ministers' Conference	2009	The Australian National Breastfeeding Strategy 2010-2015	Govt	Cth
3	Department of Health and Ageing	2010	2010 Implementation Plan for the Australian National Breastfeeding Strategy 2010-2015	Govt	Cth
4	National Health and Medical Research Council	2012	Infant Feeding Guidelines Information for health workers	Govt	Cth
5	Department of Health and Ageing	2014	Donor Human Milk Banking in Australia- Issues and Background Paper	Govt	Cth
6	Australia and New Zealand Ministerial Forum on Food Regulation	2018	Final Communique. 29 June 2018	Govt	Cth
7	AHMAC - Clinical Principal Committee - Human Milk Working Group	2019	Communique	Govt	Cth
8	COAG Health Council	2019	Australian National Breastfeeding Strategy: 2019 and Beyond	Govt	Cth
9	Healthdirect Australia- Pregnancy, Birth and Baby		Donor breast milk and milk banks	Govt	Cth
10	NSW Health, Health and Social Policy Branch	2018	Policy Directive: Breastfeeding in NSW: Promotion, Protection and Support PD2018_034	Govt	S/T
11	State of Victoria (Department of Education and Early Childhood Development)	2014	Victorian Breastfeeding Guidelines for health professionals	Govt	S/T
12	Safer Care Victoria -Victorian Agency for Health Information	2018	Breastfeeding for neonates	Govt	S/T
13	Royal Children's Hospital, Melbourne	2018	Clinical Guidelines (Nursing): Breastfeeding support and promotion	Govt	L
14	NSW Health, South-East Sydney Local Health District	2016	Local Operating Procedure. Clinical Policies, Procedures & Guidelines: Supplementary feeding of breastfed babies in the postnatal period	Govt	L
15	Government of Western Australia, North Metropolitan Health Service, Women and Newborn Health Service, King Edward Memorial Hospital, Obstetrics & Gynaecology	2019	Clinical Practice Guideline: Newborn feeding: Medical indications for formula feeds	Govt	L
16	Queensland Health	2011	Medically Indicated Complementary Feed Consent	Govt	S/T
17	Australian College of Midwives	2016	Baby Friendly Health Initiative, Australia: BFHI Handbook for Maternity Facilities	NGO	-
18	Australian College of Midwives (ACM)	2014	Position Statement on the use of Donor Human Milk	NGO	-
19	Australian Breastfeeding Association (ABA)	2004	Breastfeeding Leadership Plan	NGO	-
20	Australian Breastfeeding Association (ABA)	2014	Position Statement on Donor Milk	NGO	-

*Level of Government: Cth= Commonwealth; S/T= State or Territory; L= Local administrative area or facility

No.	Author	Year	Title	Govt /NGO	Level of government*
21	The Paediatrics & Child Health Division of The Royal Australasian College of Physicians (RACP)	2007	Breastfeeding	NGO	-
22	Royal Australian College of General Practitioners (RACGP)	2007	Position statement on breastfeeding	NGO	-
23	Australian Medical Association	2017	Position Statement: Infant Feeding and Parental Health	NGO	-
Milk banking					
24	Hartmann et al	2007	Best practice guidelines for the operation of a donor human milk bank in an Australian NICU	NGO	-
25	Sydney Local Health District, Royal Prince Alfred Hospital	2014	Guideline Women and Babies: Enteral Nutrition for the Preterm Infant	Govt	L
26	Healthy WA, Government of Western Australia, Department of Health		Donating your breast milk	Govt	S/T
27	Metro North Hospital and Health Service, Royal Brisbane and Women's Hospital (RBWH) Milk Bank	2016	Becoming a Breast Milk Donor	Govt	L
28	Government of Western Australia, North Metropolitan Health Service, King Edward Memorial Hospital, PREM milk bank	-	Blood tests for milk donors	Govt	L
29	PREM Bank, King Edward Memorial Hospital, Health WA	-	Donor Screening Assessment Introduction	Govt	L
30	NSW Health	2018	Pasteurised Donor Human Milk for Vulnerable Babies	Govt	S/T
31	NSW Health	2018	Policy Directive: Pasteurised Donor Human Milk For Vulnerable Infants PD2018_043	Govt	S/T
32	NSW Ministry of Health	2018	Breast care when your baby has died	Govt	S/T
33	Infection Control and Prevention Department, Royal Women's Hospital - Royal Children's Hospital Melbourne	2012	Directed donations of breastmilk	Govt	L
34	Tasmanian Health Service	2018	Donor Human Milk Use	Govt	L
35	Queensland Health	2018	Mad cow disease ¹ - why you can't donate blood, breast milk and tissues	Govt	S/T
36	State Government of Victoria, Department of Health & Human Services	2015	2015-16 Statement of Priorities Agreement between Minister for Health and Mercy Public Hospitals Inc.	Govt-NGO	S/T
37	Australian Red Cross Blood Service	2018	Business Plan 2018–19	Govt-NGO	-
38	Mothers' Milk Bank Charity, Australia	-	Receive Milk	NGO	-
39	Eats on Feets (Walker and Armstrong)	2012	The Four Pillars of Safe Breast Milk Sharing	NGO	-

*Level of Government: Cth= Commonwealth; S/T= State or Territory; L= Local administrative area or facility

No.	Author	Year	Title	Govt /NGO	Level of government*
Infection Control					
40	Australian Government Department of Health	2018	Clinical Practice Guidelines: Pregnancy Care	Govt	Cth
41	Australian Government Department of Health	2018	HTLV-1 in Central Australia	Govt	Cth
42	National Health and Medical Research Council	2019	Australian Guidelines for the Prevention and Control of Infection in Healthcare	Govt	Cth
43	Healthdirect Australia, Pregnancy, Birth and Baby	-	HIV and pregnancy	Govt	Cth
44	Safer Care Victoria -Victorian Agency for Health Information	2018	Human immunodeficiency virus (HIV) - perinatal	Govt	S/T
45	SA Health	2018	Clinical Directive: Expressed Breast Milk Safe Management and Administration in SA	Govt	S/T
46	Canberra Hospital and Health Services	2017	Clinical Guideline: Expressed Breast Milk Incident Guide	Govt	L
47	Australian Children's Education and Care Quality Authority	-	National Quality Framework: Sample breastfeeding policy	Govt	Cth
48	NSW Health, Health Protection NSW	2017	Policy Directive: HIV, Hepatitis B and Hepatitis C – Management of Health Care Workers Potentially Exposed PD2017_010	Govt	S/T
49	Queensland Health	2017	Guideline: Management of occupational exposure to blood and body fluids 2017	Govt	S/T

*Level of Government: Cth= Commonwealth; S/T= State or Territory; L= Local administrative area or facility

Chapter 6. Results: Actor awareness of milk sharing

As described in chapter 3, the AMPR framework (218, 219) was used to understand how milk sharing was regulated via the constructs of awareness, motivations, pathways and rewards. Chapter 6 is the first of four chapters reporting findings of the analysis of data from the interviews with mothers; milk bank staff; health professionals and policy makers.

In line with theoretical understandings of the role of ‘awareness’ in the regulation of behaviour, this chapter examines how awareness regulates milk sharing. The chapter sets out how actors first became aware of the idea of milk sharing, the sources of their awareness, the issues they were aware of, and the processes that shaped awareness, summarised in Table 8. The analysis examines the importance of awareness as a source of power and regulatory mechanism in the wider regulatory regime by comparing the way actor groups acquired and controlled awareness.

Table 8 The sources, issues and processes of awareness about milk sharing of four actor groups, and their effects on breastfeeding.

Awareness	Actor groups			
	Mothers	Milk Banks	Health Professionals	Policy Makers
<i>Sources</i>	Family and culture, Peers, Social media	Medical literature, Colleagues, Other milk banks	Personal experience, Work	Policy advice, Mass media
<i>Issues</i>	Access, Unaware of options to use donor milk, Misrepresentation of milk sharing as high risk	Risk, PDHM displacing a mother's own milk, Legitimacy	Risk, Unaware of options	Risk, Unaware of importance of milk
<i>Processes</i>	Shaming, Technology - social media	Clinical demands of NICUs	Lack of policy, Professional risks, Wilful blindness	Policy silos, Mothers lack a voice in governance of milk in health system.
<i>How actor awareness of milk sharing affected breastfeeding</i>				
<i>Direct effects on breastfeeding</i>	Lack of options to share milk in ways that include knowledge and relationships associated with breastfeeding. Covert milk sharing removes mothers' voices and breastfeeding knowledge from policy forums for milk. Limited potential for milk sharing to promote breastfeeding.	Awareness of PDHM disconnected from knowledge of breastfeeding. Lack of awareness of informal milk sharing and its associations with breastfeeding knowledge. Limited potential for PDHM to promote breastfeeding.	Limited awareness and provision of medically-supervised milk sharing options in health system that maintain breastfeeding knowledge. No potential for milk sharing to promote breastfeeding.	Obscurity of milk banking and informal sharing in policy limits its potential to promote breastfeeding.
<i>Effects on competition between breastfeeding and CMFs</i>	Weakens governance of milk sharing. Milk sharing not promoted and does not counter high levels of awareness of CMFs. Use of CMFs unchallenged.	Medicalization of milk frames milk sharing as high risk and breastfeeding as unsafe. Lack of PDHM promotion maintains use of CMFs.	Focus on risks of milk sharing may frame breastfeeding as unsafe. No challenge to CMFs in infant feeding decisions.	Weak knowledge and governance of milk that gives CMF advantages in infant feeding policy.

6.1 Sources of awareness

For most actors, the idea of donor milk was novel. Each actor group acquired awareness of milk sharing and knowledge of its practices through different routes, from the individual level to system level guidance. The data also showed the importance of mothers' multiple roles, in professions and areas of policy making dominated by women, which informed the awareness of other actor groups.

6.1.1 Family and culture

Participants in all groups became aware of historical wet-nursing through literature, book clubs and tertiary studies or heard stories of cross-feeding in previous generations, an immigrant family's country of origin or within ABA groups in the past. As observed in the data below, these accounts helped normalize milk sharing.

'Knowing that my mum had done it, like you know that idea that actually maybe it's not that weird, and ... as you talk to people who were mums in the 60s and 70s, it does seem like it was more common. And even as you talk to people my grandparents age, you discover that there was a lot more milk sharing that went on then' (MACYV, donor and recipient mother).

Mothers in the study were highly aware of cross-feeding, with a quarter (12/48) having shared milk in this way within a continuum of milk sharing practices. However, family stories of cross-feeding or sharing milk had been buried, and often told after a female participant had disclosed her own experience of milk sharing to an older female relative. In general, these stories emerged in interviews in every actor group, including policy makers, but were kept private:

'How common is wet-nursing in Australia? ...My mother wet-nursed my cousin. Yeah, she had a baby at the same time and his mother couldn't feed properly so she fed them both. You wouldn't know that, you wouldn't flaunt it anywhere' (SDOH02, policy maker).

6.1.2 Peers

For mothers in this study, other mothers (peers) were the principal source of awareness of milk sharing. Mothers typically became aware of milk sharing when seeking advice from peers for breastfeeding problems or ways to dispose of surplus milk. Typically, these encounters occurred in situations where breastfeeding was supported, and mothers wanted to avoid CMF:

'And my midwife wasn't happy with how her weight was going. ...I didn't want to start giving her bottles. And then I had a friend who had issues with low milk supply... and she told me about supplementing at the breast and also about donor milk, which I had never even heard of up until that point. ...She said to me, you can ask people online for donor milk, women

who have milk to spare can give milk to mums who don't have enough milk. And I was kind of like, wow that sounds like a whole new world' (MWAR, recipient mother, who used donor milk until her baby was 7.5 months old).

Discovery of this 'new world' of milk sharing was ad hoc, and mothers described 'stumbling' across the idea of donor milk through friends, internet searches, and social media groups that ranged from personal networks to larger parenting forums, some with thousands of members. These groups exposed mothers to experienced donors or recipients, who referred them to milk banks or social media pages dedicated to milk sharing.

'A lady I'd been talking to through the Gestational Diabetes Facebook page, she actually brought some colostrum up to me ...and we cried. So that's how we first sort of got into it. She offered, yeah, told me about the Human Milk for Human Babies Facebook page, because I hadn't really known about it or thought about it before' (MQLDY, recipient mother).

In other actor groups, it was the participant's experience as a mother that typically introduced them to milk sharing. Several health professionals knew of milk exchanges or cross-feeding in their personal networks, and three had received or donated milk themselves. Midwives with young children at the time of the interview used online breastfeeding and parenting groups, in which they saw milk sharing 'in a lot of conversations' (MW04, health professional).

6.1.3 Media

The use of social media was integral to motherhood. However, mothers distinguished between social media and mass media as sources on milk sharing. In mass media, mothers described reports that endorsed milk banking and sensationalized informal sharing as reckless, and most felt this misrepresented their experiences:

'Those terrible advertorial Daily Mail, Mamma Mia type things find something that they can bag about it, and scaremonger about it. That's when it comes out into the media, usually if there's something bad going on: 'This mum's driving around the countryside getting donations from random people.' They'll put a negative spin on it. There's not much public knowledge on it that's positive' (MQLDX, donor and recipient mother).

In view of mass media's misrepresentation of milk sharing as a shameful activity (the comments... infuriate me' (MACTZ, donor mother), mothers were reluctant to comment on their experience in public. Consequently, discussion of milk sharing retreated to safe spaces, for example closed social media groups.

In contrast, mass media reports that became 'hot' topics were sometimes the initial source of information about milk sharing for some government policy makers:

'And a particular company mentioned in the media that they had an import permit for the importation of milk, but they actually hadn't imported any. And that then started the States and Territories and the Department of Health asking some questions about importation of these products and actually led to a number of questions around how do we manage it? How do we regulate it?' (SACT12, policy maker).

6.1.4 Health system and health professional education

In this study, few medical staff knew about milk banking or informal sharing, and mothers viewed the health system as lacking awareness, as an institution. Donor milk was not part of antenatal education, and mothers were not informed about its use. When mothers discussed supplementary feeding with a health professional, donor milk was rarely mentioned as an option:

'I was recommended formula by a lactation consultant, it wasn't recommended that I find a donor ...and I didn't even really think of it as an option. ...I didn't know about the milk bank' (MQLDU, donor mother to milk bank and informally).

Mothers held the health system responsible for their lack of awareness of milk sharing, viewing it as a failure of informed consent, and described their distress in these situations:

'I don't know why any of them didn't say, well did you know that there's an SNS⁶⁸ and did you know about donor milk? Because I wouldn't have starved (baby) for eight weeks. I wouldn't have withheld formula from him, if I'd known that donor milk existed, and how to source it safely ...I wasn't fully formed of my options' (MQLDW, recipient mother).

A few participants with medical conditions during pregnancy had asked health professionals about using a milk bank but none were offered protocols for directed donation.⁶⁹ None had the experience of being offered PDHM in a NICU,⁷⁰ but one participant's partner described his frantic efforts to source PDHM independently when his wife was in intensive care:

'I just couldn't believe how difficult it was to do ... it didn't feel very structured ... it was like I was asking a question that no one had asked before, 'Well I want my baby to have donor milk' and they were like, 'Oh no, well that doesn't happen, not here, it has to be preemie

⁶⁸ Supplementary nursing system (a method of supplementary feeding an infant at the breast using fine tubing taped to the nipple and connected to a bottle)

⁶⁹ The medically supervised use of unpasteurized milk from a known, tested donor

⁷⁰ Neonatal intensive care unit

before they get access to it' ...Yeah, waiting for the new dad in the hospital, ringing around, ...crazy' (Partner of MQLDV, recipient mother).

Countering the lack of awareness of milk sharing in the health system, a few mothers and health professionals in the study described situations where midwives visiting mothers for a post-natal check-up in their homes, cautiously introduced the idea of obtaining milk from friends:

'There were different visiting midwives each time. The first one who came was an older lady and she said, 'You know I'm not supposed to say this, the doctors say you should give formula, but can you get breastmilk from anywhere? ...If it was me, I'd think about if I had any friends who were breastfeeding'' (MWAZ, donor and recipient mother).

In mothers' groups run by health services or ABA,⁷¹ milk sharing was rarely discussed openly and awareness of milk sharing circulated in private discussions between members. In a rural area, one participant described how knowledge of milk sharing was held by a 'select group,' consisting of a few ABA members, a lactation consultant and a midwife (MVICJ, donor and recipient mother). In contrast, informal milk sharing was normalized in communities with strong cultures of breastfeeding in public and local health services:

'It's very community oriented and there was a lot of breast milk sharing. Like a lot of it. And so it was really common. Like that stranger who rang me, it wasn't a thing, it was 'Yeah sure of course you can.' ...So for me to offer it just felt a thing you do and was going to be accepted ... It was a real cultural shock coming to (city)' (MNSWZ, donor mother).

In contrast, milk bank managers and staff first became aware of donor milk through medical channels, overseas clinical work, conferences and visits to milk banks. Many then established a milk bank or introduced PDHM to their health service. Ongoing information about milk banking was obtained from the medical literature, 'on the job' training and consulting other milk banks.

Amongst health professionals, milk sharing was normalized for more senior midwives who witnessed the routine collection of donor milk by nurses on post-natal wards until the 1990s. They described how milk sharing subsequently shifted from an institutional norm ('common knowledge') to private anecdotes about milk sharing with colleagues and patients. In their current positions, health professionals observed patients using expressed milk from relatives and friends, and some turned a blind eye this practice. Midwives on post-natal wards in hospitals that served Indigenous and

⁷¹ Australian Breastfeeding Association

immigrant communities⁷² also witnessed cross-feeding by family members, including grandmothers, which was practiced covertly or openly: 'Women who just say, 'Well, that's what I do" (SVIC04, health professional).

Accordingly, awareness varied with professional subspecialties. Doulas and midwives were more aware of women with surplus milk if other mothers needed it, while lactation consultants tended to work with women with insufficient milk:

'So, I was a lactation consultant and a doula. I only knew the ones who had the excess milk because I was a doula. You wouldn't find out as an LC because you're only seeing train wrecks, ...You're not seeing women with oversupply usually... those women will be sorted out by ABA' (MW01, health professional).

Policy makers in the health system encountered milk sharing from the perspective of their policy domain, sometimes with little point of reference for infant feeding, especially if removed from clinical maternity services. As one policy maker discussing infection risks said:

'But I'm not an expert, I'm just thinking that as a breastfeeding mother, what I would have thought at the time?' (SDOH02, policy maker).

Many medical staff had limited education in breastfeeding, and few received undergraduate education on milk banking or informal sharing,⁷³ and limited post-graduate education on donor milk. One health professional provided separate education sessions ('a safe space') for trainee paediatricians in her hospital that enabled them to expose gaps in their knowledge:

'So they do have a 'yuck' factor about it because when it comes up about donor milk, you can see probably about half of them going ...'What do you mean women bringing milk in for other women?' So some of them are quite naive. ...And others are 'Oh yeah, I had that at another hospital" (SVIC04, health professional).

There were concerns that NICUs no longer required nurses to be qualified midwives and educated in the physiology of lactation and sociocultural aspects of breastfeeding, at the same time that access to PDHM was expanding (SVIC04, health professional). Lactation consultants commented on the absence of donor milk in BFHI⁷⁴ accreditation, but its emergence in courses for IBCLE⁷⁵ exams and

⁷² Cross-feeding was observed in cultural groups described as from Slovenia, Assyria, Vietnam, Tonga and other Pacific Islands, or of 'Asian,' 'Chinese,' or 'Arabic' heritage [SVIC04].

⁷³ Although two mothers in the study, who were also health professionals, learnt about donor milk as students.

⁷⁴ Baby Friendly Hospital Initiative

⁷⁵ International Board of Lactation Consultant Examiners

professional development, including LCA NZ⁷⁶ conferences. Others became aware of milk sharing from mothers and the media, and this cross-fertilization of roles and sources informed them as policy makers in NGOs:

'My own experience, as a counsellor talking to mums and certainly working as an IBCLC, is that more people do seem to be asking about donor milk now than they perhaps did ten years, five or ten years ago ...But I think that social media has certainly got the message out there a whole lot. Something turned up in my Facebook feed today about lesbian bikies on a breastmilk run... like 'Oh my goodness!'" (SVIC05, policy maker).

6.1.5 Policy and legislation

Awareness of milk sharing was limited by legislation for human tissue that restricted advertising by milk banks and approaches to individual mothers as potential donors:

'If only someone had asked, [mothers] would have given their milk... [but] because it's considered human tissue, they're not allowed to ask individuals. ...You couldn't say, 'Oh, you're leaving hospital, you've got an abundance of milk, ... do you want to donate some of your milk?'" (SVIC05, policy maker).

In government agencies, some policy makers only became aware of donor milk from requests for policy advice on milk banks or the importation of milk. The emergence of human milk products, for example human milk-based fortifiers, also raised new policy issues and regulatory responsibilities:

'There's a lot of evolution of the products now that's happening... claiming that it can help with necrotising enterocolitis, ...starting to make a therapeutic claim, and it starts to interface with therapeutic goods regulation' (SACT15, policy maker).

NGOs in this study were aware of milk sharing through their position statements on donor milk (Chapter 5), and members who worked directly with mothers. However, for government policy makers, their knowledge of milk sharing was often filtered by inter-agency health committees and who they consulted, for example paediatricians, who were not knowledgeable about lactation. Few sought community opinion (although some thought this advisable) (SNSW03, policy maker). In these settings, personal histories of breastfeeding mattered:

'It's actually something the CEO said, when she walks in to do fundraising or liaise with a health professional or politician. If the person has breastfed the baby or been breastfed,

⁷⁶ Lactation Consultants of Australia and New Zealand

she's home and hosed! If they haven't, it's an uphill battle. She said, 'I've never worked in an organisation where the person's personal history is more important' (health professional, LC04).

6.2 Issues - the focus of awareness

Actors described specific issues about milk sharing that captured their attention, and the importance of breastfeeding, which was also a strong motivation (discussed further in the next chapter).

Awareness often focused on a single milk sharing sector, accessing milk, or concerns about legitimacy, risk or ethics. These single issues often distorted perceptions of milk sharing and shaped its regulation.

6.2.1 Milk sharing sectors

Actor groups varied in their awareness of milk sharing sectors. Mothers in the study thought that the public was more aware of milk banking than informal sharing. One participant described the reaction of her mothers' group, in which CMF feeding was predominant, to her story of donating milk informally:

'All of them have said 'If we knew that we had that option in our early days, then we would've looked into that as well'... They'd all made the assumption that milk sharing was for premature babies that were still in the humidicribs.' (MWAW, donor mother)

Similarly, health professionals, milk banks and policy makers were focussed on milk banking. A few participants thought that informal sharing had growing relevance to their work area (SACT05, policy maker). Several federal government agencies that were initially focussed on the importation of milk for milk banks subsequently became more aware of its other potential uses:

'So we had a discussion with Department of Health as to where it would fit from our perspective, and it's such a tricky one, because ...we don't know what the defined use for it is. I think we're pretty confident it'll go to milk banks, that was the idea, or black market, who knows –the body builders' (SACT10, policy maker).

Mothers were the most aware and knowledgeable of informal milk sharing practices, along with the administrators of milk sharing social media pages. Milk banks and their donors best understood the details of milk bank requirements. However, only mothers were aware of how constraints on their time, energy and resources shaped the way they shared milk, as discussed in Chapter 7 on pathways.

6.2.2 Milk availability and access

Actors struggled to grasp the scale of milk sharing sectors and the availability of milk in Australia. The amount of surplus milk in the community came as a surprise to one milk bank:

'I just don't think anyone was aware that we were going to be so completely inundated. And that was from all across Australia, everywhere, just absolutely amazing, and even to the point 'Well where can I drive to meet you?' (MB05B, milk bank).

Despite this hidden abundance, mothers in the study thought that health professionals and the public did not understand that access to milk banks was highly restricted, and mothers often only became aware of informal milk sharing after donation or access to a milk bank was thwarted:

'Whatever I was pumping at work, which was usually about 500mls, would go to the freezer and it built up. I had to start Googling what I could do with it, because I didn't want to just throw it out. ...I thought I could just give it to a local hospital or something, but you know you've got to take all these tests and jump through all these hoops. So then I found there was a Facebook page where you can just give it to local mums and so I did that' (MVICY, donor mother).

In contrast, health professionals' knowledge about accessing milk banks and PDHM was largely obtained from working in NICUs, and most midwives did not have this specialized knowledge. One midwife reported being unable to help obtain PDHM for a pregnant woman with a double mastectomy and relying on this mother's own research of the Mothers' Milk Bank (MW06, health professional).

Health professionals who were aware of covert milk sharing in hospitals were unsure of its extent. Reports ranged from 'once a year' (SACT3-4, clinical policy makers) to 'five different women in the space of a few months who came in with some expressed milk from one of their friends' (LC03, health professional). Health professionals were aware that mothers tried to avoid suspicion by bringing in small volumes of donor milk labelled as their own, but staff awareness of informal sharing on post-natal wards was hampered by unrestricted visiting hours, bedside bar fridges and single rooms, which enabled milk sharing 'behind closed doors' (LC01, health professional). In Special Care nurseries and NICUs, mothers were more closely monitored.

Most health professionals had limited awareness of the details of milk sharing in the community. One participant shocked her colleagues when she described local milk sharing activity on social media:

'It's really off the Richter scale. There's messages 'I'm in [suburb] and I want to empty my freezer, I've had some screening, who wants my milk?' And the responses are huge.'
(SACT09, health professional).

On social media pages for milk sharing, administrators described a steady increase in activity and the diversity of users who accessed donor milk ('single parent, multiple parent, same sex, all sorts of relationships' and 'trans parents'), in addition to more 'mainstream' users and contexts:

'I wouldn't classify the majority of the people sharing the milk as your Byron Bay hippie type. A lot of them were well-educated metro dwellers' (MNSWY-HM4HB, policy maker).

6.2.3 Legitimacy

Most actors first encountered milk sharing as a novel or fringe idea and sought to legitimize it. For mothers, awareness of milk banks legitimated the principle of sharing milk, and this was validated when they saw the range of offers and requests from women in conventional society:⁷⁷

'We were really lucky to come across I think it was 8 litres initially, a lady who was with the Army or Defence Force, and she moved to [region] and she didn't know how to transport it without it defrosting' (MACTY, recipient mother).

However, mothers had little knowledge of policy around shared milk until they were prevented from using it in hospital settings. The hospital policies they encountered de-legitimized informal sharing, and these negative experiences were shared on social media.

'Feeling like a bad person by smuggling milk in ... I've written a few posts online about the way that it made me feel, that I was doing something wrong just feeding my baby while we were in hospital. A lot of the nurses actually said to me 'You know, I think it's great, but this is the rule...' I think all the nurses knew' (MQLDY, recipient mother).

Mothers also understood that health services and NGOs were wary of discussing donor milk for fear of endorsing informal milk sharing and incurring legal liability.

Conversely, health professionals involved with milk banks emphasised their legitimacy and described an uneasy relationship with informal milk sharing. The struggle of milk banks to become established, and their legal complexity, gave them a vulnerability that few other actors understood. Some wanted to distance themselves from informal sharing to maintain credibility with other health professionals

⁷⁷ 'Human Milk for Human Babies' or 'Eats On Feets'

('we don't really have contact with the informal sector at all' MB03, milk bank). Other milk banks acknowledged informal milk sharing and recognized that some donors supplied both sectors:

'We are, I believe, very responsible and aware of the fact that there is an informal milk sharing community that has been impacted by the fact that we are collecting milk' (MB05B, milk bank).

Most milk banks appeared to have limited knowledge of informal practices in the community and health facilities ('I think it happens much more often than we know about it' (SSA1, milk bank), but revealing awareness of the illicit was risky. For example, a few milk bank staff mentioned informal sharing when senior clinicians were not present, or had witnessed the harsh consequences of disclosure for mothers:

'When they've said 'I didn't have enough, this is my sister's milk. I want to use it for my baby' and the paediatrician being really angry about that' (SSA1, milk bank).

In contrast, midwives who observed milk sharing and cross-feeding tended to treat these practices with respect for family diversity and cultural traditions, a perspective embedded in midwifery training:

'I worked where there was a large Lebanese Muslim population, and a lot of the sisters and sisters in law would come and visit, and then the newborn would be feeding from them, and we'd walk in and 'Oh OK,' and wouldn't do anything about it. It's their baby' (MVICV, recipient mother and health professional).

Nonetheless, these health professionals described having to learn to normalize cross-feeding for themselves and other staff.

6.2.4 Risk and Safety

Safety was a common concern of all actors. However, actors differed in their perception and framing of risk from different domains (infant feeding, infection control, maternity care and culture). Most participant mothers, milk banks, midwives and lactation consultants framed the risks of donor milk relative to the risks of CMF feeding, for specific categories of infants, trading off potential harms against nutritional and immunological benefits, and other risks:

'There are other microorganisms, if the milk's not handled pretty well - that's why we do our micro testing. Does it matter for a term baby as much as it does for a preterm baby? Probably not, but again there's a risk involved... that would mean different things to different

people. If I'm thinking about it from a milk bank point of view, ...it's a reputational thing. If it's a single person, they may perceive that risk somewhat differently (MB03, milk bank).

Breastfeeding mothers were aware that milk had potential to transmit infections, medicines and drugs, including alcohol and nicotine. Their level of knowledge about these risks varied. Some were familiar with donor screening and test requirements on milk bank web sites, and a few had knowledge as milk bank donors or recipients. In general, mothers' attitudes towards risks were based on their experience of antenatal care and high level of confidence in the safety of their own milk:

'They've all had babies recently, so they've all gone through the same blood testing that I had. I asked all of them, 'Have you had blood tests? Do you have any illnesses? Are you taking any medication? Smoking? Alcohol?' That sort of thing' (MACTY, recipient mother).

Milk bank participants were acutely aware of the importance of safety to the health of vulnerable infants in NICUs and the acceptance of PDHM by parents and medical staff, and their awareness was informed by their records of donor screening and milk testing. Health professionals, like milk banks, were focussed primarily on the risk of transmitting 'high profile' blood borne viruses (HIV and Hepatitis B). However, milk banks and other participants with specialist expertise in infection control and foetal immunology were aware of risks from less recognized viruses, for example HTLV and CMV, and queried the capacity of most health professionals and mothers to assess these risks.⁷⁸ Knowledge of risk and its management had a large influence on the way milk was shared, and is discussed further as a constraint on actor pathways (in chapter 8).

For policy makers, safety was a core responsibility of their agency or organization. Policy makers had general awareness of the potential for infection from milk but left assessment to technical experts. In this way, risk was controlled by a small sub-group of highly risk-averse actors, removed from milk sharing practices:

'I guess the objective for the discussion paper was commercialisation of human milk... these products are coming to us from overseas. ...But we did know you can get human milk from the Gold Coast bank and that there was this informal system through Facebook or the Internet, where you just talk yourself up with somebody and get the milk' (SDOH01, policy maker).

⁷⁸ For example, a recipient infant may lack antibodies to antigens in the donor's milk, particularly if the infant was born prematurely, before the placental transfer of antibodies that occurs in the last trimester of pregnancy [SSA02].

6.2.5 Displacement of breastfeeding

Actors varied in their awareness of the potential of donor milk to displace breastfeeding. Most mothers who shared milk and NGOs were aware of institutional and societal barriers to breastfeeding, and described how CMF marketing displaced awareness of donor milk:

'And you see adverts for formula everywhere, for toddler milk and it's in the supermarket so there's wide awareness of formula. So if donor milk is supposed to be better for babies, then I think more attention should be given to it.... a lot of money goes into marketing formula and no money goes into marketing donor milk' (MVICO, donor mother).

In contrast to donor milk, which was rarely endorsed by health professionals, the recommendations of health professionals to use CMF legitimized it.

At the individual level, some donors were concerned that using donor milk could reduce a recipient mother's milk production, but recipient mothers faced an invidious choice between donor milk and CMF. Most recipients worked hard to build their milk supply, where possible. In contrast, milk banks were very concerned about PDHM displacing a mother's own milk physically and psychologically. To manage this risk, NICU staff implemented lactation education to mothers at risk of premature birth. One hospital delayed consent for PDHM until a few days after NICU admission to encourage mothers to express milk and redesigned labels for PDHM to look more medicinal than labels for the mother's own milk (MB04, milk bank). Conversely, some actors noted that, donor milk was likely to support breastfeeding when milk banks and clinicians worked with mothers on lactation and became aware of gaps in lactation research.

6.2.6 Ethics

Milk sharing raised an array of ethical issues, especially when trade or commercial milk sharing or was considered:

'There's the ethical [risk] about bringing it in from another country, because you don't know ... the circumstances under which women have provided that. Are women in a situation where they are forced to provide milk to make money, coerced? I think, within Australia, the ethical issues... are probably less. ...If a woman chooses to do that to earn money, that's one thing, but does her own child suffer because of it? Then, what is actually the scientific risk of transmission of any disease, bacteria, or virus from the milk? We should be providing that advice' (SDOH02, policy maker).

Even within systems of altruistic donation in Australia, mothers and milk banks were aware of the potential for exploitation and the need for informed consent when recruiting donors or allocating milk:

'The [milk bank] still has a duty of care...the issue becomes a bit clouded because of the lack of regulation in milk banking, because we don't have to really answer to anybody, as far as what's required. But as clinicians and people who are employed in healthcare settings, we have a duty of care to our patients to provide safe care' (MB05A, milk bank).

Mothers and some health professionals and NGOs saw access to donor milk as a human right (see Motivations), but few actors raised concerns about the inequitable distribution of milk and breastfeeding in Australian society (35). No government agencies discussed donor milk within human rights frameworks, and most considered ethical and social values 'out of scope' for their agency, as something to be resolved by the Department of Health or markets.

6.3 Processes that shaped awareness

The processes that shaped awareness of milk sharing were social and institutional. These social processes aimed to only disclose milk sharing when it was safe (careful conversations or turning a blind eye). Institutional processes that shaped awareness included models of maternity care and milk bank governance. Policy makers had insights into policy making processes that were obscure to others, while technology and data collection (and its gaps) could amplify or mask specific types of milk sharing.

6.3.1 Careful conversations

Mothers reported that their awareness of milk sharing was constrained by social processes that hid it, for example 'careful conversations.' Milk donation was rarely discussed ('Like it just doesn't come up because it's not very common' MQLDV, recipient mother), or could be emotionally demanding. Recipients often had to manage their sense of failure, shame or disappointment about not being able to breastfeed.

Donors were sensitive to these feelings and reported keeping awareness of informal milk sharing to 'small circles' (MACTX, donor mother), by informing only close friends or women who were pregnant or making offers in private, socially safe situations. A few mothers were open advocates: 'I would tell everybody that it's an option' (MVICN, donor mother).

Mothers were also reluctant to discuss their experiences outside trusted circles for fear of disapproval from family members and health professionals or verbal attacks from peers. In public spaces, mothers found that suggesting donor milk as an option could be interpreted as shaming

mothers who use CMF ('formula shaming' or 'Lactivism') and invoke a backlash from supporters of CMF ('fed is best') or misogynists and internet trolls:

'It's hard, because there's so much judgement. You get called a Lactivist, and a breastfeeding Nazi, and all of these horrible terms when you're a breastfeeding advocate. ... For example, going along to the ...catch ups, ...and I will end up just being quiet because I don't want to be the one that goes, 'Well actually, ... have you heard about donor milk?' (MVICT, donor mother).

Echoing the 'careful conversations' of mothers, medical staff were also hesitant to discuss donor milk to avoid shaming mothers ('rubbing their noses in it' MW05, health professional), challenging institutional and social norms for CMF feeding, or incurring the disapproval of colleagues, disciplinary action, conflicts about the value and safety of milk or 'the song and dance' of reporting informal sharing as a 'reportable incident' under safety management protocols (SVIC04, health professional; MW03, MW04, midwives).

Health professionals were also concerned that awareness of donor milk could pathologize normal lactation and normalize bottle feeding, invoke revulsion or interfere with maternal-infant bonding.⁷⁹ One health professional described her careful response to a mother in an antenatal class who asked about using a friend's milk:

'I had to be very careful because there were nine other mothers in that room. They had to be assured that we weren't going to be giving other milk to their baby if their baby goes to the nursery, because they might have been fearful of that. ...So I had to had to make sure they were confident that I would follow policy and I wanted to be non-judgemental' (LC03, health professional).

6.3.2 Wilful blindness

Health professionals' lack of awareness or reluctance to discuss informal milk sharing openly contributed to wilful blindness and institutional ignorance about it. The invisibility of informal sharing was compounded by policy gaps. Few health professionals were aware of protocols for milk sharing outside milk banks. Some were aware of the ACM⁸⁰ and ABA position statements on donor milk and the lack of LCANZ policy. Three participants had written local protocols for directed donation but cautioned that staff and patients had to be aware of their existence (SVIC04, LC02, health

⁷⁹ However, milk sharing was increasingly 'a common conversation' with pregnant women, who asked about donor milk during pregnancy because of concerns about medical conditions that delayed lactation [MW04] and routine antenatal expression of colostrum.

⁸⁰ Australian College of Midwives

professionals). A lack of awareness of milk sharing policy contributed to a lack of hospital planning and resources for milk banks.

The visibility of milk sharing was also constricted by medical sub-cultures and hierarchies:

'In the Birth Centre, we would talk about it more officially in our group meetings... because there's a group of midwives or health professionals who are on the same page... they're not going to be 'judgey' about this, and they were going to share information and talk about it. ...The special care nursery is an interesting place for that kind of conversation: so as long as they don't know things are happening, they're happy just to pretend it was not happening' (MW05, health professional).

Neonatologists were seen as the instigators of policy on donor milk, but they were hampered by its low profile in other medical specialties (MB01, MB03, milk banks), and their awareness of informal milk sharing was restricted by their work in Special Care and NICU settings (SVIC04, lactation consultant). Consequently, some health professionals thought that mothers should demand policy for donor milk but do so through political channels (SACT3-4, policy makers), because they were not empowered to 'rock the boat' within the health system (SACT09, health professional).

6.3.3 Models of maternity care

Awareness of milk sharing was shaped by different models of maternity care. A high proportion of mothers in this study were in contact with homebirth networks, in which informal milk sharing was common.⁸¹ As shown above, 'standard care' maternity services in hospitals with did not facilitate disclosure of milk sharing because midwives worked in teams, patients were discharged from hospital within 24-48 hours of birth and had few post-natal home visits. In contrast, midwives working in the few available 'continuity of care' services and Birth Centres had more contact with the mothers in their care, which fostered trust and open communication about milk sharing. One health professional thought that the health system struggled to grasp how women's knowledge of milk sharing circulated independently of the health system, particularly in cultures in which education and support during birth and breastfeeding were provided by doulas and female relatives (MW01, health professional).

6.3.4 Milk bank governance

The governance, structure and location of milk banks and influenced awareness of clinicians, recipients and donors and the wider community. Milk banks embedded in hospitals had close contact

⁸¹Nearly 15% of mothers (7/48) in this study had a homebirth, compared with 0.3% of the Australian population. (688)

with medical staff and recipient mothers. As shown earlier, milk banks that picked up milk from donors' homes became aware of local informal milk sharing practices, while community-managed milk banks could also see their social role in building communities:

'It has so many benefits for bringing the community together, in such a positive way around the health of babies and the awareness of the need for healthy nutrition. ... We've provided for twins recently ...and the Dad was caught up. He rang me, he said his mate who was out surfing is going to come in from his surf, drive to the airport and take the milk to the hospital... So they're all getting together for the one purpose' (MB02, milk bank).

Similarly, some milk banks and health professionals saw a need for broader debate about the role of milk banks in supporting breastfeeding, that was not just focussed on a product (MB02 and MB04, milk banks). However, others were reluctant to engage in public debate because of concern that raising awareness of milk banking endorsed informal sharing:

'Milk banking has brought an awareness that here's a product, if we can't get it through a milk bank, then we'll get it through other means, because they want to avoid formula' (MB02, milk bank).

Despite these tensions, those involved in milk banks had a passionate commitment to the promotion of PDHM in Australia after being 'so far behind the rest of the world' (MB02).

6.3.5 Policy processes

Milk sharing was also shaped by awareness of policy making processes. While milk banks understood the policies that applied to donor milk in their situation, only policy makers in higher levels of government were aware of the broader policy environment. However, even their knowledge of relevant policy was restricted to the laws and regulations administered by their agency (see Pathways). Some were not aware of differences in the legal classification of milk between States and Territories or the use of international milk banking guidelines in Australia, and most were unaware of directed donation protocols. Consequently, policymakers varied in their understanding of the need to coordinate policy around milk. For example, one participant suggested standardizing the nutrient composition of PDHM by pooling milk from multiple donors (SACT10, policy maker) but did not appreciate that pooling was contrary to requirements for traceability (96, 593).

At the Commonwealth level, policy makers were aware of the complexity of regulatory questions surrounding milk and the risk that they remained unresolved ('they just go round and round') (SDOH02, policy maker). At this level, a handful of policy makers understood the multiple channels and processes for developing policy for milk through various AHMAC committees. Those aware of

the Clinical Principal Committee Working Group on Donor Human Milk hoped it would address health and ethical issues, while others doubted their capacity to influence informal sharing ('It's actually very hard to do anything about' SDOH01, policy maker).

6.3.6 Technology and data

Awareness of milk sharing was strongly shaped by technology. Most actors were aware of the reliance of milk sharing on social media, breastmilk pumps and freezers. The ubiquity of these technologies for milk expression tended to crowd out awareness of cross-feeding and ways to use donor milk that protected 'feeding at the breast.'

Participants had varying opinions on the role of social media in milk sharing. Policy makers saw it as a vehicle that pushed informal milk sharing beyond their reach. One NGO regretted that women had to 'retreat to Facebook to feed their babies' without public debate and official guidance on the safety and efficacy of donor milk (SNSW01, policy maker). While mothers were aware that social media could amplify hostility to informal milk sharing, they exploited its power to shape awareness in positive ways. Administrators of social media pages for milk sharing promoted awareness of informal sharing by ensuring their pages were tagged and appeared in news feeds. However, visibility of the details of milk exchanges were restricted by Facebook's structure and privacy settings:

'There is a lot of stuff that happens in private messages that we don't know about so there is definitely more milk sharing going on than what we see on our pages' (EOF/MVICQ, policy maker).

A lack of awareness of milk sharing resulted from a lack of data on its prevalence and practices. Milk banks did not publish complete statistics on milk they collected and dispensed, and informal milk sharing practices were not included in infant feeding surveys. Few policy makers understood the need for data on a broad range of infant feeding practices to contextualize the use of donor milk. Mothers was also hampered by a lack of publicly available data on hospital policies for donor milk:

'And so if I was a woman thinking about ... my baby's going to be premature for whatever reason, where's the best place for me to be, I want milk bank availability, there is no way you could be able to find that out... information for women is woeful at a hospital by hospital level' (SNSW01, policy maker).

6.4 Awareness as power in the regulatory regime

This chapter has described what actor groups know about milk sharing and how this awareness is produced, distributed and shaped through different sources and processes. When awareness is

analysed across all the actor groups and the whole regulatory regime for milk sharing, its importance to the social and legal regulation of milk sharing emerges.

6.4.1 What actors were aware of

No actor group had knowledge of all types of milk sharing (Figure 5). Mothers in the study had the greatest awareness of milk sharing practices across community and medical settings, while policy makers were removed from these practices, and milk banks and some health professionals had unique knowledge of milk sharing.

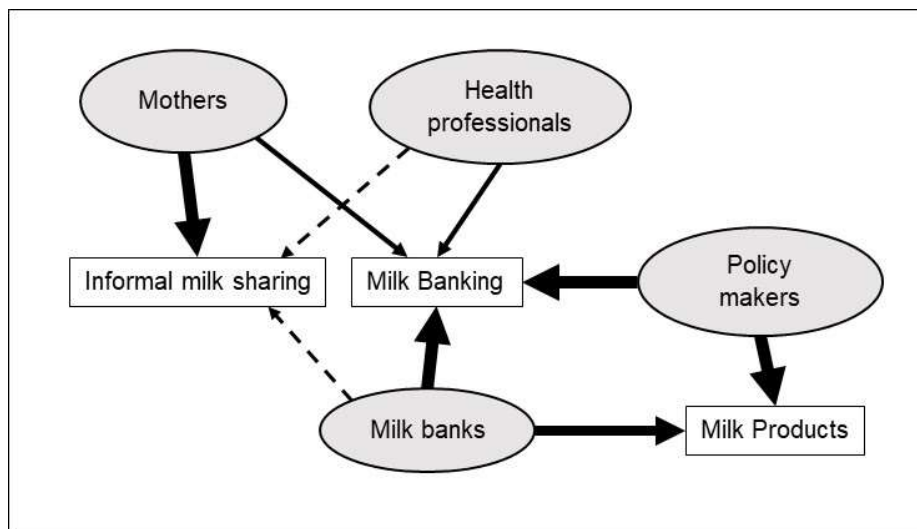


Figure 5 Awareness of milk sharing practices and issues of four actor groups (mothers, health professionals, milk bank administrators and policy makers).

Awareness and perceptions of milk sharing's risks (and benefits) were primary mechanisms through which milk sharing was regulated. However, these perceptions varied. Risk averse positions of milk banks and health professionals stemmed from an understanding of the vulnerability of infants in NICUs, the priorities of hospitals or expertise in infectious disease, while more nuanced attitudes to risk were held by mothers with full-term infants and health professionals working in the community. Actor positions on safety were polarized by a lack of awareness of policy solutions in the middle ground, for example directed donation.

Actor groups also had major differences in the focus of their awareness. Milk banks focussed on the efficacy of donor milk, while mothers needed no convincing of this, and were focused on how to access milk. The importation of milk was important to policy makers and milk banks, but mothers and health professionals in the study showed little awareness of this issue (partly because of the timing

of my research). Policy makers and milk banks understood the complexity of government policy processes, which other actors were not exposed to. In contrast, health professionals and policy makers with clinical experience had insight into the fine-grained regulatory processes at the local or 'ward' level.

6.4.2 How awareness was produced and distributed

The position of an actor in the regime shaped their awareness of the drivers of milk sharing (Figure 5). Milk banks had an overview of supply and demand of milk in their sector, but less awareness of the systemic drivers of milk sharing in the community. This knowledge was also obscure to many policy makers. Consequently, actors who bridged actor groups were valuable links to knowledge necessary for the development of effective policy (if their perspectives were voiced or sought).

The analysis of awareness shows the importance of direct experience to awareness. Mothers became aware of milk sharing as its practitioners, and health professionals' knowledge also relied on personal and work experience in the absence of education and policy on donor milk. However, this gendered, experiential knowledge was often controlled by 'surveillance', self-censorship or discounting. These social mechanisms that controlled awareness were also structured by institutions, for example models of maternity care, online spaces or siloed policy or medical disciplines.

Without direct experience, actors lacked awareness of the relational aspects of milk sharing and its role within a continuum of breastfeeding practices. Consequently, actors removed from the experience of breastfeeding treated milk instrumentally, as a product not a process (211). Mothers and some health professionals described how knowledge of the relational and embodied nature of milk sharing and its ties to breastfeeding, were devalued in Western models of medicalized maternity care and lactation. However, this knowledge was 'unspoken.' Actors described what they were 'permitted' to know about milk sharing and permitted to share. For example, milk banks and health professionals had difficulty admitting to detailed knowledge of informal sharing for fear of legitimizing it (Figure 5, dotted line).

These accounts of suppression contributed to the negative framing and misrepresentation of informal sharing in the media, driving it further 'underground'. In contrast, mothers saw stories about milk donation as empowering, and capable of countering narratives of scarcity and struggle in lactation. Reflecting on these narratives, mothers in the study compared their limited awareness of milk sharing with high levels of awareness of CMF, which they attributed to policy that enabled CMF marketing. Consequently, awareness of milk banking and informal sharing did not flow readily between sectors, settings or social groups or promote breastfeeding, while actors were saturated with knowledge of CMFs.

6.5 Summary of analysis of awareness

6.5.1 How awareness regulated milk sharing

Awareness was a source of regulatory power: awareness could shape actor behaviour by promoting milk sharing or amplifying warnings. However, milk sharing was regulated principally through a lack of awareness. The analysis of awareness showed how knowledge of milk sharing was suppressed by social mechanisms, like shaming, policy gaps and its misrepresentation through the prism of a medical discipline, knowledge system or the media (Table 8). Without awareness of milk sharing options, milk sharing fails to occur. Equally, turning a blind eye to milk sharing in health facilities was not a benign act, but rendered it invisible, and removed women's voices from policy debate about its regulation.

In addition, fragmented awareness of milk sharing by policymakers restricted policy options and prevented integration of policies for milk sharing and breastfeeding. Becoming aware of milk sharing involved women becoming aware of their own power to produce and distribute surplus milk, but women's autonomy was countered by the power of others over their bodies and milk, including through medicalized systems of knowledge. Consequently, the map of where awareness is focused or directed (Figure 5) is a map of how coercive power and autonomy are exercised in milk sharing's regulatory regime.

Awareness is also important to theories of regulation. In the regulation of infant feeding, self-regulation is prominent, as outlined in Chapters 2 and 3 of this thesis.⁸² Self-regulation relies on non-state actors to police bad behaviour. However, mothers and health professionals are ill-equipped to fulfil this policing function over the governance of milk without awareness of the other actors and interests in the 'regulatory regime' for milk: transparency is critical to good governance.

6.5.2 How awareness of milk sharing affected breastfeeding

It is easy, in the fine-grained description of actor awareness for milk sharing, to lose sight of its effects on breastfeeding. Despite asking all study participants how milk sharing affected breastfeeding, few could articulate this or the regulatory mechanisms involved. Perhaps this is a finding in itself, that connections between shared milk and breastfeeding were obscure, or obscured by the institutions and social structures that regulated milk sharing in Australia.

⁸² Milk banks self-regulate, industry self-regulates infant formula marketing, and, in theory, an unfettered market in milk determines supply and demand, and parents are informed and autonomous.

Awareness —and ignorance— of milk sharing were powerful regulatory mechanisms for breastfeeding. Suppression of awareness of milk sharing shaped breastfeeding directly and indirectly, by providing CMFs with a competitive advantage in the stakes for awareness by mothers, health professionals and policy makers. All actor groups lacked awareness of the diversity of milk sharing practices, which removed them as options in decisions on infant feeding. Without these options, and coupled with ubiquitous CMF marketing, CMF easily out-competed milk sharing for consumer and policy attention, and promoted CMF as normal and safe, while breastfeeding was difficult and donor milk suspect (Table 8).

A discussion of awareness raises epistemological questions about which types of knowledge are privileged in systems of social and legal regulation. Awareness of milk sharing did not come from formal education and arose from direct experience 'on the job' —of being a mother exchanging milk, a health professional working with lactating women or a policy maker responding to a policy issue. This experiential knowledge was held in 'silos' by different actor groups and competed for legitimacy with other forms of knowledge. Silos prevented actors from integrating their knowledge of milk sharing with breastfeeding and developing common approaches to safety and ethics.

In each actor group, integrating knowledge of milk sharing with breastfeeding relied on mothers with embodied experience of breastfeeding. Without these bodies at the table, women lacked representation in policy decisions concerning milk. At times, even these voices were silenced by internalized gender discrimination that perpetuated ignorance of milk sharing, and disconnected milk from breastfeeding. On the other hand, remaining 'under the radar' enabled women to share milk without interference, but in doing so, they obscured the knowledge and relationships that accompanied milk shared informally. Overall, a lack of awareness of milk sharing and the processes that associated it with breastfeeding weakened the governance of milk, and gave CMFs an advantage in infant feeding decisions and policymaking. The motivations that underpinned these outcomes are investigated in the following chapter.

Chapter 7. Results: Actor motivations for milk sharing

Chapter 7 examines the motivations of four actor groups towards milk sharing, their alignment and conflicts and the ways these motivations regulated milk sharing. The analysis identified motivations that were common across actor groups and specific to actor groups (Table 9). Common motivations, (indicated by boxes), were immediate and apparent, for example, infant safety, or infant feeding goals. Some motivations were more important to some actor groups (indicated by thicker lines). These common motivations were influenced by broader motivating concepts, based on societal norms and political ideas about gender and world views concerning individualism and knowledge systems (indicated in bold text in Figure 6). This configuration, of aligned and conflicting motivations, revealed avenues of cooperation and fault lines of distrust across the regulatory regime, that shaped the way milk is shared and how this affected breastfeeding (Table 9).

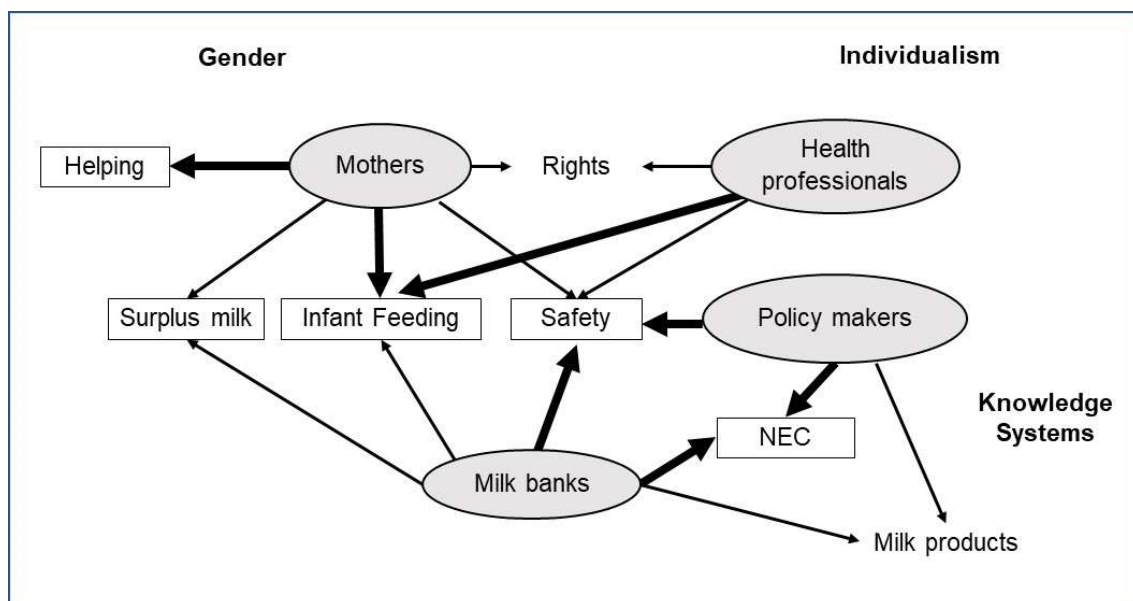


Figure 6 The motivations towards milk sharing of four actor groups: mothers, health professionals, the milk bank sector and policy makers.

Chapter 7 Results - Motivations

Table 9 The common and specific motivations for positions on milk sharing of four actor groups, and broader motivating concepts and processes that shaped motivations, and their effects on breastfeeding.

Motivations		Actor groups				
		Domain	Mothers	Milk Banks	Health Professionals	Policy Makers
Common		<i>Safety</i>	Mothers assess for themselves the risk of milk shared informally	PDHM* is safe, informal milk sharing is unsafe	Staff need guidance to assess risks of milk sharing in multiple settings	Manage harms according to organizational scope**
	<i>Infant Feeding</i>	<i>Breastfeeding</i>	Support breastfeeding	Support maternal breastfeeding***	Support maternal breastfeeding	Breastfeeding may not be an organizational objective
		<i>Exclusive milk diet</i>	Provide an exclusive milk diet, from a range of sources	Provide an exclusive maternal milk diet and PDHM	Provide an exclusive maternal milk diet	-
		<i>CMF</i>	Avoid CMF	Avoid CMF for infants vulnerable to NEC and selected cases	CMF as only supplementation option according to policy	CMF as only supplementation option, Trade in accordance with food regulatory system.
		<i>Surplus milk</i>	Manage surplus milk	Not waste milk	Comply with policy for milk as infectious fluid	-
		<i>Rights</i>	Human rights: Infant and maternal rights to breastfeeding and milk	Medical ethics -informed consent, equitable access to PDHM for NICUs	Medical ethics -informed decision making and consent	Organizational or member interests
Specific		<i>Helping</i>	Helping	-	-	-
		<i>Relational</i>	Relationships between donors and recipients	Anonymous donation	Recognition of breastfeeding relationship	Responsive to sectoral interests
		<i>Legitimacy</i>	Milk bank donors and recipients legitimate	Legitimacy in policy and funding*	Professional risk*	Organizational risks*
		<i>Other</i>	-	Reduce NEC, Clinical priorities of NICUs	-	Policy making rules
		Broader motivating concepts				
		<i>Gender</i>	Maternal identity, Shaming	Removal of emotion	Power in the health system	Status of women and infants in policy agenda
		<i>Individualism</i>	Local interdependence	Public funding, transparency	Public-private sector interests	Neoliberalism
		<i>Knowledge systems</i>	Experiential and published sources	Published clinical trials	Evidence-based guidelines	Gendered research gaps
		Processes that shaped motivations				
		<i>Alignment</i>	Motivations aligned between donors and recipients. Motivations contested with medical authorities.	Motivations for nutrition and safety aligned for PDHM. Motivations conflict for informally sourced milk.	Motivational alignment varies	Motivational conflicts unresolved. No policy framework to integrate milk sharing with breastfeeding.

* Pasteurized donor human milk.

** Includes avoidance of legal liability and business risks (discussed further in chapter 8 on actor pathways), cost incentives and resourcing (discussed further in chapter 9 on actor rewards).

*** Maternal breastfeeding: by the infant's birth mother

Chapter 7 Results - Motivations

	Actor groups			
	Mothers	Milk Banks	Health Professionals	Policy Makers
How actor motivations for milk sharing affected breastfeeding				
<i>Direct effects on breastfeeding</i>	Motivations for milk sharing support breastfeeding through aligned objectives for milk diets, maternal rights, identity, relational meanings and empowerment.	Motivations for milk banking support importance of milk diets and breastfeeding in NICUs. PDHM may displace breastfeeding. Focus on milk's risks may imply breastfeeding is unsafe.	Conflicting motivations of health professionals may restrict provision of lactation support and enable milk sharing to displace breastfeeding.	Conflicting motivations of policy makers create policy gaps and lack of policy and governance mechanisms for milk sharing to protect, promote or support breastfeeding. Milk banks may displace resources for breastfeeding.
<i>Effects on competition between breastfeeding and CMFs</i>	Milk sharing challenges institutional and social norms for CMF use but has little effect on policy.	Objectives of milk banks do not include provision of breastfeeding support or challenge CMF use outside NICUs.	Restricts policy advocacy to integrate milk sharing with breastfeeding. Reinforces institutional and social norms for CMF use.	Policy enables milk's commodification and trade, and CMF use.

* Pasteurized donor human milk.

** Includes avoidance of legal liability and business risks (discussed further in chapter 8 on actor pathways), cost incentives and resourcing (discussed further in chapter 9 on actor rewards).

*** Maternal breastfeeding: by the infant's birth mother

7.1 Common motivations

Actor positions on milk sharing were motivated by core concerns, held in common by all actor groups, for infant safety, optimal infant feeding, and human rights in the provision of care for infants and mothers. These motivations depended on beliefs about the effects of donor milk on breastfeeding, the value of an exclusive milk diet and women's autonomy. Nuances in these beliefs, and definitions of benefits and harms, motivated actors to support or reject various forms of milk sharing, putting them in agreement or in conflict.

7.1.1 Safety

The importance of infant safety was an unquestioned societal and institutional norm. However, an actor's opinion of the safety⁸³ of milk sharing depended on an actor's awareness of risk (discussed in the previous chapter on awareness), and processes to assess and manage risks (discussed in the next chapter on pathways). An actor's stance on safety typically focussed on their perception of the physical safety of milk as a substance. Some mothers and health professionals defined safety more broadly, to include the psychological safety of an infant, mother and her community, for example when considering cross-feeding:

'If you go to the Tongan families, you're never worried about the babies, because somebody would feed it. ...That baby could have got fed by any number of women in the family and that was not an issue. ...It comes back to those broad safety issues: that safety is the physical safety, the biological safety and the emotional safety of people, and that's paramount' (MW03, health professional).

When discussing risk, actors with expertise in infection control emphasised the potential microbiological risks of shared milk relative to CMF:

'Well, I think there's probably not an appreciation of the storing of the milk as a risk too...I don't have any trouble believing it's the best product.... But it's not regarded as a dangerous product, so people don't take the same care with it... I think one's got to be careful not to over-promote breast milk at the expense of some other products that are reasonably safe. Formula is not as good as breast milk from your own mother, I fully agree, ...[but] formula I suspect overall is safer than sharing breast milk, would be my view (SACT05, policy maker).

⁸³ Actors used the terms 'safety' and 'risk' interchangeably. The use of these terms indicated the actor's motivating orientation towards milk sharing, with safety denoting a positive orientation and risk a negative orientation.

However, actors working in other areas of public health were concerned that framing milk as an infectious bodily fluid, risked damaging the reputation of milk as a 'safe nutritious product' (SACT05, policy maker) and the women who produced it ('It'll all sound derogatory' SACT02, policy maker).

Health professionals with expertise in lactation described their position as intermediaries between mothers and paediatricians around questions of risk ('I have sympathy for, but concerns about, online milk sharing,' LC02). Some judged policies for the safe handling of milk as extreme ('this is madness') but necessary ('there's still risks') (LC03). Health professionals, milk banks, policy makers and many mothers understood the risk aversion⁸⁴ of institutions:

'That's the institutional response: 'Is there a risk?' The answer is yes. 'How big is the risk?' Well, it's difficult to completely quantify that, but it is a risk. Things go wrong and so you need safeguards' (SACT05, policy maker).

7.1.2 Optimal infant feeding

Motivations around optimal infant feeding included supporting breastfeeding, providing an exclusive milk diet and avoiding CMFs. Most actors in this study recognized maternal breastfeeding⁸⁵ and a mother's own milk as the 'best' way to feed infants and that donor milk promoted the importance of milk:

'Saying that we have a milk bank is an indication of how much we value the importance of breastmilk. That we, in our nursery, do not think that formula is an acceptable substitute for our most vulnerable babies' (MB01, milk bank).

In defining optimal feeding, mothers and health professionals were motivated by different guidelines for breastfeeding exclusivity and duration (discussed in Chapter 5 on legal structures). One donor wanted to help a mother with cancer reach a 12 month feeding target:

'And she was looking for donor milk to get her daughter to reach a year ...It gave me that kick to kind of really prioritise the pumping a little bit more, to try and help this woman reach one year with her child' (MVICT, donor mother).

Motivations to breastfeed

Given the importance of breastfeeding, actor motivations towards milk sharing depended on whether they believed it supported or displaced breastfeeding. Most mothers in the study believed

⁸⁴ Perceptions, assessment and management of medical, legal and business risks are discussed in Pathways.

⁸⁵ Breastfeeding only by the biological mother

that donor milk and PDHM displaced CMF, and demonstrated the benefits of milk that helped mothers 'persevere with breastfeeding' (MWAY, donor mother). This was also observed in NICUs:

'A 25 weeks, the mum can't express so we feed that baby completely [PDHM] for the whole week. And then mum's milk starts to come in and she gets ...expressing like a mad idiot and builds up quite a nice milk supply. Then ... months down the track, ...she's exhausted, ...and when a clinician turns around and says, 'It's ok, you're at 34 weeks, now we can do formula' – you've lost the breastfeeding. But if you can say, 'How about we reintroduce some more donor milk? I'll match you 50-50,' ... and I reassure her that I'll fully support her, it boosts her confidence, gives her hope, that energy that she needs to keep going, and quite often we'll get a baby going home fully breastfed' (MB05A, milk bank).

Donors and recipients saw informal milk sharing as 'more than milk,' because it was often accompanied by knowledge and relationships that supported breastfeeding (MQLDW, recipient mother):

'And my daughter was so keen on the breast, that she didn't have any issues with the supply line. ... it was amazing to have that connection, and I needed it as much as she did because I had felt like a failure previously. It really healed a lot of that stuff, and I could see, going through the experience of having so much support this time, that it was the lack of support last time where we went wrong' (MWAS, donor and recipient mother).

However, the potential of donor milk to displace breastfeeding was also acknowledged by mothers and milk banks:

'It's still a form of supplementation. So if you are using donor milk and trying to increase your supply you still need to...put in that time to pump. It can be very tempting to fall into the trap of, 'I've got access to this donor milk, so I don't need to breastfeed as often now.' Like I suppose it can absolutely threaten breastfeeding' (MVICT, donor mother).

Others thought that it was difficult for donor milk to displace feeding at the breast, but recognized situations where breastfeeding was not possible:

'In situations where a mother can't, or would prefer not to, there would be women that would choose [donor milk] over formula...issues like prior mastectomy or breast surgery or sexual abuse' (HM4HB Admin).

In NICUs, the risk of PDHM displacing a mother's own milk (MOM) was taken seriously, but it occurred when medical staff lacked adequate knowledge, facilities or time to support lactation, for

example when lactation consultant positions were lost from health system budget cuts (MB03, MB04). At a system-level, donor milk could also displace investment in wider breastfeeding policy. Some milk banks were concerned that they might be 'part of the problem rather than the solution' (MB04):

'I would hate to see money spent on making donor human milk available to absolutely everybody, without the same amount of money being spent on supporting mothers to breastfeed their own infant. That's to me the priority' (SSA1, milk bank).

Some health professionals were concerned that discussing donor milk with pregnant women might reduce their intention to breastfeed or 'pathologize' normal lactation (MW01, MW03).

In contrast to feeding donor milk in a bottle, cross-feeding was highly supportive of breastfeeding, as long as the mother was not displaced, an issue discussed further in section 7.2.4.4.

Exclusive human milk diets

The motivation to provide an exclusive milk diet for infants was central to any form of milk sharing. The value of a milk diet was based on recommendations to breastfeed and perceptions about the harms of CMF. This thesis does not explore the reasons for supplementing infants (described elsewhere, in the literature on breastfeeding). Instead, it examines what motivated the decision to use shared milk, rather than CMF, when supplementation was required. Several mothers and health professionals referred to WHO recommendations for supplementation that prioritized 'breast milk from a healthy wet-nurse or a human-milk bank' over feeding CMF (7):

'It's going back to the WHO recommendations, which is the woman's own breastmilk first, donor breastmilk second, formula third. It's just us following WHO guidelines' (MW03, health professional).

Participants justified an exclusive milk diet by referring to scientific studies of milk and its wider effects on health:

'I think that we're now learning so much more about the importance of breastmilk, and its role in more than just infant feeding, but also in support of the immune system... for humans as a species... There was that Lancet series that came out earlier in the year...and the economic impacts, as well as the health impacts, of not receiving breastmilk are huge. ...I guess now, as a mother, you think about your children's generation and your grandchildren's generation' (MVICT, donor mother).

Maintaining an exclusive milk diet was important to some donors, who selected recipients on the basis that the recipient mother did not use CMF. Other donors were less critical, knowing how hard it was to source milk (discussed further in chapter 8 on pathways) and the complex reasons for milk insufficiency (MVICT):

'I offered it to her because she was predominantly formula feeding. She had to go back to work really early –it was terrible, ... but he got at least one bottle a day of breastmilk...so that feels really special' (MWAS, donor and recipient mother).

However, the promotion of an exclusive milk diet concerned some milk banks and health professionals who thought it inadvertently diminished the value of a mother's own milk and encouraged informal milk sharing (MW03, health professional, SSA1 milk bank).

Avoiding Commercial Milk Formula

In addition to providing the benefits of milk, mothers, milk banks and some health professionals were motivated to avoid the harms of CMFs.⁸⁶

'Her little boy was premature and she had insufficient glandular tissue... so the paediatrician put him on formula, and then he would end up in hospital vomiting or having reactions to the formula because he couldn't tolerate it. So, when I found out that there's those sort of things out there, and people who really do need breast milk... that's why I was pumping, for that reason, because I can actually help, why not do it?' (MWAU, donor mother).

Another mother, who was a health professional, became a donor after her own experience of gestational diabetes and delayed lactogenesis, and use of CMF ('those three times I needed to have 30 mls'), which she attributed to her infant's multiple food allergies, confirmed by allergists and gastroenterologists (MQLDX, donor and recipient mother).

One policy maker in a government agency understood the determination of women to feed milk by telling the story of how she and several other children in her class at school in the 1960s were known as 'the children affected by the caustic soda-contaminated formula' (SVIC02).

However, some health professionals and policy makers resisted beliefs that CMF was harmful, and donor milk was always more beneficial, especially for healthy, full-term infants:

⁸⁶ Actors did not always distinguish their beliefs about the harms of infant formula, as a product, from the harms of bottle feeding, as a feeding method. This is possibly because most milk sharing involved feeding donor milk by bottle, although some mothers used supply lines to feed donor milk at the breast or cross-feeding.

'So for a term baby, by the time [PDHM] has gone through so much processing, there isn't a lot of evidence to suggest that the donor milk is much better than the formula, in terms of nutrient composition and whatever live factors are left' (SACT10, policy maker).

One mother described the polarized attitudes of medical staff towards supplementation using cross-feeding by her sister, rather than CMFs (MACTV, donor and recipient mother):

'We loved the night nurses because they just threw all the rules out the window [but] ...most of the day nurses were totally freaked out... So it was funny, all day being told that what you are doing was completely irrational and there was perfectly good formula, and then, all night being told 'This is wonderful, keep going, you're doing a great thing' ... those polar responses' (MACTV, donor and recipient mother).

The refusal of some mothers to use CMF and refusal of health professionals to consider donor milk was an unbridgeable divide in motivations, and a flashpoint for conflict and distress. To some mothers, the medical and social harms of CMFs were a 'threat,' as described by an administrator of a social media page, observing posts requesting milk by mothers on post-natal wards:

'Some of them, it was just that the baby had had a slow start, jaundice or whatever, and they needed to get more fluids through the baby. And some of them were looking for colostrum, particularly for young babies. It might have been that the mother had gestational diabetes, and so now there were questions about blood sugar levels in the baby. I guess the threat...of hospital staff delivering formula to the baby' (HM4HB Admin-MNSWY).

One recipient who refused CMF in hospital said it was an experience that eclipsed the trauma of giving birth (MACTV, recipient mother) and several donors were motivated by the extreme pressure on mothers to use CMF, when breastfeeding support was inadequate.

7.1.3 Human rights

Human rights to health, informed decision-making and autonomy were powerful, core motivations to support milk sharing for some mothers, health professionals and policy makers. These rights motivated advocacy for milk and fuelled resistance to using CMFs. Some mothers expressed an infant's right to milk as an absolute 'biological need:'

'I see it as my baby's need rather than my personal choices. I'm doing the best I can for him rather than pushing my values or my desires onto the situation... in situations like ours where I can't provide, my baby still has a right to breast milk, ...it's kind of saying, as a society it's all of our issue, caring for babies' (MVICL, recipient mother).

Access to milk was also seen as a mother's right and that it was 'unethical' not to provide it if she could not breastfeed' (SNSW01, policy maker). In addition, a woman's right to control of her body were acknowledged by mothers and some health professionals:

'When I first mentioned about donating milk, my husband was like, 'Oh yeah, but do you really think you should?' I'm like, 'Well you going to stop me?' No, it's your body, you can do what you want with it. Exactly. So, if you don't like it, there's the door' (MVICK, donor mother).

However, tensions arose in implementing infant and maternal rights to milk. One recipient mother, with insufficient glandular tissue and who was struggling to source donor milk, felt the burden of realizing her child's right to milk in a society that did little to provide it or remove barriers to breastfeeding (MVICL).

Informed, autonomous decision making

A central human rights principle in infant feeding was informed decision-making, which was valued by mothers, health professionals and milk banks. Mothers in the study wanted to be informed of the option to use donor milk, but policy and practice rarely supported this. Busy doctors in general practice were unlikely to consider donor milk unless they had a special interest in breastfeeding, and legal concerns inhibited discussion of informal milk sharing. In contrast, midwives described a 'woman-centred' approach that respected women's autonomy:

'It's really important as a midwife providing care to that woman and working with her, it's about validating her experience, validating her knowledge, it's about you've got a trusting relationship with her; if she discloses to you that she's going to get some milk, it's about having a balanced conversation' (MW03, health professional).

Views of women's autonomy also differed between social media pages for informal milk sharing. One was described as 'paternalistic-we know best' ('spoon feeding') and the other as 'women know best' ('leaving women to figure it out by themselves,' HM4HB Admin-MNSWY).

Equity in access to milk

Another human rights principle was equity of access to milk, which motivated mothers, milk banks and some health professionals. One mother in a regional area was motivated to improve access to milk (and breastfeeding support) and became an administrator of a social media page for shared milk:

'Living in [town] you become aware of the absence of services, and so it's facilitating that access... We don't have any IBCLCs⁸⁷ in private practice here. Some of the GP's knowledge is, let's put it politely, limited' (HM4HB Admin).

However, redistributing milk to population groups with low rates of breastfeeding was not described by actors. Some health professionals recognized that when they supported informal milk sharing, it was for well-resourced women:

'We have women that challenge policies, look outside the box, very well educated, often women who have done their homework. So we feel like we can fully back them up, because they're already well informed' (MW05, health professional).

In contrast, milk banks supplying PDHM to public health system NICUs supported the equitable access to donor milk, but noted that achieving this and overcoming 'a lot of gaps and a lot of inequality in access' required 'consistent national policy' (MB05B, milk bank) and policy champions:

'I honestly believe it's person dependent, ...their values and what they believe in too. The person in that position now has got extensive management experience across maternity services so can see the whole picture, not just the narrow view, and very much sees the need for pre-term babies to deserve the best start in life' (MB06, milk bank).

Advocacy and resistance

An important motivation for some actors for milk sharing was related to advocacy for breastfeeding. For example, one mother described donation as her embodied resistance to personal and societal anxiety about milk insufficiency:

'And my biggest attitude was that if I trust my body to make enough that I need, I'll always have enough, so just give it up because somebody needs it more than us... because there was always that tendency to hold some back, in case' (MWAY, donor mother).

More broadly, some mothers and health professionals supported milk sharing to resist norms for CMF use and marketing in society and institutions ('challenge establishment rules' MVICZ, donor and recipient mother). Health professionals supportive of milk sharing saw it as empowering:

⁸⁷ International Board Certified Lactation Consultant

'The reason why we're pushing for milk banks is because we know how superior it is and how protective is... and it's empowering for women, and not disempowering women, the way formula does' (MW01, health professional).

To advocate for policy change and milk banks, highly motivated champions were important, and an understanding of the institutional politics:

'I think change comes from both: women coming to us and saying we want a milk bank here, ...and passionate midwives that would really support that as well. Yeah, the two of them would be the biggest driver. Lactation consultants, ...we would definitely need to have the nursery on board, and then they need to incorporate paediatricians' (MW02, health professional).

Yet advocacy for donor milk was not sufficient. Mothers also perceived and resisted commercial interests in infant feeding. Marketing of CMF through hospitals incensed one mother who was threatened with child protection services for refusing CMF and using her friend's milk:

'There was a lot disgust about it because it was another mother's milk, ... And I had numerous nights where ...I sat there ...with the bottle (of formula) in my hand crying, about to give in. ... Like it's everywhere ...there are just cupboards full of pre-made formula. On the nurses' station out the front, there was a big pile of pre-made formula with a 'free sample' sign on the front ... and I went straight to the nurse unit manager about it, and it ended up it getting taken down the next day' (MACTW, recipient mother).

7.2 Specific motivations

In addition to the motivations that actors shared and provided common purpose, participants described motivations that were unique drivers of action for that group. For donor mothers, specific motivations were the need to manage surplus milk and their desire to help others, while milk banks were driven by the clinical requirements of NICUs to manage necrotizing enterocolitis (NEC). Health professionals were motivated by institutional demands, and policy makers needed to work within the scope of their organizations. These specific motivations could dominate other objectives or destabilize the alignment of actors around common beliefs and interests.

7.2.1 Necrotizing enterocolitis

For NICU and milk bank staff, the primary motivation to use PDHM was to reduce morbidity and mortality from necrotizing enterocolitis (NEC) and to improve feed tolerance, issues associated with use of infant CMF in extremely low birthweight premature infants.⁸⁸

'I've nursed babies to their death before from NEC. It's not nice, it's terrible. And watching them go and have gut surgery, long years of maintenance' (MB06, milk bank).

For one milk bank, the use of donor milk decreased the risk of NEC from 5-10% to 2-3% in their affiliated NICU (MB04, milk bank). Avoiding the high costs of surgical NEC drove the acceptance of milk banks in the health system:

'And if you look at a surgical case of NEC it's probably up around the \$300,000 mark now in Australia, including the surgery and doing the re-anastomosis afterwards, so they don't have short gut syndrome and there's the neurological deficits...' (MB05B, milk bank).

The efficacy of PDHM for other medical conditions of premature infants⁸⁹ was more contentious. Use of PDHM for infants older than 33 weeks gestation was decided on a case-by-case basis, as supplies permitted. However, there was evidence of greater acceptance of broader clinical uses of PDHM. One milk bank thought that 'the vast majority of babies in NICUs would get donor milk if it was there' (MB05A).

7.2.2 Human milk-derived fortifiers and products

At the time of this study, human-derived milk fortifiers were not available in Australia.⁹⁰ However, participants mentioned three overseas manufacturers as potential importers, of which one had contacted many Australian NICUs, milk banks and policy makers:

'There is human milk fortifier from the States called Prolacta and the person from that company has come out to give us an in-service and our neonatologist is very interested ...it's very expensive... There's different products, some will have a certain amount of extra protein.... The rep said that [Hospital] were considering using it. ...This rep was trying to get the authority from each state... to get it all around Australia (MB06, milk bank).

⁸⁸ (333)

⁸⁹ For example bronchopulmonary dysplasia, retinopathy of premature infants or late onset sepsis (689, 690).

⁹⁰ Human-derive milk fortifiers were developed to further reduce the risk of NEC and improve the growth rates of premature infants while maintaining an exclusive milk diet of MOM and/or PDHM.

The cost (\$9000 per litre) and regulatory challenges of these products motivated government agencies and researchers to prioritize them to the exclusion of other milk sharing issues:

'We want to try and prioritize research, but the human milk fortifier is the top one. But then looking at different methods of pasteurization is huge –if you look at health economics and benefits. Or do you look at other cohorts that you could be feeding? ...Lots and lots and lots of potential research' (MB05B, milk bank).

These developments had implications for the commercial expansion and governance of donor milk but was little discussed, although some participants were concerned that an emerging 'industry around donor milk' might divert milk from infant feeding (LC03, health professional; MB04, milk bank).

7.2.3 Surplus milk

Milk sharing was also motivated by surplus milk, a 'supply-side' factor, driven by motivations to accumulate milk and not waste it. Women's motivations for storing milk were personal, technological, and structural, for example to enable work and study:

'When she was about three or four months old, my partner got laid off from work, so I had to return to work a lot quicker than I expected. ...But because I was working only casually at that point, there were days when I would be at home and I didn't want my supply to drop off. So, I made sure I was definitely pumping more than she needed' (MVICY, donor mother).

A large part of milk sharing was opportunistic. Stored milk became 'surplus' if it approached its 'use by' date or freezer capacity, for example near Christmas (MB03):

'They'll often contact me and say, 'Hey I've got the Crisco hamper coming, so I need to clear my freezer'' (MQLDY, recipient mother).

One recipient of milk from over 80 women summarized how surplus milk was generated in three ways:

'There's the ones that have the oversupply, and they pump because otherwise they would be in agony, and would be getting mastitis all the time, ...They're just incredible, they could 'feed an army' kind of mums. And then there's a group that are just altruistic, they literally pump for the sake of donating... and they might get 100mls a day in total, and they're just doing it for the pure reason that they want to help out some other mums. And then there's the premmie mums, that's the third group ...they have a normal supply, but their babies only have one or two mls a feed, so they've got freezers full' (MVICR, recipient mother).

Milk was donated because it was valued, for its biophysical properties and social meanings. These meanings included the work of pumping milk and concepts of its ownership by the mother, her infant or community (MB02, SSA01). Milk banks, respected these meanings,⁹¹ and avoided a 'hard sell:'

'A couple of times, when they've rung us and can't do it [donate] and we've just gone 'That's perfectly okay, it's your milk, it's your decision'.... they're blown away - they thought they would get a hard sell. And I say, 'That's perfectly okay, that's your baby's milk' (MB05B, milk bank).

The meaning of milk was indicated by the language used for its handling and disposal. Mothers described milk as a 'precious food' and regretted tipping their milk 'down the sink:'

'I certainly wanted to get that milk to a place where it would actually be used by a baby. Without the milk bank, the nurse pretty much said that it just needs to go down the sink. ...So the idea of just pouring it down the sink really offended me because I'd gone to so much effort to express that and ...my husband had to take an extra two weeks off work to be at home to help us' (MACTX, donor mother).

In contrast, in some health settings, milk was disposed of as biological waste ('throwing it in the bin' LC03, health professional). Disrespect of milk or wasting it risked the reputations of recipient mothers and milk banks (EOF Admin-MVICQ). Two donors to milk banks switched to the informal sector because they were disillusioned that PDHM beyond its expiry date for NICU use was discarded, rather than used for less vulnerable infants.

The personal meanings of milk could include the donor's body or identity:

'I was seeing it as everything... life, precious life blood. ...And its personal, yes, for sure. And whilst it might have been relatively simple for me to express compared to friends, I'm not just opening a... beer or something. Like it's expressed from my body' (MVICZ, donor mother).

This donor described feeling 'violated' or uncomfortable at the thought of her milk being mishandled or given to people she didn't trust. Others were more prosaic:

⁹¹ Especially for donors whose infant had died, which some milk banks accepted.

'As long as you're upfront about what you want to do with it ...a mum might be really happy to, rather than throw it out, give it for a milk bath or cream or whatever' (MVICW, donor mother).

However, surplus milk, and milk sharing could also be motivated by negative experiences, and infused with distress. Half the mothers in this study reported unrelenting painful latching of infants ('tongue tie') that contributed to low milk supply or reliance on pumping and battling medical controversy about this condition (being told to 'put up with the pain' MVICK, donor mother). One mother described her efforts to obtain treatment for her infant's latching problem for six months, over which period she donated 43 litres of milk to 20 mothers.

7.2.4 Helping

A specific motivation of milk donors was their motivation to help others. Donor motivations to help were part of their identity, defining them as social beings rather a 'milk factory,' and they saw their acts of milk sharing as relational or moral rather than simply the exchange of a product:

'I wouldn't drive past a car accident. I wouldn't leave a mother struggling at 2 o'clock in the morning unable to feed her baby' (MWAW, donor mother).

Donors described how wanting to help came from an understanding of the difficulties faced by breastfeeding women ('knowing how hard it was' MVICT, donor mother), and personal or social norms for volunteering.

In my research, the main reasons mothers gave for donation were: care for another mother or family (79%); 'baby factors' (69%); returning to work (67%); as part of parenting advice (52%); helping their community (38%); baby-sitting arrangements (33%) and unplanned separations or household emergencies, including hospitalization (23%). For many donors, the focus of their help was the infant, described by some as 'visceral' ('I just want to feed all the babies,' MVICM, donor and recipient mother). These situations included a wide range of infant and maternal conditions,⁹² and the youngest infants were prioritized. Milk banks and health professionals recognized the strength of emotional responses to premature infants that mobilized 'public opinion' to donate milk (MW03, health professional).

⁹² These included infant prematurity, cardiac surgery, latch problems ('tongue tie'), and allergies to CMF and medical indications for supplementation, for example very high birthweight, risk of hypoglycaemia, jaundice, exceeding clinical thresholds for neonatal weight loss or reduced urinary output. Maternal conditions included short-term breastfeeding problems, (including delays in the second stage of lactogenesis from gestational diabetes, obstetric interventions and caesarean birth, and nipple trauma), and long-term limits to milk production (cancer, insufficient glandular tissue, breast surgery, endocrine disorders, sometimes associated with assisted reproduction).

However, some donors provided milk to older infants:

'Well, when I had so much milk, I thought, 'Yeah we'll help all the premature babies.' But then I felt good about Human Milk for Human Babies because the milk bank is for a lot of the smaller babies, and the older babies are a couple of months old don't receive that. So a lot of people have to resort to formula then, and they really don't want to. So this was kind of helping babies who are a little bit older stay on breastmilk' (MWAU, donor mother).

Donors were highly responsive to tragic events. One participant joined a group of about 30 women who supplied milk for eight months to an infant whose mother had died (MVICP, donor mother). Some donors were motivated because they empathised with a recipient mother's desperation and disappointment at not being able to fully breastfeed, or wanted to alleviate her stress:

'I found it personally really sad reading these stories about women who had been breastfeeding their babies and then weren't able to anymore, and the fact that they then went out to ask for milk. I thought okay, well, I won't need any more than that. For me, the fact that you need it and you're asking for it is good enough' (MACTX, donor mother).

All actors, from mothers to policy makers, responded to a recipient's powerful 'backstory', which helped sustain donation or advocacy. However, several donors and recipients expressed concern about the 'marketing' power of these stories over the principle of equity to access milk:

'The cancer card is quite powerful, a young woman with cancer, and I don't like that. I hate that. ... I don't want to be deemed the most deserving when everyone should have breastmilk for their babies' (MVICR, recipient mother).

Other donors were less interested in the backstory, and were simply 'happy to help' (MVICT, donor mother), taking a mother's need 'at face value' (MACTX, donor mother):

'Even if they couldn't get enough milk to go out for a night. Like it didn't bother me if they took milk for that reason. They wanted milk and that's all that mattered to me' (MWAU, donor mother).

Close relationships

A donor's impulse to help was strongest when the recipient was a relative or friend. Informal milk sharing with family and close friends gave some mothers the confidence to donate to strangers:

'Well (relative) was a no-brainer – she's family, (friend)... was in my life, so I think that awareness, knowing that I could help. They were the first two donations that I made... And

now that I'm comfortable, the confidence is there, and... I'm prepared to donate' (MWAW, donor mother).

Motivations to share milk were reinforced by the development of friendships between mothers or bonds between the donor mother and recipient infant. These 'relational aspects' were removed by anonymous donation to milk banks ('formalizing things'):

'I guess that relational aspect is pretty special. So that's why I see formalising things could be a lot of benefit, but it could also lose some things along the way as well' (MWAR, recipient mother).

Collective purpose

The motivation to help was underpinned by cultures of volunteering and donation learnt through families and communities, including experience of donating blood or other tissues. For some mothers, helping arose from a sense of solidarity with mothers or was part of the normal support they provided to each other. Others reported strong cultures of helping in face-to-face or online social groups interested in 'natural' or 'gentle'-parenting' and cohesive geographic communities:

'If anyone needs anything, if something goes wrong, you can just put the call out and people will come and help. And whether that's dropping off meals, or bringing donor milk, or whatever it is... there's a very supportive community, geographically defined by the hills' (MVICU, donor and recipient mother)

However, community expectations could also burden recipients. The collective provision of help was also bounded. One administrator of a social media page for informal milk sharing summarized the intention of users to 'look after each other' rather than 'change the world':

'It seems to be quite benevolent, we're all humans, let's look after each other, kind of response... supportive is probably the tone of the community. It's not each person looking after their own interests first [but] I'm not sure that they're doing it from a ...whole society perspective. I think it's more about helping another mother or another baby who is in need. They're not looking at it as a macro 'let's change the world' kind of thing' (HM4HB Admin).

Reciprocity

Deeply felt experiences of being helped or receiving kindness at a time of vulnerability, for example a life-threatening event during pregnancy, were powerful motivations to 'give back' or 'pay it forward' through milk donation, and these mothers engaged in milk sharing as a form of reciprocity. These experiences added to the emotional intensity and meaning of milk sharing. Milk banks and donors

proudly reported that some recipients later become donors. Six mothers in the study (13%)⁹³ linked their milk sharing to assisted reproduction, which sensitized them to the effects of milk donation on maternal identity:

'I have been at the lowest low thinking that I wasn't going to be able to produce my own eggs... there is no further rock-bottom that I could've gone. ...And because we knew what it would be like to receive, for us, it was an easy thing to be able to donate. And I had said to my husband 'If I could donate my eggs, I would, but I can't. So if I can't donate my eggs, I'd gladly donate milk. I can't start the process. I'll certainly be there at the end'' (MWAW, donor mother).

Cross-feeding

Motivations to cross-feed differed from those for sharing expressed milk and centred on the need to soothe a baby, in addition to providing nutrition:

'She was going to uni a day a week, for about three hours, and so while she was away I'd just feed (friend's baby) as well, which was an easier way of keeping her calm, because she was a bit of a nervous bub, a bit anxious' (MACTR, donor and recipient mother).

Recipient mothers acknowledged the nurturing care provided by cross-feeding as 'so much more than just the milk' (MACTW, recipient mother). The closeness, affection and bonding of cross-feeding was a bonus for some recipients but a concern for others:

'I do have one or two women who have said 'I'm more than happy to feed her for you if you want,' but that makes me feel, I guess, diminished as a mother -that I can't feed her. So if she took the bottle, I'd prefer to do that with her ... rather than have that bond go to someone else' (MACTY, recipient mother).

For this reason, cross-feeding tended to occur between close family members and friends. Three mothers in the study cross-fed reciprocally, arrangements that were valued for their overall convenience. A particular, and less recognised, motivation to cross-feed was to diagnose or train an infant with a problem latching, as described by three mothers and a lactation consultant:

'And then the other doctor came and he was like 'Oh yeah, it's a small tongue-tie but we'll snip it.' And then after the snip, I was feeding him and he said 'How does it feel?' And I said

⁹³ Milk sharing occurred in the lactation that followed IVF treatment for one donor and one recipient mother. Two donors provided milk to infants born through surrogacy. Another rejected a request for milk by an adopting mother through a surrogacy arrangement as too 'entitled.'

'Oh, it feels much better, it's like breastfeeding my nephew.' And he's like, 'Oh you've fed other babies?' And I was like 'Oh yeah'. And he was like 'Oh so you *knew* there was something wrong?' And it was just interesting that he thought that was significant... where the other paediatrician had just thought... I was cracked in the head' (MACTV, donor and recipient mother).

These examples illustrate that the specific motivations of mothers were contextualized, and often highly aligned between donor and recipients, in which the desire to manage surplus milk met a wide range of reasons for needing milk, anchored by common beliefs about infant nutrition and safety (Table 9).

7.2.5 Other policy objectives

Removed from the motivations of mothers to help, were the motivations of policy makers that were outside infant feeding, to do with trade, risk or requirements to operate within their organization's objectives, legal scope and resources:

'This idea that the overall policy objective is to promote breastfeeding is not an objective of (the organization). ...I am not aware that promoting breastfeeding is within our domain of issues for consideration. It would be if it appeared in a Ministerial Policy Guideline' (NZ01, policy maker).

The potential importation of milk was a primary focus of federal policy makers ('There's certainly a lot of interest in this stuff being brought in' (SACT12, policy maker), but they were highly restricted by international rules of trade ('We are a member of the WTO and so you can't stop trade' SACT11, policy maker). In addition, government policy makers had to consider the 'case for regulation' and adhere to standards of policy development, or grapple with complex problems associated outside current frameworks, for example, ethical concerns arising from paid donation:

'The donors are paid for it overseas, it's potentially surrogates who have found another product to sell... that's happening in some countries apparently. In America, certainly, the donors are paid, but I can't tell you the circumstances of the donors. I think we heard that in Cambodia the practice had been banned because it was too exploitative... So there are all those ethical issues that sit behind it, which cannot be accommodated in the food regulatory system' (SDOH01, policy maker).

Several government policy makers described their agencies as reactive rather than proactive, and not motivated to take action or seek policy alternatives without a crisis: 'Until you have a dead body

nothing happens' (SACT05), 'a national security incident,' 'war time' or negative public opinion –a media 'blow up' (SACT11).

Other actors described being motivated by windows of opportunity. In one jurisdiction, a pilot program for a milk bank enabled several eligible NICUs to 'jump on board' and build consensus for policy on PDHM (MB06, milk bank). However, for resource-strapped NGOs, milk sharing was down their list of priorities.

7.3 Broader motivating concepts

The common and specific motivations of actors about milk sharing described above were underpinned by broader societal concepts (Figure 6). These concepts included sociological ideas about gender and motherhood that intersected with philosophical and political economic ideas about individualism and systems of knowledge that are privileged in the health system.

7.3.1 Gendered norms and motherhood

Participants who understood the importance of breastfeeding to maternal identity understood the depth of mothers' motivations to share milk, as described in the literature review (chapter 2) (371, 457, 474, 691-697).

All actors associated motherhood with responsibility and innate concern for the nutrition, nurture and protection of infants and social virtues of care, generosity and self-sacrifice necessary for donation:

'I saw an article saying, 'If formula disappeared tomorrow, ten to fifteen percent of babies in the country would starve to death.' And I'm like, well no, that is not true... mothers would step up and make sure that their neighbour's baby was not starving, if that's what it took. And that's what groups like Human Milk for Human Babies show' (MWAZ, donor and recipient mother).

To mothers who shared milk informally, breastfeeding mothers were seen as trustworthy because they were motivated for the 'right' reasons:

'I think there's an understanding that you're feeding your own baby, ... and therefore would not be wanting to feed a baby if she [the mother] was sick.... So I guess there's this trust that the women who are donating milk are doing so for the right reasons, and not the wrong reasons' (MVICT, donor mother).

These meanings meant that most mothers, lactation consultants and midwives understood breastfeeding as relational and emotional, and recognized a mother's inability to breastfeed as a source of grief and challenge to her identity:

'The devastation for me of not being able to do what I thought would just come so naturally. It definitely eased the pain knowing that they were still getting breastmilk, which was my plan from day one, it definitely helped alleviate some of that' (MVICV, recipient mother).

Actors sympathetic to milk sharing understood the difficulties of breastfeeding for a range of individual, institutional and structural reasons. Several health professionals agreed that society 'sets women up for failure' and shames them (MW03, health professional). Milk insufficiency was often associated with complicated labour and obstetric intervention, which one mother described as a 'double whammy' of failure 'stamped across your forehead and you're not a mum' (MWAW, donor mother). For many recipient mothers, this shame was intensified by labelling slow infant weight gain as 'failure to thrive' (MACTY, recipient mother; MACTU, donor and recipient mother; MACTR, donor mother). However, when these mothers turned to milk sharing, they received extremely mixed messages that could reproduce or disrupt gender norms:

'It's considered a body fluid, and it's from breasts, and breasts are sexual, and that's 'icky'... that's what I think society says' (MQLDX, donor and recipient mother).

Patriarchal power in the health system was also seen by some mothers as the cause of 'fearmongering' about the disease risks of informal sharing ('Empowered women are a bit dangerous and a bit scary, loose cannons' MWAS, recipient mother). Societal and institutional norms, including in milk banking, also created expectations that women were compliant. In contrast, women who shared milk informally defied medical authority and family members and peers who fed CMFs. In addition, when these mothers tried to investigate the causes of lactation insufficiency, they encountered institutional indifference:

'So on this international Low Milk Supply Group, ... it's common all over the world. And when they do the blood tests ...and they compare it to the levels for lactating women, they find out that they've got Hashimoto's, hyperthyroid issues, polycystic ovary syndrome, or a lot of us are insulin resistant, ...I went to an endocrinologist, thinking that this would be amazing, from a physiological point of view, ...and she just said, 'Oh it's not really my area. I'm not interested.' Yeah, it's dismissed' (MQLDW, recipient mother).

Despite these barriers, for many recipients, informal milk sharing was transformative, and liberated them from constructs of maternal identity based on guilt and shame (examined further in the chapter on Rewards):

'I realised how far I'd come, that I could ask her to feed my baby... this actually wasn't a challenge to my capabilities, and I was enough of a mother, enough of a woman. ...I am good enough. This was about community, and this was about my baby's immediate needs. ...And then ...breastfeeding suddenly became this global thing. There really is no difference between person A, feeding person B's baby, you know, we are all just mothers... we all need to support each other... and in that moment I could not separate it, we're all just in it together' (MWAS, donor and recipient mother).

7.3.2 Individualism

The communal impulse and embodied drivers behind milk sharing, described in this chapter, were at odds with Western ideas about individualism, and knowledge systems that neglected the experiences of mothers.

Donor and recipient mothers were motivated by ideas that challenged individualistic and market-based concepts of society, shown by their intentions to act in solidarity with other mothers, recognize rights to milk, or protest institutional failures to protect and support breastfeeding. These personal motivations were driven by realizations of interdependence and distributed care that were scaled-up through social media pages and milk banks. Consequently, milk sharing disrupted neoliberal concepts of isolated, self-sufficient motherhood embedded in consumerist society and policy for 'maternal breastfeeding'.

However, in its current form in Australia, milk sharing's collective principles were not directed to address systemic problems in infant feeding. In navigating the tensions between collective and individualistic impulses, many mothers and health professionals were motivated to act locally, within their span of control or agency. In these small-scale, personal interactions, mothers resisted being framed as mere producers and consumers of a commodity:

'Everyone that donates is a willing participant, they want to... They're not a cow, they're a human, and it's been given with love. And a lot of women... they're just like, 'Yeah, you it need for your baby, that's fine, I'll sit and pump every day for you'' (MWAX, recipient mother).

7.3.3 Knowledge systems

Actor motivations towards milk sharing were underpinned by contrasting systems of scientific and experiential knowledge. Published scientific evidence was used to justify positions on milk sharing by milk banks, health professionals, policy makers and many mothers. However, as outlined in the literature review (chapter 2), the way this evidence shaped views of milk as a product, rather than milk sharing processes, created divisions between actors. In these debates, milk banks and policy makers dominated. They set standards of evidence and political and research agendas that focused on PDHM. Milk banks sought evidence of the efficacy of donor milk as a therapeutic product in a highly medicalized setting, rather than evidence that supported harm minimization approaches to informal milk sharing, or societal goals for breastfeeding (MB04, milk bank).

However, quantitative evidence to support the use of PDHM in NICUs needed to be appropriate to local contexts. One milk bank participant described the evidence supporting the use of PDHM in Australia as 'scant' (MB03), when adjusted for local low rates of NEC (5-10%) compared with the USA (20-25%) (MB04). However, this evidence was difficult to obtain in NICUs because of confounding, for example from probiotics or lactation support, and ethical barriers:

'Human milk is always going to be better than formula ...but the evidence base for donor milk, to be honest, is pretty old. You'll never be able to do those studies again where you randomise something to formula or donor milk. So you're going to have to accept the evidence is there and move on' (MB03, milk bank).

However, explaining the absence of evidence for the use of PDHM in the community was contentious and interpreted as not supporting breastfeeding (MB03, milk bank). One mother described losing her motivation to donate milk after she talked with 'quite a number of obstetricians, paediatricians and general practitioners' who questioned the value of exclusive milk diets (MVICN, donor mother). These misunderstandings about motivations inhibited public engagement by milk banks and contributed to uncertainty about their role in breastfeeding policy (MB04, milk bank). In turn, a lack of policy and public funding for milk banks and research left this sector increasingly reliant on private sources of funding, with implications for the independence of evidence:

'The bucket's getting smaller just means there'll be more industry-funded research, which means it will be potentially more compromised' (MB01, milk bank).

Arguably, biomedical knowledge about milk and milk sharing was inextricably linked to ideas about gender that discriminated against women and lactation. As shown in this chapter, women in this study found their physical, emotional and social selves dismissed and omitted in research and

evidence on lactation and endocrine health. Similarly, milk banks described how emotion around the topic of lactation was deemed a barrier to the objectivity necessary for clinical, research and funding decisions, with one male milk bank participant observing the advantage of being perceived as free of the emotional bias towards milk that others attributed to female colleagues (MB04, milk bank).

7.4 Summary of analysis of motivations

7.4.1 How motivations regulated milk sharing

This chapter described the multiple biological drivers, policies, and social ideas that motivated actors, and explained their positions on milk sharing. The common motivations of actors were aligned around providing a safe, exclusive milk diet for infants, but actors diverged in their perceptions of donor milk's risk and efficacy relative to CMFs, and their effects on breastfeeding (Table 9). The motivations of mothers, health professionals and milk banks were also shaped by deeper motivating principles about human rights. Motivations specific to donor mothers were pragmatic and relational (to manage surplus milk and help others). In contrast, most milk banks were driven by medical objectives and evidence that focussed on milk as a product. Health professionals had to contend with conflicting motives and judge their appropriateness in different settings. Policy makers faced other challenges, to meet organizational objectives outside these core concerns.

Motivations regulated milk sharing in functional and symbolic ways. For some actors, dissonance and complexity in objectives led to paralysis, and signalled a broken infant feeding system. To others, motivations to share milk indicated a functional social system, that offered collective approaches to problems in infant feeding that arose from individualized motherhood and infant care. Actors often had to find 'like-minded' allies and sound each other out.

When motivations were aligned between actors, for example between mothers, milk banks and health professionals, their milk sharing activities were legitimized, and there was trust, a common purpose and will. Aligned motivations between actors enabled coalition-building and the potential for change at the system level. My research agrees with (218, 307), and shows that passionate, motivated champions were also important, combined with an understanding of commercial interests in CMFs in the health system.

From a regulatory perspective, the motivations of actors, and whether they were aligned or in conflict, set up patterns of compliance and defiance across the regulatory regime. Where motivations are not aligned, distrust could occur and motivational postures between actor groups had potential to become hostile or defiant and encourage 'game playing' (covert behaviour) (698). Moral imperatives to breastfeed that were not supported in practice motivated informal milk sharing.

Breastfeeding difficulties were structured by deeper problems: gendered power relations in the health system and the systems of knowledge that neglected research on lactation. On the other hand, gender was not wholly oppressive: mothers identified biology and gender as the wellspring of their power and motivation to provide milk, help and find pragmatic solutions in solidarity with other mothers.

However, there was more to motivations than a supply of milk. The meaning of milk was intimately tied to the meaning of breastfeeding to mothers. Without this understanding, milk banks, health professionals and policy makers struggled to grasp the deeper social drivers of 'surplus' milk and demand, and their connection with breastfeeding. The analysis of motivations revealed structures of power around milk, based on gender and world views about individualism and systems of knowledge. Actors removed from these philosophical and political motivations failed to appreciate why mothers and some health professionals shared milk outside policy guidelines. Understanding these power structures and their motivating interests was essential to understanding how the regulatory regime for milk sharing shaped breastfeeding.

7.4.2 How motivations for milk sharing affected breastfeeding

What effects did these aligned and conflicting ideas, meanings and alliances for milk sharing have on breastfeeding? Actor motivations were critical to breastfeeding. Unless actors upheld breastfeeding as the primary objective, other motivations undermined breastfeeding or diverted actors to objectives that could displace it. The intention to provide an exclusive milk diet potentially promoted breastfeeding, but unless actors prioritized breastfeeding and understood the need for lactation support, an exclusive milk diet was seen as equivalent to breastfeeding or created dependence on donor milk and its commercialization.

Motivations explained some of the institutional failures to support breastfeeding and the experiences of women. Dissonance about the risks of milk and milk sharing also potentially framed breastfeeding as unsafe, and promoted medicalized approaches to infant feeding, and distrust of women's embodied knowledge, which sabotages breastfeeding. A deeper lack of alignment of motivations across the regulatory regime for milk sharing allowed actors to pursue narrow goals, concerned with milk banking, research, the commercialization of milk or international trade without heed to their implications for breastfeeding.

Importantly, some mothers, health professionals and policy makers understood that a lack of alignment around public health interests in breastfeeding led to failures to protect breastfeeding from CMF marketing, and left donor milk unable to compete with commercial interests in CMFs. The misalignment of actor objectives in infant feeding also opened gaps for financial incentives for milk

banks and milk products, and by allowing this, regulators had 'created a monster' (MW03, health professional).

Overall, the misalignment of motivations between actors ill-equipped Australia's regulatory regime to handle some of the complex clinical and moral judgements necessary to handle commercial interests. When motivations conflict, those of mothers matter, because they can act 'beyond the state' and ultimately control the production and allocation of milk. The next chapter on pathways examines how these complex ideas combined with and social and material factors to enable or constrain milk sharing in practice.

Chapter 8. Results: Actor pathways for milk sharing

Chapter 8 presents findings from the interviews about the 'possible courses of action' or pathways for milk sharing available to mothers, milk banks, health professionals and policy makers. Pathways include 'practical solutions, technologies and processes' and 'mind-sets' that constrain or enable milk sharing (219). Actor pathways were shaped by three broad factors: resources, rules and mindsets (summarised in Table 10). Resources affected the capacity of mothers and milk banks to supply and manage donor milk. Rules concerned the distribution of milk, costs and management of potential harms. Actors engaged with these resources and rules according to overarching mind-sets, often guided by risk and requirements for pragmatism and efficiency in infant feeding.

8.1 Pathways -resources

8.1.1 Supply of milk

A fundamental, but often overlooked, resource that was essential for any milk sharing pathway was a supply of donor milk. This resource was critical for mothers and milk banks, who linked the potential demand for donor milk to inadequate rates of breastfeeding in the wider community:

'I don't know that there will ever be enough breastmilk to go around, but right here and now there isn't, and so we have to prioritise. And once every baby that's an in-patient is fully breastfed then I'll start thinking about the community babies. But we're a long way off that' (MB05A, milk bank).

Others expressed little concern about the overall supply of milk because of the willingness of women to donate milk ('They just come out of the woodwork' MB02, milk bank; 'We have had over 2000 inquiries from women who just want to be part of it' MB05B, milk bank).

Policy makers distanced themselves from the issue of milk supply, including from overseas, as beyond their scope and an issue for the 'market:'

'The Biosecurity Act and Imported Food Control Act are not about stopping things coming into the country. That's not for us to assess... All of those things are commercial decisions made by the entrepreneurs who decide that there is demand, a market' (SACT11 and 13, policy makers).

Confidence in the supply of donor milk to milk banks was based on the restricted usage of PDHM by a finite number of premature infants who required small volumes:

'There's six milk banks now and 25 NICUs. ...There are more than 3600 prem babies born every year that are under 32 weeks ...that do not have access to donor human milk. ... We have done a lot of work [on] the demands and the actual usages of the NICUs with donor milk... supply has not been an issue' (MB05B, milk bank).

However, supplies of PDHM were perceived to be scarce, for several reasons: allocation, cost (discussed further below) and 'wastage,' when milk reached its expiry date, failed to meet test standards or was difficult to dispense:

'If a baby's ...500 grams, really tiny, might be getting 1 or 2 mls, ...The smallest [bottle] we get is 30 mls... and then you throw the rest of it out, because you can't keep that. And then human milk fortifier, makes it go frothy ...so we have to have a little bit extra to cope with that. ...Another source of wastage ...[is] the expiry. [The milk bank] will only hold milk for 12 weeks, in which case they ditch it. So there's ...more wastage than use probably' (SSA01, milk bank).

Milk banks did not perceive that they competed for supplies of milk with other milk banks or the informal sector, and that they serviced different groups with different products (market segmentation):

'When the new donors were ringing, we were saying 'Look we are currently at capacity, ... have you considered informal milk sharing?' ...So we make sure that we are not just collecting every single drop.' (MB05B, milk bank).

One milk bank thought that competition for the supply of milk was a lesser concern in Australia than it was overseas, and that a relationship with informal milk sharing needed to be worked out.

As milk banking expanded, some milk banks saw that their structures influenced supply:

'We're not doing it to take anybody's business. We're doing it because we can and because the need's there ...Ultimately [it] will probably be something like a hub-and-spoke model, where some of the bigger centres will be collecting sites for us, send us donor milk we then pasteurize and have a sort of a two-way' (MB03, milk bank).

Chapter 8 Results - Pathways

Table 10 Pathways to milk sharing for four actor groups and how they were shaped by resources, rules and mind-sets, and their effects on breastfeeding.

		Actor groups			
		Mothers	Milk Banks	Health Professionals	Policy Makers
Resources	<i>Supply of milk</i>	Donor milk supply and reliability	Recruiting donors, NICU stores of milk	Knowing patients with surplus milk	Importation
	<i>Maternal time</i>	Time to produce, manage and share milk, ensure safety.	Time of donors to attend milk bank, screening and testing.	-	Public investment in Paid Parental Leave.
	<i>Equipment, social media and logistics</i>	Breast pumps, freezers. Social media. Private car.	Facility and equipment, Tracing system, pathology services. Transport and cold chains.	Limited role in handling donor milk.	-
	<i>Human resources and relationships</i>	Breastfeeding knowledge, social networks, relationships and sympathetic health professionals. Mothers lack of power in health settings.	Staff with expertise in lactation, infection control and food safety. No milk banking association. Ad hoc champions and alliances.	Gatekeeper role. Knowledge of lactation. Limited alliances.	Policy makers consult with milk banks and health professionals. Mothers rarely consulted.
Rules	<i>Allocation of milk</i>	Donor allocation to milk banks or mothers in community (various criteria)	Doctors allocate PDHM on medical criteria. Limited allocation to public.	PDHM allocated on medical criteria. Directed donation protocol limited. Knowing recipient mothers.	Policies for PDHM allocation. Position statements on informal milk sharing.
	<i>Access to milk</i>	Restricted access to PDHM. Requests for milk, including via social media. Restricted donor access to milk banks. Religious or cultural rules (e.g. kinship).	Regulatory barriers to milk bank establishment and operation.	Policies vary for PDHM, or prohibit or omit donor milk	No national policy. Health service and NGO policy on access to PDHM and donor milk varies.
	<i>Costs</i>	Altruistic donation.	Establishment and operational costs. Cost recovery of PDHM from health system. (or families if supplied to public).	Salaried positions.	Cost of policy development. Lack of health system budgets for milk banks and lactation support.
	Managing risks and harms				
	<i>Ethics: consent and privacy</i>	Consent implied. Donors and recipients known. Laws and norms for privacy.	Laws for informed consent and privacy, anonymous donation. Research ethics.	Policies for informed consent and privacy. Limited options for donor milk Consent for PDHM and CMFs inconsistent.	-
	<i>Legal liability</i>	Untested	Legal liability. Business and reputational risks.	Legal liability. Hospital waivers.	Legal and business risks.
	<i>Safety</i>	Antenatal care. Limited additional blood testing. Donor screening by recipients. Hygienic milk management.	Operational guidelines for milk banks.	Directed donation protocols. Limited use of guidelines for health professionals.	Public health and maternity care. Warnings about informal milk sharing.
Mind-sets	<i>Principles for efficiency, pragmatism and risk</i>	'Low-hanging fruit' - community settings 'Can-do' - health settings	'Can-do'	'Avoiding trouble'	'Avoiding trouble' or 'Low-hanging fruit'

Chapter 8 Results - Pathways

	Actor groups			
	Mothers	Milk Banks	Health Professionals	Policy Makers
How actor pathways for milk sharing affected breastfeeding				
<i>Direct effects on breastfeeding</i>	Maternal resources, relationships and rules connect informal milk sharing to breastfeeding knowledge and support. Pathways for milk sharing that empower breastfeeding mothers support breastfeeding.	Milk banking removes connection to breastfeeding mothers. PDHM displaces breastfeeding without lactation support from health professionals. Mothers poorly represented in milk banking governance. Milk banking interests and governance not integrated with national breastfeeding objectives.	Health professional pathways to facilitate milk sharing constrained. Health professionals lack breastfeeding education and agency in institutions to enable milk sharing that supports breastfeeding.	Policies create business risks, regulatory and cost burdens for donor milk. Policy does not integrate informal milk sharing, milk banking or trade with breastfeeding. Policies for milk sharing and importation displace or distract from investment in breastfeeding. Policymaking process disempowers breastfeeding mothers.
<i>Effects on competition between breastfeeding and CMFs</i>	Maternal pathways support breastfeeding and displace CMFs, but do not address structural barriers to breastfeeding.	PDHM helps displace CMFs in NICUs, but milk banking does not address structural barriers to breastfeeding.	Support for PDHM displaces CMF in NICUs. Outside NICUs, health professionals must support CMFs, entrenching structural barriers to breastfeeding.	Regulation of donor milk frames milk as dangerous bodily fluid and breastfeeding as unsafe compared to CMFs. Regulatory burdens disadvantage donor milk compared to CMFs. Governance of infant feeding does not address commercial power in CMFs or milk, and neglects breastfeeding.

These centralized models of milk banking raised issues about local rights to supplies of milk and its ownership ('Our' milk doesn't go anywhere else, and we don't get milk from anywhere else' SSA01, milk bank). One milk bank tried to ensure that the supply of PDHM encouraged local milk supply:

'Now we have a five-year contract to provide for the [other region]... [and] we've asked for them to be able to reciprocate. Because if we're providing milk, we ask for local community mothers to give back to us as an exchange ...so you get local mothers supporting local families' (MB02, milk bank).

In contrast, in the community, perceptions of milk supply varied. Recipient mothers were often stressed about finding reliable supplies of milk, but an administrator of a social media page dedicated to informal milk sharing thought that there were more donors than mothers seeking milk ('We never seemed to have a shortage of people offering milk' MNSWY_HM4HB Admin, policy maker). Many recipient mothers only required small supplies to bridge an early, temporary breastfeeding problem. In contrast, older full-term infants fed exclusively on donor milk sometimes required more than a litre of milk per day, requiring a supply network of over 40 women.

A mother's demand for and supply of donor milk also shifted with geographic and structural factors, including workplace conditions (shift work, on call, and needing to pump in a work vehicle):

'We were in [regional town] for my placement, so there was no one in the area that could help. ...And then once we came back to [city], I started working...more than full time ...so I just can't pump enough milk. And we just happened to find someone on Human Milk for Human Babies...we've since had three bulk lots from her... she's incredible' (MWAQ, recipient mother).

8.1.2 Maternal time

Maternal time was reported as a resource constraint. Lactation occurred for a brief period in a woman's life ('You can... volunteer at the local library when you're 80 years old ...but you can't donate milk for the rest of your life' MVICY, donor mother). The window to provide milk was further narrowed by a donor's stage of lactation, guidelines about pumping and milk bank restrictions on accepting milk according to an infant's age. All forms of milk sharing required busy mothers of infants and young children to find time to learn about milk donation and manage communication, logistics and safety (see below). Time constraints made pathways to share milk transient, with implications for transferring and retaining knowledge about milk sharing.

In their daily lives, donors needed time to pump milk, which was 'at a bit of a premium' (MVICP donor mother), especially if they had multiple children or were returning to work:

'I'm not going to put them in day care for three days a week and then on the days that I'm home with them spend time expressing for somebody else, when I should be spending that time with them' (MQLDZ, donor mother).

Milk banks added time-consuming logistic requirements for donors. Most required mothers to travel to be screened and tested and to deliver milk. One milk bank saved time by going to the donor's home. Similarly, informal milk sharing took time, for mothers to interact and meet. For recipients, 'chasing milk' (sourcing, managing and picking up milk) was 'almost was a fulltime job':

'We went onto donor milk when he was about four months and kept him on donor milk until he was 14 months... I would just kind of pick up milk anywhere and everywhere...I was posting and responding to posts... on a busy week I could do a milk collection every day. Monday to Friday I'd be in the car with [infant], and driving from [suburb] to [suburb]' (MVICR, recipient mother).

Supportive partners and family were crucial to helping mothers manage the demands of milk sharing with caring for children and work:⁹⁴

'If I was to have another one now, [first child] would be less than two, so I'd be quite busy with my time as well as feeding a new baby and then trying to find time to donate as well. ... and my partner is FIFO⁹⁵, he's away two weeks at a time. ...And I have a business that I run from home. So yeah, pretty flat out...No, I don't think I'd donate next time' (MWAT, donor mother).

Time pressures meant that donors sought efficient ways to exchange milk. Most relied on recipients to collect it. A single mother described the easiest way, logistically and emotionally, for her to donate milk:

'I just deal with people that are going to show up when they say they're going to show up and that's it... with as little ...interaction around that as possible. Because... there's no convenient time when you've got young children... I didn't want to have somebody else's drama attached to that process... If it wasn't easy, I just couldn't be bothered' (MWAY, donor mother).

Others felt less pressured donating through networks ('We all do what we can and that's enough' MVICP, donor mother).

⁹⁴ Most mothers in the study (94%) were married or in de facto relationships

⁹⁵ Fly-in-fly-out, referring to work in remote locations that requires long absences from home.

Cross-feeding could be convenient, but cross-feeding donors had little flexibility in responding to the demands of infants. This time commitment was difficult to justify outside families, close relationships, emergencies or reciprocal arrangements.

Various forms of paid and unpaid parental leave provided time that enabled mothers to produce and seek donor milk:

'I was on maternity leave when [recipient mother] had [infant] and so the ability to provide that milk was a lot easier. Once I return to work, I'm not going to be able to give as much as I did and I need to make sure [own infant] has got what he needs first' (MQLDZ, donor mother).

Despite parental leave, the scarcity of maternal time from big picture conflicts in policy had the potential to drive a markets in milk:

'We are trying to get women back into the workplace after they give birth to be productive, boost the economy ...but when you're in the workplace there aren't any ...that are particularly breastfeeding-friendly, including this department. ...So we've got really big policies that are conflicting with each other. And if you can potentially ... buy commercial human milk, that's probably a much better option as a mum' (SDOH01, policy maker).

8.1.3 Equipment, social media and logistics

Sharing milk was enabled by the availability of equipment, described by participants as 'pretty basic,' (MB02, milk bank) and technologies, in particular social media. However, milk sharing was sometimes restricted by the capacity of mothers to organize and transport milk (logistics).

Equipment

The equipment needed to share milk was readily available in the households of breastfeeding women in Australia. Most mothers already owned breast pumps, freezers, cooler bags and mobile phones to manage the logistics of sharing milk. A few invested in new pumps or additional freezers, for example to stockpile milk before their child's birth:

'We actually have a chest freezer ...in a lounge room, but it's the only spot that it fits, that's full of donor breastmilk already' (MVICR, recipient mother).

Milk banks relied on these domestic resources, which generally met milk bank standards for hygiene and safety. Milk banks required premises, pasteurizers, laminar flow cabinets, industrial freezers, data loggers, containers and disposables for safe milk management. Although not 'high tech', the limited scale of milk bank equipment sometimes restricted the supply of PDHM.

Most milk banks outsourced pathology services for testing donors and milk. To keep costs down, microbiological testing of milk used food testing laboratories rather than human pathology services, but this depended on the legal regulation of milk in each jurisdiction. Similarly, Australian milk banks needed to comply with hospital requirements for traceability and medical records, which prevented them from pooling milk from multiple donors and added to the cost of PDHM:

'So [State] Health released their policy, but there was no standard tracking form or system. You just do your own. To be tracked, the barcode on the container of PDHM needs to be reflected in the electronic medical record of every baby who received milk from that particular bottle. For that reason, we have decided that we will just use one bottle for one baby, a single donor.... different hospitals were going to try different things' (MB06, milk bank).

In contrast, health professionals outside NICUs rarely handled donor milk and needed few resources to engage with milk sharing.

Social media

The internet and social media were central to milk sharing, whether personal or dedicated sites, raised awareness of donor milk, (as discussed in chapter 6), and helped donors and recipients find each other efficiently. However, these empowering technologies also raised anxieties about safety, by extending concepts of a 'known donor' and redefining who was a 'stranger:'

'So I put a call out on my Facebook page, my private one. ... I had friends offering to share it in their networks, if they couldn't donate themselves. ...And on a group ...that my lactation consultant runs, I mentioned how stressful it was sourcing donor milk... I didn't want to get milk from strangers, I wanted to know the people who I was getting it from. So, they were friends, or friends of friends. I met them all, I met all of their babies' (MQLDW, recipient mother).

Social media enabled more equitable access to milk, unrestricted by social attitudes:

'They don't have a sister or a friend or an aunty that they can approach, and it was a way for them to do it without attracting unwanted comment from critics in their local communities' (HM4HB Admin-MNSWY).

Harassment by men and critics of milk sharing tended to drive milk sharing into closed social media groups:

'Some freaky guys would often ask for my milk, and they were obviously body building and whatever, it was just a bit creepy [on] Human Milk for Human Baby pages. ...But [the natural parenting group], even though it's all online ... there's just people that you know a little better, more inclined to really, really work at breastfeeding. So I started offering there. I wouldn't have posted that I had milk available in my generic mummy groups... I can't be bothered dealing with the stupid comments or the debates' (MWAY, donor mother).

'Gentle' and 'natural' parenting groups often had an ethos that created a supportive environment ('I think now a lot of women find their village in social media,' SVIC05, policy maker), and enabled informed milk sharing to flourish with input from sympathetic health professionals:

'They're really, really adamant that there must be no talk about 'Fed Is Best.' They advocate just having information and however you choose to feed your baby is entirely your choice. ...there's no formula shaming, there's to be no use of expressed breastmilk shaming. ...As a result of those really strict rules, you end up with ...well-informed, well-rounded conversations. ...There's LCs in the group, there's midwives, mums, ...breastfeeding advocates...people who have got grandkids...the information they get is really good' (MW04, health professional).

However, the hidden nature of these exchanges could make informal sharing appear 'dodgy:'

'We'd meet in the Kmart carpark and you'd have the car running and babies in the car ...and you're running across going 'Are you such and such?' and then you're transferring things and looking over your shoulder to check on the baby the whole time, so that they're not screaming and stuff, but it looks like a drug deal, it looks terrible' (MQLDY, recipient mother).

For policy makers, social media made control and messaging about milk sharing more complex:

'I think social media helps people source more information and options. But it also ...builds fear and sensationalises things. So, I think social media actually makes it harder in some ways for us to get a measured message across' (SVIC05, policy maker).

Logistics

Pathways for mothers and milk banks were restricted by the logistic capacity of mothers to organize, manage and distribute milk. Logistic barriers limited donation to milk banks:

'She can only donate it in a certain fashion to the milk bank, she has to have it in bottles... and she pumps, takes it up to the [milk bank] herself. And I think that puts a lot of new mums

off donating milk...and they're trying to deal with a new baby... At times she's run out of bottles... and so she's then given me that milk' (MWAX, recipient mother).

Transport was a major barrier for recipient mothers to accessing milk. Without a car or the capacity to drive (for example, after a caesarean birth)⁹⁶ collecting milk via public transport was exhausting ('each pickup is about three buses... so it's a lot of effort' MACTW, recipient mother).

Mothers described the 'cognitive load' of managing milk and relationships. Some donors also needed to keep it simple and offered their milk to the first taker ('first in, first served' MWAY, donor mother). Many recipient mothers constantly scanned social media for offers of milk or organized networks of 'scouts.' Some participants were concerned that mothers without these resources were excluded from milk sharing.⁹⁷

'It's not straightforward and I know single mums... there's no way they would have the capacity to orchestrate donor milk collections. ...there's a huge amount of emotional labour involved in sourcing donor milk, ...it's something that's got to be organised and stressed over' (MVICP, donor mother).

Local sources of milk were prized, and cross-feeding relied on proximity. However, like milk banks, some mothers co-ordinated the movement of milk over thousands of kilometres. Milk was typically transported frozen, using cold chains and depots. Few mothers used commercial couriers because of transport regulations to handle shipped milk as a bodily fluid, which added to its cost. One mother utilised the delivery run of a refrigerated truck of a local organic meat company. Family members and friends were recruited to carry consignments of milk by plane, and mothers who travelled planned supplies of milk in their destinations using interstate or overseas social media pages for milk sharing.

8.1.4 Human resources and relationships

All forms of milk sharing relied on human resources: the bodies of breastfeeding women and their lactation knowledge and skill. In addition, health professionals were powerful gatekeepers in milk sharing:

⁹⁶ Caesarean births are common and occur in about one third of births in Australia ((688)

⁹⁷ Mothers in the study had a high level of education, and 73% (35/48) had completed a Bachelor's degree or higher qualification, compared with 24% of the Australian population in 2016 ((699) Two women in the study (6%) had not completed Year 12.

The incomes of mothers in the study were higher than those of the general population. Gross household income for 2015 exceeded AUD\$100,000 for 61% (29/48) of participants and was less than AUD \$50,000 for 10% (5/48) of the sample. In contrast, census data showed that in 2015-16, gross household income exceeded AUD\$104,000 for 40% and was less than AUD \$49,608 for 30% of the Australian population ((700)

'I ended up buying a pump and then I found some of the Australian groups, 'Exclusive Expressers,' and I learnt...pretty much everything through them, from other mums in the same situation. The advice midwives give about expressing is about stimulating your milk to come in, not about a long term supply ...that's when the game really starts. Mums definitely had more experience' (MWAY, donor mother).

Models of Australian milk banking struggled to provide lactation support, in addition to finding staff with technical expertise in infection control and food processing:

'We could do a lot more if we had more funding, some paid positions... we could be managing the logistics, ...the education, supervising, and the whole operation of the bank would be so much greater...I do quite a bit of counselling for mums that are struggling, that might use [PDHM] for a short term' (MB02, milk bank).

Pathways to share milk were shaped by relationships and power between different actors. Although these relationships could be obscured by anonymity, they shaped ethical rules and formal systems of milk kinship, which could affect access for some cultural and religious groups (including Islam):⁹⁸

'When we said that we couldn't guarantee ...that donor milk would go to a same-sex [recipient], one donor's husband, didn't want his wife to donate the milk. ...We said that's ...not worth creating issues in your relationship, by taking your milk' (MB05B, milk bank).

In informal sharing, close relationships helped mothers to access milk ('If I can alleviate a little bit of stress with any of my loved ones, then it's an easy decision to make' MWAU, donor mother), and mothers relied on their families and social networks:

'I had enough breastfeeding friends ... to get through that hump between my milk not coming in early enough and her losing too much weight ...So one of my friends through the ABA forum ... had been expressing for the breastmilk bank and ... she started pumping milk for me ...and each would drop around milk and dinner for me each day' (MWAZ, donor and recipient mother).

The care provided in these relationships shaped perceptions of safety, even when mothers shared milk with 'strangers' from social media pages:

⁹⁸ The milk banks in this study had the technological capacity to accommodate milk kinship because they did not pool milk from multiple donors and had the recording systems to maintain anonymity while providing appropriate milk (from a donor whose infant was the same gender as the recipient infant). However, the potential use of reproductive technology complicated relationships and risked violation of milk kinship taboos (that recipients of milk from the same donor should not marry).

'The original lady was really nurturing and guided me through everything, and told me what to look out for... She was such a strong believer in the process, and she said it helped save her two kids as well' (MVICX, recipient mother).

However, relationships required work. Milk banks and recipient mothers described how they worked to ensure that donation was a positive experience. Despite this, some donors supplying milk banks felt a lack of relationship, and also shared milk informally because it was 'more personal' (MWAY, donor mother).

At higher levels of the system, collaborations between actors shaped the governance of milk sharing. Intentional, optimistic relationships were needed to overcome regulatory or social barriers, whether to establish a non-profit milk bank or administer national social media pages for informal sharing. However, these collaborations were rare. For example, Australian milk banks lacked a national association 'to provide a bigger voice to deal with all the other regulatory issues' (MB03, milk bank). Without such alliances, actors interested in milk sharing battled to influence policy makers and health authorities:

'Then the lactation consultants got all excited and said, 'Oh why can't we start a milk bank here?' ...and I think the maternity midwifery director was interested, and we had a meeting and ... an evening forum... [Milk bank] came over to give a talk, ...the local ABA were interested, and we had a few meetings. But they couldn't really get the medical side on-board, or the hospital' (SVIC03, health professional).

In these loose alliances, mothers who shared milk lacked representation. For example, NGOs might support milk banking but were reluctant to be associated with informal milk sharing. To address their lack of power in health settings, mothers exercised power indirectly, through relationships with sympathetic health professionals. Consequently, health professionals emerged as powerful actors in milk sharing. Those with expertise in lactation and an awareness of local supplies of milk could facilitate milk sharing:

'And then my midwife said, 'I have a client who has been wanting to donate and I will put you in touch with her' and so she gave me all the rest of the milk that I needed. I only needed milk for three weeks... I didn't know where to go for milk before' (MVICQ, donor and recipient mother).

However, all too often, mothers in the study reported relationships with health professionals that were negative, which prevented informal sharing or forced it to be practiced covertly:

'That doctor in particular was very, very, very against milk sharing... the clinic nurse actually got on my post on Facebook and was talking about how unsafe it was... I got pulled into the office by one of the head paediatricians and just yelled at... And they wouldn't let us feed the bottles because they weren't sure the milk was mine or my friend's. So... I just had my friend come in ...and she wet-nursed him for me' (MACTW, recipient mother).

8.2 Pathways -rules

All actor pathways were shaped by the legal structures described in Chapter 5. These legal structures intersected with social rules exercised through relationships and social norms, described below, about the distribution of milk, its costs and management of potential risks.

8.2.1 Allocation of milk

Rules about allocation, or who got donor milk from the available supply, was controlled by donors, who decided which milk sharing sector to supply. These allocation decisions reflected actor motivations (discussed in chapter7), relationships, ethics and access to milk banks.

Donors who supplied milk banks prioritized milk for infants in NICUs and trusted the clinical decisions of milk banks and medical staff ('I've not had any [donors] that wanted to know where it went at all' MB03, milk bank). Most milk banks were not responsible for the allocation of PDHM to individual infants, which was determined by doctors, either neonatologists in hospitals or general practitioners in the community.⁹⁹ In NICUs, the allocation of PDHM was determined by policies that prioritized eligible infants at risk of NEC ('It's a very scarce, very expensive resource that we should be apportioning to the babies that benefit most from it' MB03, milk bank).¹⁰⁰ However there was variation between hospitals and clinicians in allocation policies:

'Anybody less than 34 weeks or less than 1,500 grams, they're offered [PDHM]. Some of our partners that purchase from us probably won't be as liberal, so they might go less than 28 weeks, just because for them it's probably more of a scarce, expensive resource. And then theoretically we stop at about 35 weeks but that is flexible' (MB03, milk bank).

Clinical discretion in the allocation of PDHM included consideration of the mother's attitude to breastfeeding:

⁹⁹ According to the procedures of the one milk bank that supplied the public, a doctor's written approval was required, and then the milk bank allocated PDHM according to medical need, taking into account infant and maternal conditions.

¹⁰⁰ See Chapters 4 (Legal Structures) and 6 (Motivations) for policies for donor milk and PDHM. NICU policies allocated PDHM to infants up to about 32 weeks gestational age.

'You get two groups of mums. The ones that just never bother and these kids get donor milk until they big enough to not really be at risk of NEC, then they get switched to formula. And you get the other mothers that are so grateful, ...they still express but probably just don't get enough, and those we keep going for a little bit longer, if the mum's really keen. ...So we have rules that we bend either way, ...I think what we're then doing is supporting the mother who wants to breastfeed, subconsciously' (MB03, milk bank).

Some milk banks were also starting to supply PDHM to lower level care units, including in private hospitals, justified by clinical and equity principles and saving health system costs:

'We've been expanding into the secondary hospitals or the smaller special care units...and I think that's where the inequity that we identified exists. ...We've taken it one step further and increased feed tolerance, shorter length of stay, and those will ultimately save money. Because those places would have babies, that if they can't feed them quickly enough, will have to come to a tertiary centre to get a central line, take a long time to get onto feeds and then go back. Or they get delivered here, and by the time they're ready to go back they're still on donor milk, and had to be transitioned to formula, which probably still put them at risk [of NEC]' (MB03, milk bank).

One milk bank that also supplied the public allocated milk for a wider range of infant and maternal medical conditions:

'The hospital [milk banks], well they're insular and they're focused on their NICU babies. ...We could do a lot with a small amount of milk [in] that first week, so the integrity of the gut is maintained for ...those babies that are at risk of diabetes, infection, severe allergies' (MB02, milk bank).

In informal arrangements, allocation decisions by donors prioritized the youngest and most unwell infants and infants with whom they had close relationships. Allocation decisions gave donors power, and many mothers found the ethical allocation of milk deeply uncomfortable ('There's a lot of pressure to decide which baby is worthy enough' MVICL, recipient mother). Sometimes recipients needed to demonstrate their worthiness, for example their 'heroic' effort to source milk ('I would have hired a truck to get it' MWAY, donor mother). However, some donors deliberately avoided these power dynamics by refusing to differentiate between recipients, and allocated milk to the first mother that responded or split batches evenly:

'I'd said to my regular recipient, 'Would you mind if I split what I've got, or how much do you need, because you're my priority?' And she said, 'Look if you want to do half and half, I'm

OK.' So I gave half to the mum that's local to me and half to my regular recipient (MWAO, donor mother)

However, these attempts at fairness could be inequitable, because they tended to distribute milk to mothers with the most resources (as discussed in the previous section on logistics). In contrast, policy makers were concerned about allocation only in terms of the potential diversion of donor milk from infants to other users, for example 'body builders.' To prevent this, some policy makers proposed that PDHM in Australia, including imported milk products, should be regulated through food standards that required use under medical supervision.¹⁰¹ Overall, these allocation decisions restricted access to specific types of donor milk, as discussed in the next section.

8.2.2 Access to milk

Pathways for milk sharing were highly restricted by access to donor milk. All actors described how access to PDHM was restricted by the small number and capacity of milk banks, and legal barriers to their operation and viability, as described in Chapter 5. Milk banks and policy makers described the lack of clear regulatory pathways ('to know what the devil to do' MB05A, milk bank).

At the local level, milk banks navigated complex lines of governance through hospitals, government agencies and insurers, which added to their costs and limited their development:

'The Department of Health has said they will prioritise helping us to expand, but ...they really can't decide who should be responsible for us:is it tissue, is it food, is it marketing? Where do we sit? And so about five different areas of the Department have input into what we are doing ...very tedious' (MB01, milk bank).

At the national level, milk banks were impeded by fragmented State/Territory laws, while federal laws for food allowed international milk banks access to Australian markets:

'The [milk bank] looked at how it was going to be regulated... We were told that it was just too difficult, and they weren't quite sure how to regulate you. So New South Wales and South Australia are regulating us as a food and, fine, we comply with FSANZ, we have got food licenses. Queensland is Human Tissue, Victoria is both... Northern Territory, ACT and Tasmania are food.... At least ...we can say we abide by FSANZ and are regulated under Food

¹⁰¹ For example, Australia New Zealand Food Standards Code – Standard 2.9.5 – Food for special medical purposes

Standard 3.2.2¹⁰² ...[but] I think that was more around Prolacta getting an import license to bring in their product' (MB05B, milk bank).

Navigating these complex policy pathways required leadership, which was missing in Australia's federal systems of governance:

'We certainly acknowledged that WHO recommends in descending order of priority: breastfeeding from the mother, donated human milk and then infant formula. ...But having said that, because we're talking about regulatory frameworks that are controlled by the states and territories, the Commonwealth is only in position to influence, and encourage and facilitate consensus' (SDOH01, policy maker).

Access to milk through importation was ethically contentious, but some milk banks and policy makers thought that importation was a solution to improving access to human milk products:

'Anything that restricts import ...then potentially doesn't allow babies to receive human milk... that's a restriction in access' (SDOH02, policy maker)

However, policy to allow importation was recognized as a step that 'opened the door' to the commercialization of milk and ethical risks, as discussed in the chapters 6, 7 and 9 on awareness, motivations and rewards.

'If we decide it's okay to bring in this product for neonates, it's the thin end of the wedge ... If it's okay for our most vulnerable babies, then can't it be okay for the ones that were born at term, but need a bit of extra help, and [for] whoever wants to buy it? So ... are saying no for the neonates, which is a hard thing to do, or do you accept that you are going to commercialise a product? ...The thought of a company like this, based in India, is that it's exploiting poor people. ... it's just not clear-cut. And I guess I feel vaguely uncomfortable with it' (SDOH1, policy maker).

Access also trumped domestic food security in milk. When milk was legally classified as a food, as it was at Australia's national border, it was subject to WTO¹⁰³ rules and policies geared to 'free' markets, rather than the domestic milk production (breastfeeding):

'There is nothing in the Biosecurity Act, ...nothing in the Export Control Act that deals with food security. It's all about, is the product coming or going, does it actually meet the

¹⁰² In 2021, FSANZ standards for food safety include Standard 3.2.2 Food Safety Practices and General Requirements <https://www.foodstandards.gov.au/code/Pages/default.aspx> accessed 21 September 2021.

¹⁰³ World Trade Organization

receiving country requirements? That's really what it comes down to... there is no Commonwealth legislation, to my knowledge, that actually deals with food security' (SACT11 and 13, policy makers).

To counter this problem, other policy makers suggested classifying milk as a human tissue, which provided limited scope, under TGA regulations, to protect domestic supplies, but only from export ('The government will not be happy for you to export tissue... unless they can see that demand in Australia is met' SACT15, policy maker). However, there were still gaps: the TGA did not have scope to address ethical concerns, unless directed to do so by the federal Department of Health. As a temporary solution, the government granted permits to import milk as a food at the federal level, and relied on 'post-border' restrictions on the sale of milk in human tissue legislation at the State/Territory level:

'So that means, at the state level, if this product is viewed as a human tissue, the decision-maker could say well you can import it, but you can't sell it ...Which would stop it at the border' (SDOH01, policy maker).¹⁰⁴

The threat of importation had some beneficial effects, in making policy makers keen to remove domestic barriers to Australian milk banks by harmonizing the legal classification of milk across states and territories, but this required considerable work:

'The food regulatory system can address the safety issues ... but can't address the ethical issues. ...And so, we're going to have to ask COAG Health Council whether this product fits under the Human Tissue Acts. So it's gone over to one of the Principal Committees there, ...Meanwhile, in the food stream, all of the jurisdictions have been seeking legal advice.... So it will all come together, and we'll decide whether it's fairly and squarely a food or maybe it's fairly and squarely a human tissue or ...both. And I think in Victoria that's how they view it.... The situation is very complex' (SDOH01, policy maker).

In these deliberations, policy makers were aware that decisions about importation were at a critical point and would affect future economic models for milk banking in Australia. In making these decisions, policy makers drew on their experiences with blood and other tissues:

'If we don't have enough human milk why don't we just buy it in? We had this debate about 15 years ago about blood sufficiency... So finally, the powers that be relented and said,

¹⁰⁴ However, this regulatory 'game playing' offered limited protection. The risk remained that the successful importation of milk or milk products into a state that classified them as a food only, could make them accessible elsewhere, through constitutional rights to free trade between the states.

'Okay well we will bring the plasma products in.' ...It was a live debate and we see it being repeated now for different products. ...And the chair of FRSC¹⁰⁵... is most concerned that we make the right decision ...It's quite a critical time' (SDOH1, policy maker).

At these higher levels of government, there was also recognition that imported milk risked displacing government investment in breastfeeding:

'With the advent of this product, whether it's commercial or ...through Facebook, it means that it's less urgent to get the settings right to encourage women to breastfeed' (SDOH01, policy maker).

The risk of access to products displacing access to breastfeeding was readily grasped by policy makers focused on public health and health professionals working directly with mothers, who saw the need to make breastfeeding easier:

'Part of my public health bent ...is that women should have access to something that is safe, that's reliable, that's free, that's not hard to get. ...We shouldn't have to go out of the system if it's a health-related thing. It shouldn't have to be difficult: breastfeeding... should be available to everybody' (SNSW01, policy maker).

Overall, these regulatory barriers to milk, milk banks and breastfeeding were seen as drivers of informal milk sharing:

'I think milk sharing is coming back because we can't provide [access] through milk banking... Then the Human Milk for Human Babies site set up, ...and once that got out there, I think people suddenly thought, 'I'll do that. That's an option.' ...One of the other directors has seen it quite a bit on social media... it's huge' (MB02, milk bank).

In health facilities, actor pathways were shaped by the lack of policy for shared milk, which fuelled fear about milk amongst health professionals and mothers:

'Well, there is no policy, so does that mean that it's OK or it's not? ...We often see in the paper that baby X received mother B's milk ...and shock horror, everyone is going in for tests' (SVIC05, policy maker).

To fill these gaps, some NGOs developed policies for donor milk, which were leveraged to advocate for access to donor milk and milk banks:

¹⁰⁵ Food Regulation Standing Committee

'Most of our members work in hospitals, ...so they wanted something that helped them lobby their management to get milk banks happening...It was a political strategy: our members and hospitals can say 'Look the [NGO] thinks milk banks are good idea, you need to make them happen' (SNSW01, policy maker).

However, advocates had to contend with local variation in policy for donor milk between, which occurred when health administrations decentralized and policy 'devolved' from mandatory directives to 'guidance' (SNSW01, policy maker). This patchwork of policy and funding in maternity care also limited women's options to choose hospitals and access to donor milk. This disempowerment of mothers in the health system was also a driver of informal milk sharing:

'If I want to know who's got a milk bank... it's just potluck. ...And pregnant women are incredibly vulnerable and mostly get made incredibly powerless. ...I can imagine why women go to community-based Facebook pages to get milk' (SNSW01, policy maker).

In individual health facilities, access to donor milk was dictated by hospital supplementation policies and clinician discretion about the use of unpasteurized donor milk. One mother found that she could use her relative's colostrum in a private hospital, on the approval of a paediatrician, but not in the public hospital to which her newborn was transferred. More commonly, donor milk and cross-feeding were prohibited, and their management was limited by inadequate staff knowledge of lactation. One health professional in a culturally diverse area described the need to educate junior doctors about cross-feeding on post-natal wards ('They tend to hit the panic button' LC01, health professional):

'Even though the EBM Safe Management document says that the baby must be breastfed by its biological mother, ... we don't have a policing role over what the mother does. So, you give her the information ...to support her decision. I feel it's disrespectful to impose things on parents like 'Don't let your sister breastfeed your baby,' whereas if she was at home that would be a normal thing' (MB06, milk bank).

In the wider community, pathways to access to PDHM were restricted by its cost (discussed in the next section), logistic barriers and a lack of health professional knowledge about obtaining it ('It wasn't like a vending machine,' partner of MQLDV, recipient mother). Mothers frustrated by a lack of access to banked milk saw this restriction as part of system-wide failures in breastfeeding support:

'It's a pity they don't offer milk bank milk in delayed onset lactation... somebody who may only need it for a day or two. You couldn't even see the Breastfeeding Centre for 14 days! It was all too little, too late. The system fails' (MWAZ, donor and recipient mother).

In community informal arrangements, access to milk faced similar challenges, and depended on the mothers' resources (discussed in previous sections). Many mothers and health professionals lacked knowledge of how to access milk without infrastructure (a 'platform') to connect health services with breastfeeding women:

'Women don't know about their resources. They don't know about things like 'Birth and Beyond,' there isn't a thing through the ABA¹⁰⁶ for milk sharing, there's not a policy directive... through your Early Childhood Health Centre. So how do you share milk when there is no platform to do so? ...You probably just have to know someone' (MNSWZ, donor mother).

Overall, the data showed that a lack of lactation support shaped 'rules' which restricted access of Australian women to breastfeeding and milk. In addition, powerful international trade rules, intended to improve access to milk and milk products, threatened breastfeeding. Regulatory frameworks that enabled trade lacked mechanisms to deal with milk's unique ethical complexities. The regulatory alternative, classifying milk as human tissue, addressed some ethical issues but limited access, and framed milk as an infective substance under medical control, rather than a normal source of optimal infant nutrition.

8.2.3 Costs of sharing milk

This section is about the ways that actor pathways were shaped by the costs of sharing milk and how they were distributed. Milk sharing was unaffordable for some mothers and the regulatory costs of milk banking made PDHM unaffordable for some hospitals.

Rules for altruistic donation and cost recovery meant that donors bore the brunt of costs, with milk banks able to recover costs through the public health system. In general, mothers supported these cost structures, to keep milk safe and affordable for recipients, but recognized that milk sharing was uncompensated work:

'It's work, I consider it to be work to express and store and donate and manage that around a family... My body produces milk, and I would get paid to do other kinds of work' (MQLDZ, donor mother).

The costs of maternal labour involved in producing milk were socialized, to some extent, by paid parental leave.¹⁰⁷ However this support did not cover the added labour and financial costs for donor

¹⁰⁶ Australian Breastfeeding Association

¹⁰⁷ Mothers had universal access to 18 weeks Paid Parental Leave at the national minimum wage from the government ((701) and variable amounts of paid and unpaid leave from employers.

and recipient mothers of sharing milk (pumps, storage bags, electricity and transport), while other actors were paid or reimbursed. In addition, mothers bore many of the costs of ensuring milk was safe, through managing their health and handling milk (discussed further below). A few mothers who donated milk informally underwent additional blood testing, but this was prohibitive unless bulk billed:

'And I saw some posts on the site saying, 'I'd like to start donating to someone, but I've gone to my GP and asked them about doing blood tests, and the GP said it cost...\$350" (MVICX, recipient mother).

Mothers in my research were able to absorb the costs of donating and sourcing milk because they had above average household incomes. However, some mothers and health professionals were concerned that milk sharing was unaffordable for many, especially donating to milk banks ('you need a royal lifestyle to be a candidate' MWAY, donor mother).

Milk banks in the study had to recover operating costs, including staff salaries. Some used volunteer and student labour, and all relied on altruistic donation. To become established, most milk banks struggled to obtain government funding and required the support of philanthropic foundations and one-off grants:¹⁰⁸

'We had a meeting with the policy advisor for [State], along with the Minister for Health and the local member. And 'Terrific, wonderful...no, we don't have any money. Oh, it's federal.' You go to federal, it's state: usual buck-passing. ...I've been to see the local federal member. And she's supportive and organised a \$9,000 grant for us last year to help with the new pasteuriser' (MB02 milk bank).

The full cost of PDHM was up to \$500 per litre for some milk banks.¹⁰⁹ To partially recover costs, milk banks charged \$110 to \$328 per litre for PDHM. In contrast, ready-to-use CMF for premature infants cost hospitals about \$10 per litre. Hospitals recovered the cost of PDHM used in NICUs through the public health system and funded additional costs of transporting, storing and handling PDHM and lactation support.¹¹⁰ One milk bank that supplied the public was a registered charity and recovered

¹⁰⁸ Over the course of this study, funding models for some milk banks evolved, with a substantial grant from the federal government (\$2 million) to Lifeblood Milk (a not-for-profit) ((684)and private investment in the Australian Breast Milk Bank as a for-profit company. However, this milk bank was not operational at the time of the study.

¹⁰⁹ This cost included staff salary (for one full-time equivalent), donor screening and testing (\$125 per donor for serology) and testing milk (\$65 per batch for microbiological testing before and after pasteurization).

¹¹⁰ For example, NSW policy for use of PDHM stipulated the need for NICUs to provide additional lactation support ((593)

costs from recipient families by asking for a charitable donation, which was tax deductible but not reimbursed by health insurers.

Milk banks and health professionals working in policy areas described the regulatory costs of donor milk, including policy development, compliance and governance. Some of these analyses were biased against breastfeeding. For example, policy processes analysed the cost and benefits of donor milk, which ignored the ('free' or unpaid) contribution of donors and any benefits to breastfeeding:

'We have to do a cost-benefit assessment [and] show that there's a benefit to consumers or benefit to other parties... I'm not sure we would get into the benefits of human milk products from a breastfeeding perspective... It would be if it appeared in a Ministerial Policy Guideline' (NZ01, policy maker).

The use of PDHM in public hospitals required policy development across multiple policy areas and levels of government, and local hospital resources:

'The Statewide Breastfeeding Reference Group is responsible for the updated Policy Directive: *Breastfeeding in [State]*.... there is also another called *Breast Milk Safe Management* for [State] Health facilities... At the moment, it says just 'adopt local processes' [for donor milk]. So it makes it very difficult for each facility. ...It needs to be referred to in our Policy Compliance Procedure/Guidelines, how we here at [hospital] are going to comply with that procedure. So, it has a lot more local processes in it ...we had to do a bit of fishing around. The other group was the Clinical Advisory Group (CAG) for PDHM [with] representatives from the head neonatologist of each individual NICU... people from the Ministry of Health, people from Maternal Newborn Division, ...Population Health and obviously the [milk bank]' (MB06, milk bank).

At the federal level, the regulatory costs for milk would increase if milk was regulated as a therapeutic good ('It would increase the costs enormously... regulating them almost to a commercial approach' SACT15, policy maker). One milk bank was concerned that the failure to tackle the regulatory complexity of milk put clinical, legal and business objectives in conflict, and without legal clarity and public funding for milk banking, business goals won out and fostered commercial interests in milk (MB04, milk bank). However, few policy makers considered how the regulatory costs for donor milk created advantages for CMFs, as discussed in chapter 1. Other economic factors that shaped milk sharing, are discussed in chapter 9, on rewards.

8.2.4 Managing risks

Having managed the resources needed for milk sharing, and institutional and social rules about milk allocation, access and costs, pathways for milk sharing were dominated by rules to manage various risks. These risks concerned ethics, legal liability and safety.

But first, some actors identified the broader risk that milk sharing posed to breastfeeding. To one milk bank, the greatest risk was that donor milk masked government failures to invest in breastfeeding and curb commercial interests in infant feeding (MB04, milk bank), as discussed in chapter (section 6.2.5) and chapter 7 (section 7.1.2.1). This was echoed by other milk banks, NGO policy makers and many mothers who saw the risk of milk sharing displacing lactation support and mothers' motivations to breastfeed:

'Milk banks ...are really aware of the fact that they don't want access to donor milk impacting on the discharge rates with breastfeeding. So there's a lot of support that needs to now go into the NICUs ...to make sure that women are encouraged to express and establish lactation and not to just see 'Oh the baby's got donor milk, I don't need to worry about expressing' (MB05B milk bank).

'The second most reported reason that women stop breastfeeding ... is perceived low milk supply. ...If there was an option to purchase breastmilk ...I think there probably is some risk that it would impact on women breastfeeding their own baby' (SVIC05, policy maker).

To manage the risk of displacing breastfeeding, one State government required NICUs using PDHM to report quarterly on a range of outcomes ('breastfeeding rates on discharge ...babies fed, volumes fed, wastage' (MB05B, milk bank) but it was not clear whether similarly intense reporting was required for CMFs.

Ethical risks

Sharing milk was beset with ethical issues, concerning moral questions and disparities in power between actors, which required rules to manage conflicts of interest, consent and privacy.

At the federal level, the importation of milk raised concerns about exploitation, but policy makers lacked legal structures to manage this issue. For example, policy makers assessing potential disease risks of imported milk under the Biosecurity Act had no power to manage ethical risks:

'Obviously we don't want to be promoting something that has ethical concerns, but we just don't have a basis to be able to say no, based just on ethics. ...We just don't have that remit' (SDOH02, policy maker).

Similarly, policy makers with responsibility for the safety of imported food stated that there was no policy pathway to address ethical issues within the food regulatory system:

'We don't get into the moral space around that. We're really there to implement the will of the government. And if there is no barrier through either government policy or legislation, we manage whatever the risk is ...within our jurisdiction' (SACT11, policy maker).

However, scope to consider exploitation existed in precedents for the importation of human tissue (702, 703):

'Australia should not import human breastmilk unless it can be established that the milk was obtained in a manner that is consistent with the relevant Australian legislation, ethical standards or ethical guidelines' (SACT10, policy maker).

The problem with this advice was the lack of clarity about the 'legislation, ethical standards or ethical guidelines' that applied to milk in Australia. One policy maker described this as an ethical 'woolliness' in infant feeding which manifest as an 'undercurrent,' 'politics,' or 'preferencing' of CMFs over donor milk at global and clinical levels:

'I think it's unethical not to provide human milk as a substitute if women can't breastfeed. I've been a bit disappointed by some of my neonatal colleagues, ... the obstetricians ... There is a woolliness in that area around breastmilk....I don't know who it's coming from, but there's some good strong lobby that is continuing to say 'It's OK not to have breastmilk in NICUs'....The Royal College of Paediatricians in the UK has just had to defend their position to accept formula company sponsorship ...So when I look at all of that, I think well, there's obviously an undercurrent that formula is OK and that ... milk banks are expensive and...hugely regulatory heavy. ...They're not simple things. So, if you're in a nursery that really thinks that formula's OK, you're not going to bother to do all of that. And so there's... something else going on around the politics, or the preferencing' (SNSW01, policy maker).

Ethical concerns also arose in informal arrangements, in disparities in power between donors and recipients. These interpersonal dynamics involved a sensitivity to conflicting interests, gender identity and avoiding offence. Donors were sometimes reluctant to make direct offers of milk in case this was seen as judgemental. Equally, recipients felt inhibited about asking for milk and pressuring donors:

'I think as women we also experience that whole, we shouldn't really ask for things... like you don't have a right to ask, ... unless it gets offered' (MWAX, recipient mother).

Recipients disliked asking intrusive questions or putting a donor in an awkward position of refusing and were careful not to appear entitled or ungrateful. Asking for milk required recipients to subsume feelings of shame about their adequacy as mothers:

'So any kind of emotions of inadequacy, of not being able to fulfil that role, has to be pushed to the side, because you have to get on with it' (MWAX, recipient mother).

Accessing milk through social media lessened some of this awkwardness, but amplified competition for milk. The physical and emotional toll of accessing milk without institutional support, of appearing 'pushy' and having to constantly justify a need for milk, meant that some recipient mothers dropped out of the race. To remove these ethical burdens, one mother with insufficient glandular tissue proposed access to PDHM on prescription:

'If there was enough around, I would just use donor milk. Even better if I can get it from the milk bank or I could get a prescription for it... that says 'This is OK and you and your baby needs this, and this is society taking care of you and your baby'' (MVICL, recipient mother).

Consent

The conditions under which actors produced, exchanged and used milk were framed by rules for consent. Consent, and its absence, made power explicit. Consent upheld rights-based concepts for informed and autonomous decision making. Donors consented to the use of their milk for a specific purpose, including research, and recipient families provided consent on behalf of their infant, based on knowledge of milk's benefits and harms compared to its alternatives. Withholding consent (to PDHM or CMF) was a way for mothers to regain power.

In health settings, gaps in consent diminished women's control of infant feeding. Obtaining consent from recipient parents was highly variable and favoured the use of CMF. NICUs required consent for PDHM but not CMF, while post-natal wards typically required consent to use CMF (donor milk was not an option):

'We only require consent [for PDHM] from the mother, but it's often a family decision, so the father gets involved with that as well. Which is interesting, because if the ...baby was fed formula, the father wouldn't be involved in that decision' (SSA01, milk bank).

'Some women had to sign waivers to say that they were happy to give formula. Some didn't, it was just administered without their permission' (HM4HB Admin).

Lactation support was an important component of informed consent for PDHM, but this could disadvantage donor milk:

'We have our nursing staff or our doctors consent... I think [other hospital] have their LCs¹¹¹ do it, so that the women then get the advice they need about improving their supply. But we don't have 24/7 LC support. ...There's many nursing staff who still don't see risks for giving formula... [and it's] more work for a nurse if we have a baby in the nursery on a drip, waiting for a maternal supply [of milk]' (MB01, milk bank).

On post-natal wards, the lack of pathways for consent to use donor milk were flashpoints for conflict between mothers and health professionals. Mothers wanting to avoid CMF felt that society charged them with responsibility for infant feeding but undermined them by failing to provide legitimate access to donor milk. This 'betrayal' was a shock to new mothers who sourced milk informally, and could alienate them or shatter their confidence:

'If they could not find the source of the milk, they would test the baby to make sure that they hadn't given the baby something to be taken to court over... and so they were very risk averse. ...And I said, 'I'm more than happy to draft up a form saying I take responsibility for anything that happens to my child because I chose to give her donor milk.' And ...at that point they just thought I was hysterical and crazy... I'd locked myself in the toilet and was just crying and screaming at the team leader. I said, 'You clearly think that I'm not looking after her properly –just take her away now!' Like, that's how bad I felt' (MACTY, recipient mother).

To avoid this intense conflict around consent, mothers circumvented hospital policies by escaping surveillance, which drove covert sharing, for example by using private rooms on wards and sharing strategies on social media:

'They didn't have a milk bank available... and they were 'We've let you try breastfeeding and now you need to do formula.' And she said, 'I don't need to sign this because I don't consent.' And they said 'Well you're aware you're going against medical advice' ...So I think it was her decision not to raise it [donor milk] with the hospital, just because they weren't supportive... they were really on the formula path... One of the midwives said, 'Oh well, when you do move to formula, I really recommend NAN brand.' ...When I was in there, we closed the curtains while we were transferring the milk' (MVICO, donor mother).

'On those sorts of posts, there were a lot of women suggesting that the milk be brought in as 'This is my sister's milk' or 'This is my milk that I've pumped,' to get around the hospital policies' (HM4HB Admin).

¹¹¹ Lactation consultants

Similarly, some health professionals avoided consent by not informing mothers of options for informal sharing, because they believed they were protecting the rights of infants from risks of viruses potentially transmitted via milk, or they doubted the capacity of mothers to manage this risk. However, others thought that pathways for consent to use unpasteurized donor milk were necessary to ensure open disclosure between mothers and health professionals (You can't drive this underground...in fact, it probably needs to be brought out into the open more' (MB03, milk bank).

Privacy

Pathways for milk sharing were shaped by ethical rules to protect privacy. In health settings, the privacy of donors and recipients was legally protected, and laws and policies for anonymous donation of human tissues were strongly supported by milk banks:

'No other milk bank has not done anonymity...and I think it is probably safety for the donors, safety for the milk bank, safety for the recipient. ...If something happens there could be litigation...there's always confidentiality issues in health care' (MB03, milk bank).

Clearly, anonymity was viewed dichotomously in milk sharing sectors: as a virtue in milk banking, but a risk in informal arrangements and directed donation, where knowing the donor improved safety. However, anonymity in milk banking made it unacceptable to cultures who recognized milk kinship.¹¹² In informal arrangements, mothers respected privacy principles and did not disclose each other's identity without permission:

'I put it on my Facebook page...that I was donating the milk to the bank. I probably wouldn't talk as much... about donating to my friend's sister. ...I don't talk about donating to the cancer patient, because I am afraid that other people will judge him' (MQLDU, donor mother).

Privacy protected mothers from stigmatization in workplaces and the community. For example, one health professional described a patient who hid her use of PDHM because she did not want to reveal her double mastectomy and medical history to her in-laws. Concerns about privacy made some mothers reluctant to seek milk publicly on social media, while others preferred social media because offers and requests could be made anonymously and followed up through private messaging.

Legal risks

The threat of criminal or civil liability was a key regulator of milk sharing. Legal liability restricted milk banks and health professionals from becoming involved with informal milk sharing, which had far-

¹¹² Human Tissue Acts, milk banks guidelines and legislation for Health Records and Health Services

reaching consequences for access to milk and its safety. Potential liability made hospitals and other organizations risk averse and paralysed policy development. Despite recognizing the use of donor milk as legitimate, NGOs did not develop detailed guidelines for informal milk sharing, for fear of being sued or perceived as promoting it:

'We need to be seen as being credible and responsible with government and ...other professional organisations in the health sector ...We don't want to be seen as 'Oh yeah, come to us and we'll give you a litre of donor milk and I don't know who it came from, but she'll be right mate.' ... If they're using us to put them in touch, facilitate that sharing, does that make the [organization] liable?' (SVIC05, policy maker).

Even social media pages for milk sharing distanced themselves by claiming to be a communication platform, and that individual mothers assumed responsibility for any harms:

'Remaining neutral ...as far as the transactions go, arms' length, not being involved in the transaction. Letting the women work it out for themselves. I guess it's partly to do with reducing liability for any individual for whatever happens down the track' (MNSWY_HM4HB admin, policy maker).

However, mothers in the study concluded that there were few legal risks for them, based on the relative risks of CMF:

'I don't think there's any legal implication for me... If the baby gets damaged from formula, the parents are going to be just as upset aren't they? ...They're often very shocked when they find out the bacterial risk in formula... that sometimes has beetles in it, can cause meningitis, ...kidney problems' (MQLDX, donor and recipient mother).

Legal liability loomed large for health professionals, especially when they worked in health facilities without policy for donor milk. Policy gaps left them uncertain and hesitant about milk sharing ('Oh my god, what am I going to do? I will turn a blind eye to that' LC03, health professional), while the risks of CMF were accepted ('We don't have that same fear with formula, whereas things can go wrong there too' (SVIC05, policy maker).

Legal liability around donor milk was also determined by medical professional standards, scope of practice and insurance:

'I, personally have never facilitated finding a mother and a donor... I think that's, for me, a very grey area, if anything happened... I'm certainly happy to encourage mothers to explore

the option, but at the end of the day it's their decision. ...I'd be reluctant to be the go-between... from a professional indemnity point of view' (LC02, health professional).

However, despite the legal risks, some health professionals supported the use of milk sourced informally, knowing that they faced disciplinary action if discovered:

'One of them said, 'If they fire me for giving you what you have every right to use, then that's their choice.' And she just brought in the formula, as she was expected to, and said 'Here's your formula,' [and] tipped it down the sink, 'Here's your breastmilk, use it as you will' (MACTY, recipient mother).

For mothers and health professionals, there were few realistic pathways to challenge the risk-averse positions of institutions:

'The woman could challenge that... [if] she...contacted [the] Human Rights Commission... quite vulnerable, several days after birthing...tired, teary' (SACT03&04, health professionals).

Legal waivers did not solve these problems. Waivers were rarely used in health services or informal milk sharing arrangements because mothers and staff were unaware of them or they offered limited protection ('We can't deny culpability' LC02, health professional). The few that used waivers felt they were provided grudgingly, and changed relationships with institutions, as shown in the findings on consent (section 8.2.4.1.1). Waivers did not address safety issues or convey respect for the mother's feeding intentions. This abandonment was seen as hypocritical and left mothers questioning the motives of medical authorities to just 'cover their own arses' (MACTY, recipient mother).

Safety risks

These intense conflicts over consent and legal liability were ultimately tied to conflicts about the safety of milk sharing. Safety in milk sharing was a vast topic, which the data showed had complex effects on actor pathways, which are summarized here.

As shown in Chapter 5, laws and policies for infection control restricted legitimate pathways to share milk to milk banking and 'directed donation'. When these options were not available, mothers and health professionals had to assess and manage the safety of informal milk sharing for themselves. These assessments reflected their awareness of risks and motivations around infection control (chapters 6 and 7). When analysed using concepts from risk analysis (704), subtleties emerged in how actors assessed harms, consequences and likelihoods, and managed and accepted risks. These assessments were underpinned by structural factors, including Australia's public health system and systems of altruistic donation.

Perceived risks and consequences

Perceptions of the risks of milk sharing centred on the risk of transmitting 'blood borne viruses.' Actors were aware of the potential to transmit HIV via milk, but less certain about other hazards. HIV dominated perceptions of milk sharing as dangerous because of its catastrophic health and social consequences when it first emerged in the 1980s:

'It's done terrible damage, and I think things like that still impact on sharing of breastmilk' (SVIC05, policy maker).

The fear of HIV created social risks for mothers, ranging from stigmatization to threats of child removal:

'That doctor was South African, so she's understandably seen a lot more HIV ...she did tell me a few times that I was going to kill him... The doctors [in the hospital] then found out ...that I was using donor milk and tried their hardest to put a stop to it... They wouldn't let me take him off the hospital grounds ...I was just told I'd have Child Services take him away if I did that and bring him back to hospital and formula feed him' (MACTW, recipient mother).

Health professionals and mothers were less clear about transmission via milk of Hepatitis C and B viruses and syphilis and had varying levels of awareness of CMV and HTLV.¹¹³ Milk banks, food agencies and infectious disease experts were concerned that less attention was paid to more commonplace hazards (pathogenic bacteria and contaminants, including medicines, herbal supplements, caffeine, nicotine, alcohol and illicit drugs):

'In actual fact, HIV is probably the least of your worries. 'You're probably more worried about germ contaminants... In actual fact, it's probably easier to assess HIV status ... than it is to work out whether it's a clean bottle. It's probably hard to ask the mother hygiene questions because it's a sensitive topic ' (MB05A, milk bank).

A complexity of framing donor milk as potentially harmful was the risk of portraying breastfeeding as unsafe. For example, associating milk with blood risked over-regulation of milk:

'We have to get a very careful balance... that they're not actually doing [milk] a disservice... [Milk] is not blood... as special or as dangerous ...as blood... it is a food and it is a natural, normal food that shouldn't be feared for babies. So it's getting a balance, that we don't actually over-regulate it...that we don't view it as a medicine' (MB05A, milk bank).

¹¹³ Chapter 5 discussed the clinical significance of cytomegalovirus (CMV) and human T-cell leukaemia virus (HTLV) and other infectious agents and differences between antenatal testing and testing by milk banks.

Perceptions that milk sharing was extremely hazardous were framed by policies for the accidental feeding of expressed milk:

'I think [health professionals] are a bit coloured by the Health Department's hysteria ...It's a critical incident, it's a Severity Assessment Code 1. ... if they do give a baby someone else's milk accidentally, the sky falls in... it's always in the paper... The risks are very small, let's just chill out a bit' (SNSW01, policy maker).

One policy maker blamed the media for distorting perceptions of risk by portraying women who shared milk as 'fanatical wackos.' This portrayal also inhibited organizations from discussing actual risks and forced them to project conservative ('measured') positions:

'The media can do a lot of damage. And so, when I talk about managing risk, we need to – sadly – ...come across as very measured, whilst we know how little risk there is with milk sharing, and how so few viruses ...are passed through' (SVIC05, policy maker).

Actual risks and likelihoods

Despite perceptions of serious disease risks, actors assessed the actual likelihood of their transmission via donor milk to be very low in Australia. This was based on knowledge of infectious disease prevalence and universal access to maternity care, which included high rates of antenatal screening and testing for HIV, Hepatitis B, Hepatitis C and syphilis (but not CMV or HTLV). Accordingly, all actors in the study, including infection control experts, assessed the likelihood of transmitting HIV via milk to be 'extremely low' (but not zero) in Australia. This estimate can be quantified as less than 1.4 per million births.¹¹⁴ In addition, mothers who tested positive for HIV were advised not to breastfeed their own child, which theoretically removed them from the pool of potential donors.¹¹⁵ Similarly, experts in infectious disease considered that the risk of syphilis being transmitted via cross-feeding in Australia would be 'an extremely rare event' (SDOH03, policy maker).

¹¹⁴ In Australia, the risk of a randomly selected mother transmitting HIV via her milk is about 1.4 per million births, calculated from the number of HIV positive women who gave birth undetected and untreated:

(a) A baby born HIV positive indicates a mother who was not diagnosed or treated adequately for HIV. Two infants were born HIV positive over 2013-2017 (705).

(b) In this period, the total number of births was 1.46 million (706)

(c) In reality, the likelihood of transmission of HIV through milk would be even less because mother-to-child transmission includes all routes, including pregnancy and birth. In addition, exposures of recipient infants are like to be less than for the donor's own infant because the volume of milk donated is likely to be less.

Studies in countries with a high prevalence of HIV show that the likelihood of post-natal transmission of HIV via breastfeeding to be 18- 25% if the mother was untreated. Antiretroviral treatment of infected mothers and their infants reduced this likelihood to 1- 2% (707).

¹¹⁵ Guidance for HIV positive women who want to breastfeed their own infant in Australia was developed after this study (708)

Overall, the experience of receiving or providing maternity care underpinned confidence in the health of donors by mothers and health professionals:

'If you want to know somebody that's most likely pretty healthy, talk to a woman who's just had a baby - because she will have gone through a lot of health checks' (MWAZ, donor and recipient mother).

However, some policy makers were concerned that, despite national guidelines for antenatal care, these were not consistently implemented:

'It's in the Commonwealth Guidelines, ...so mostly women get screened but the universality is not always there...The quality of antenatal care varies hugely across the country, depending on where you are and who you're seeing. ...But I'm sure ... many women would know what they've been tested for, and so would be perfectly able to participate in milk sharing on an informal basis' (SNSW01, policy maker).

Others trusted mothers to know and not donate milk if they were infected (as discussed in chapter 7 on motivations):

'You'd have to be a pretty nasty mother to have had a positive test for something and donate milk... and that probably doesn't happen' (SSA1, milk bank).

The likelihood of microbial transmission via milk was further reduced by milk handling practices, including freezing and thawing milk, which reduced the viability of some viruses, notably CMV and HTLV.¹¹⁶ In addition, specific conditions applied to some hazards. For example, HTLV occurred at high prevalence in some Central Australian Indigenous communities, an issue that prompted a local forum with federal policy makers to ensure that perceptions of its risks didn't threaten breastfeeding (SDOH03, policy maker):

'There was a consensus statement...The idea was to try to...combat some of the alarmist messages about advising against breastfeeding in those communities that are already suffering from great food insecurity, access to safe water et cetera. ...A big part of the that forum was ensuring that Aboriginal voices were leading how we address this...they felt they needed more evidence about the associated risks' (SDOH03, policy maker).

This forum did not address cultural milk sharing practices but provided a rare example of policy coordination for infectious disease control and infant feeding. In general, such coordination was

¹¹⁶ Freezing and thawing milk to feed to their own infant was recommended in policy for breastfeeding mothers who were HTLV positive ((649)

difficult to achieve and policy prohibitions on informal milk sharing remained, driven by persistent fear of HIV:

'it's a shame that so many babies are missing out because of that very tiny risk...But...I think when HIV first came out... all the Grim Reaper ads ... it was real scare ...and we need to revisit this' (MW06, health professional).

Managing risk

To mothers who shared milk, risk needed to be managed in ways that were appropriate for different categories of infants, ranging from well infants in the community to medically fragile infants in hospitals:

'If you believe that 'breast is best' then a way of sharing milk should be supported, within some kind of framework that assures people that what they're giving to infants who are incredibly fragile, is safe' (MACTX donor mother).

Milk banks manage risk for premature infants through donor screening and testing and pasteurizing and testing milk. Donor screening included an anonymous online questionnaire about the donor's lifestyle followed by a face-to-face interview and blood tests for HIV, Hepatitis B, Hepatitis C, syphilis, HTLV and sometimes CMV, which were repeated every three months by some milk banks. These protocols were broadly consistent between milk banks, but a lack of national milk banking standards at the time meant that some milk banks had more stringent measures which gave them a competitive edge. Variation in microbiological testing procedures and thresholds used by milk banks also affected the proportion of milk they discarded (6.8% - 35%) (Milk banks MB03 and MB01) to ensure its safety for extremely vulnerable infants:

'There's always going to be some [bacterial] growth and [it] probably doesn't matter in a term bub or a mother's own baby, but in a 600 gram baby it will' (MB03, milk bank).

Milk banks regulated under food legislation described requirements for food safety:

'We are regulated as a food, so we have a Food License to produce a food, donor milk. We have been audited by [State] Food Authority twice. The first time was to get the license and they did a desktop audit and [then we] resubmitted over 1400 pages of processes and procedures. We have a HACCP plan and Critical Control Points, a Food Safety Program ... our HACCP plan is about 70 pages long, ... and then all our standard operating procedures and work instructions... our managing of the donor, our serology'' (MB05B, milk bank).

Regulating PDHM also required attention to international standards for milk banks, for example federal agencies were watching the regulation of donor milk under frameworks for human tissue and medicines by WHO and the Council of Europe (SACT15, policy maker).

These approaches to managing the safety of milk banks filtered down to mothers who shared milk informally. Many mothers described researching risks and adopting a range of risk management practices. Some used milk bank screening tools, or guidelines from overseas websites for informal sharing. These assessments included judgements about a donor's honesty and lifestyle from direct conversations, or indirectly through relationships, social circles, including social media (checking their profile, timeline, photos of infants and contacts), and, importantly, observations of the donor's infant, home and hygiene:

'When you go to someone's house, you get a really good sense of them as a person, things as a mum you want to check out. So hygiene is one, because you obviously don't want them to live in a manky house ... I've never had any issue with that...And often you see the pumping equipment in the kitchen on the drying rack, and you're like, oh yeah, so they wash it regularly... You more often than not see them feed their baby, so that's like ten out of ten gold ...then you know everything's fine, and you know why they've come to doing it' (MVICR, recipient mother).

However not all of these methods were used consistently. Meeting the donor in person and seeing her breastfeed her own healthy child was 'gold' confirmation of a donor's motivations and health ('If it's good enough for her kids, it's good enough for mine' MVICJ, donor and recipient mother).

Some health professionals with expertise in infection control were sceptical of these judgements:

'Probably infectious diseases people are just very cynical, but to me the lifestyle of the mother doesn't tell you anything about the lifestyle of the partner' (SSA02, health professional).

And some mothers were similarly cautious:

'I know of other mothers who have acquired milk through milk sharing, and then are not game to use it, in case it's contaminated. ... So there's that doubt' (MB02, milk bank).

In general, mothers' approaches to safety were modified by relationships. The closer the relationship between donor and recipient mothers, the less formal screening was used. In all situations, mothers had to overcome inhibitions about asking intrusive questions. Most donors volunteered information about their health and antenatal testing and many showed their test results:

They all, before I even ask, say, 'This is who I am, this is my baby, this is why I have so much milk. I'm healthy' (MACTY, recipient mother).

A recipient's trust was reinforced by what the donor disclosed ('The lady who smokes, her husband doesn't even know' MACTY, recipient mother). Most donors acted conservatively when they took medicines or other substances and labelled or withheld milk, using information from a range of medical sources. Some recipient mothers accepted milk with a level of contamination, for example, if she took the same medication, and then titrated affected batches of milk:

'Initially, I did turn down milk when a mum was taking antidepressants... there are small traces in there, Zoloft, usually, and I know it's safe for their babies. ...For a while I was trying to avoid it, and now I'd just space [the batch] out more' (MVICL, recipient mother).

In informal arrangements mothers did not feel that a lack of additional blood testing compromised safety to any great extent and did not use methods like 'flash heating' of milk routinely. These mothers perceived the risks from bacterial contamination of milk to be low, based on their experience of managing expressed milk safely and observing the health of their own and recipient infants. In addition, donors to milk banks and mothers in the community used similar guidelines for hygienic handling of milk. Additional blood testing was rarely undertaken by donors because of the restrictions of costs, time and logistics (as described in section 8.2.3) and most recipients felt uncomfortable about asking altruistic donors to be tested ('It feels wrong to be questioning gifts' MWAR, recipient mother).

Mothers also acknowledged that desperation could compromise safety management practices:

'When we needed the milk, we were so desperate for it at the time, it wasn't that we could, say, meet up and have a coffee and then we'll chat and then maybe we'll accept your milk ...Because it was so rare to actually find milk. ... we just said 'Alright, we'll take it on any condition, when can we come?'" (MWAQ, recipient mother).

Acceptance of risk

Following the risk management measures described above, residual risks remained in all forms of milk sharing. An actor's final position on risk depended on their risk 'appetite,' which depended partly on the vulnerability of the infants in question:

'There's a huge difference in informal milk sharing and milk banking because of the population that we're sending the milk to. ...A mum in a community who's feeding her friend's baby, ...a toddler ...is way different to feeding a 500 gram, 25-weeker in an intensive care unit' (MB01, milk bank).

Risk appetite was also shaped by institutional and social factors. Health institutions had a low tolerance of risk, and some health professionals with expertise in infection control adopted a 'zero tolerance' approach ('I consider every case of disease transmission to be a failure, if it's preventable' SSA02, health professional). However, other health professionals, especially those with expertise in lactation, were more likely to consider the relative risks of infant feeding options. This range of acceptance of risk was illustrated in a NICU when a policy for unpasteurized donor milk was developed:

'We came up with our own ...framework to ensure that we have a process, so that everyone doesn't freak out...There's a couple of doctors who are very upset about it, they think it [milk] should be discarded and not used... Yet when we first developed the policy, one of the neonatologists said, 'Oh my God, this is much ado about nothing!' (LC03, health professional).

Mothers also varied widely in their acceptance of risk. Some recipient mothers would only use milk banks. A few donors who shared milk informally refused to consider it for their own child. In weighing up the risks of different types of shared milk, mothers had to also contend with their accessibility:

'A friend in my mother's group... told me about ...that private milk bank, and I looked into it, but it was \$80 a litre which was just prohibitive... And then I went to a baby-wearing group, and they all offered me donor milk. And so I said to my [health professional] friend, 'How amazing is that?' And she went, 'Oh, don't you think they'd be a bit alternative?' ...implying that they might have recreational drugs in their milk. And that put me right off. I stopped researching and I just said, well I'm using formula' (MQLDW, recipient mother).

However, as other example in this chapter show, acceptance of the risks of informal sharing could change with guidance and experience. Other mothers considered the risks of milk sharing insignificant compared with risks around childbirth or other issues they faced as parents:

'I would feel [more] nervous putting my kids in the car [and] driving down the highway than giving them donor milk' (MVICP, donor mother).

Government agencies also accepted their limited control in managing risk ('it's actually very hard to do anything about' SDOH01, policy maker):

'I guess we sort of work in a space where we can't make people do a whole lot. It's more about just providing them the information so they can make an informed choice about what

they're going to do next... just around infection control in general, handling stuff cleanly, as you would with any food' (SDOH04, policy maker).

Health authorities were also wary that prohibitive approaches to informal milk sharing could result in public backlash:

'It's a double-edged sword. I can see if Health Departments went hard saying 'Be careful because there can be diseases transmitted in human milk ... there could be a backlash from the groups who think informal sharing is the way to go. So I think you don't 'awaken the beast' in this area.... They could react, in the sense of saying, 'This is a very healthy thing to do, WHO recommends [it], why are you scaring mums?'" (SDOH01, policy maker).

The analysis of risk revealed its effects on almost all other resources and rules in actor pathways (Figure 8). The management of risk always carried costs and restricted access to milk. Risk drove ethical rules for consent and legal liability, which kept medical oversight and organizations at arm's length, leaving mothers as the major bearers of risk. Risk also polarized actors and the dearth of harm minimization policies fostered covert milk sharing. However, when precise concepts from risk analysis were used, there was more agreement between actors about the likelihoods and consequences of harms, and differences emerged in actors' acceptance of risk. However, risk was not sufficient to explain the pathways taken by actors. The next section focuses on how actors balanced the competing demands of risk with other resources and rules, using the concept of actor mind-sets.

8.3 Pathways -actor 'mind-sets'

Pathways were also shaped by actor 'mind-sets,' or overarching principles (218, 219). In milk sharing, three main mind-sets emerged from the data, based on attitudes to efficiency, pragmatism, risk. The need for *efficiency* arose from limited resources (milk supply, maternal time, logistics or funding), while *pragmatism* was a principle based on 'what works,' driven by the urgent biological, social and legal imperatives to feed infants. A third organizing principle was *risk*. Tensions between these principles for efficiency, pragmatism and risk resulted in mind-sets that inhibited or enabled milk sharing. The proposed mind-sets that shaped pathways to share milk were characterised as inhibitory ('avoiding trouble') or enabling ('low hanging fruit' and 'can-do') (Figure 7).

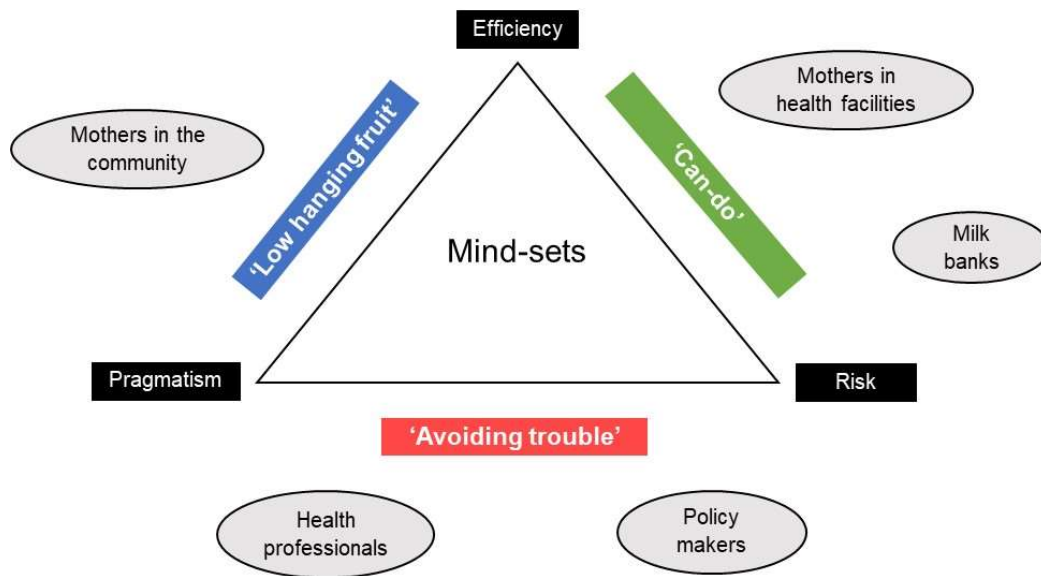


Figure 7 Mind-sets ('avoiding trouble,' 'low hanging fruit' or 'can-do') that characterized the pathways of different actors, according to tensions between principles of efficiency, pragmatism and risk.

It is important to emphasise that risk was present in all mind-sets to some degree, but dominated the mind-set of 'avoiding trouble,' indicated by the red box in Figure 7. Risk was present but less constraining in 'low hanging fruit' and 'can-do' mind-sets, and accepted or overcome, as indicated by the green boxes in Figure 7. For example, 'avoiding trouble' and 'can-do' mind-sets described the different approaches to risk of nurses to cross-feeding:

'So the day nurses were really anti-milk sharing, that it was very dangerous, very aberrant... But the night nurses were just a completely different mind-set. They were really relaxed... They said, 'This is fantastic, it's about time they started thinking about this'' and seemed to have more breastfeeding study behind them (MACTV donor and recipient mother).

8.3.1 'Avoiding trouble'

A mind-set that inhibited milk sharing was 'avoiding trouble,' characterized by risk avoidance combined with a defeatist form of pragmatism that saw barriers as insurmountable (Figure 7). In policy making and the health system, an 'avoiding trouble' mind-set focussed on legal liability and was fearful and inflexible. Structures of governance could help avoid political trouble. For example, devolved models of health administration were seen by one policy maker as a way for State and Territory governments to avoid responsibility for a lack of access to milk banks:

'Essentially there is a devolved model in most places... At a cynical level, it's because the government doesn't want [it to] be the government's fault on the front page of the newspaper. ...Now the government can say...it's actually 'X' Local Health District's fault, it's their responsibility to roll out services ...like milk banks. It's not our call' (SNSW01, policy maker).

For individuals, institutions or organizations, this mind-set contributed to policy paralysis, and inhibited problem solving and collaborations to tackle risks. 'Avoiding trouble' exposed the lack of pathways to resolve threats for these actors and maintained the status quo.

However, avoiding trouble had wider regulatory consequences and risked the loss of moral authority and disengagement of actors. Mothers and health professionals perceived risk avoidance by institutions, for example legal waivers, as authority ignoring structural problems in infant feeding and as a form of abandonment:

'What women do in their own homes is up to them. It's a hospital protocol. You know, we need to just cover our backsides' (LC02, health professional).

For some mothers, milk banks and NGOs lost authority when they distanced themselves from informal milk sharing, and their concerns were dismissed as 'fear mongering' (MWAS, donor and recipient mother). Mothers themselves avoided trouble by removing themselves and their voices from hostile environments:

'Oh no, family didn't know that I did, because I was at my [relative]'s place once and ...he said ... 'I would never get milk off some stray woman to give to my baby' ...thinking other women are disgusting' (MVICP, donor mother).

8.3.2 'Low hanging fruit'

A mind-set that enabled milk sharing was picking 'low-hanging fruit.' This mind-set exploited existing rules and resources and was dominated by opportunistic pragmatism and efficiency, with risk a lesser concern. Actors followed this mind-set when they shared milk only if it was 'easy:'

'She lives just around the corner, so it was good for both of us. She was in a share house at the time, so freezer space was limited. She had to express because her letdown was too forceful for her baby to manage, so I was just relieving her of the milk that she couldn't store. But then once her baby went to day care, there was less for me' (MQLDW, recipient mother).

In this mind-set, actors leveraged existing resources, for example public investments in safety, maternity care and paid parental leave. Adding a milk bank to a blood bank leveraged existing

facilities, technical skills and logistic capacity. Another milk bank found the easiest route for regulation was to use existing requirements for food services and ISO accreditation:

'We've sort of aligned ourselves more with food services because we had a very helpful manager that helped us do the HACCP controls in the hospital. And we ended up piggy-backing onto the hospital and getting ISO 22000 accreditation. ...We haven't gone down the route that [other milk bank] has and registered as a food business because I think that caused more problems for them than it fixed' (MB03, milk bank).

'Low hanging fruit' cropped up in social and policy environments that accepted milk sharing as safe enough, and enabled actors to capitalize on available stores of milk, relationships and knowledge, for example, a milk bank that obtained surplus milk from NICU freezers:

'We had a picture that we would have the one-off huge donations from NICUs, because ...when they get to go home to a lower acuity facility, they can only take 5 litres of milk on the plane with them ...and you would literally throw out 10-40 litres of milk' (MB05B, milk bank).

Despite enabling milk sharing, the 'low-hanging fruit' mind-set was shaped by resource constraints. Consequently, this mind-set excluded mothers with little time or who lacked a car or help. For these mothers, milk sharing could only occur if it was local or interactions with milk banks or mothers were efficient and without 'drama.' Similarly, (219) theorized that institutions had a natural tendency to use existing pathways and adopt 'low-hanging fruit' mind-sets, which reduced innovation and investments in new pathways, for example new milk processing technologies, schemes to compensate donors or resolve regulatory conflicts:

'There's no legislation that says what human milk is. ...Nobody's made any decision... nobody's challenged anything, and we haven't needed to, so nobody's bothered to change. ...They were all involved in that position statement of 2014, and nothing came from that. It's easier not to do anything than to push the issue, isn't it?... You don't want to go in and poke the bear if you don't have to' (MB03, milk bank).

Low hanging fruit mind-sets prevented policy makers from tackling the complex causes of social inequities in breastfeeding, which donor milk was unlikely to solve:

'Addressing vulnerable or disadvantaged communities is harder in terms of not singling people out, as being different or difficult or problematic or needing to be solved in a different way. ...Not wanting to breastfeed is part of a larger social thing around disadvantage...When you're in a vulnerable situation and there's 25 crazy things going on

around you, breastmilk is going to be well down on the list... I'd be bailing out too, I reckon' (SNSW01, policy maker).

Self-regulation was a form of low-hanging fruit that government saw as responsive to a sector's drivers:

'It might be because the sector's expanding too fast and that someone needs to put the brakes on that a little bit. ...The regulator can get involved but then step back if the drivers change' (SACT15, policy maker)

8.3.3 'Can-do'

Milk sharing was enabled by a 'can-do' mind-set. This mind-set was proactive and went beyond the opportunism of 'low-hanging fruit' and escaped the paralysis of 'avoiding trouble'. The 'can-do' mind-set was confronted by risks and resource constraints but overcame them. To overcome barriers, actors with this mind-set were highly motivated, for example by human rights concepts, which drove them to bend the rules and mobilize resources or inspire others and imagine alternatives. These mind-sets shaped pathways that supported an actor's agency 'with relation to their values and the capacities to live out these values,' which were important to how legitimacy and social change were achieved (219).

In this mind-set, constraints from risks and requirements for efficiency were managed actively, for example through harm minimization or new technologies and approaches. A 'can-do' attitude used a knowledge of the rules and found ways to distribute the load through collaborations and social networks. The 'can-do' mind-set was characteristic of many actors in this study, for example those who resisted prohibitions and shared milk covertly, or the committed individuals who overcame legal and funding barriers to establish milk banks.

'if I think about [milk bank], they have established the [research facility] that is internationally recognised...and a very assertive Professor of Paediatrics on the board, who just said, 'We are going to do this.' ...There were some very high fliers with a high level of credibility and so the Health Department said, 'That's OK' (MB01, milk bank).

At a larger scale, a 'can-do' mind-set was adopted by actors who worked to change the system, for example policy makers who developed guidance for directed donation that empowered health professionals, or adopted processes to set research agendas for donor milk that empowered consumers (the recipient families) 'so that the dominant voices get mixed up' (SSA01, milk bank. Actors with a 'can-do' mind-set recognized authority but had sufficient agency to achieve their

objectives. They had a more dynamic relationship with power than actors cowed by the need to 'avoid trouble' or the limited ambition of 'low hanging fruit:'.

'Our position statement, we think, was based on the evidence. The [State] Health Department had a different take on the evidence and wrote a different policy. So the Health Department rang me up in hysterics and [said], 'You have to remove your position statement, it goes against our policy,' And I had to say 'Actually we're not writing it for you, we're writing it for our members and we're a professional organisation that's not beholden to what you tell us. And so we will write a position statement on what we like, thanks very much' (SNSW01, policy maker).

Policy champions, innovators and advocates exhibited 'can-do' approaches:

'These hospitals... were going to pay into this pilot, but then when [State] Health found out they said 'No, if we're going to have milk for preterm babies then all NICUs in [State] need to have access.' ...Someone new comes into a position and it's almost like the whole mood changes...so they're the people that have moved into those positions and have facilitated or prioritised human milk and lactation, ...this shift in attention' (MB06, milk bank).

8.4 Summary of analysis of pathways

8.4.1 How pathways regulated milk sharing

This chapter described the complex factors that shaped the pathways of four actor groups involved in milk sharing (mothers, milk banks, health professionals and policy makers). These factors included resources, rules, and overarching principles or mind-sets used in different milk sharing sectors (Table 10 and Figure 8). When these elements of pathways were disaggregated, the analysis showed how small shifts in resources or rules could change the pathways available to an actor, and the settings and conditions in which they shared milk –openly or covertly, with support or shame, and in ways that supported breastfeeding or displaced it.

The analysis showed that although milk banking or informal sharing appeared to be very separate courses of action, they were based on shared resources and common rules. All forms of milk sharing relied on maternal resources: their supply of donor milk, time, logistic capacity, equipment and relationships. Mothers without these resources faced physical constraints on how they allocated and accessed milk. Actor pathways were also shaped by legal and social rules about milk allocation and access, its costs and safety. Overall, these rules and policies created high levels of social and business risk, regulatory and cost burdens for donor milk.

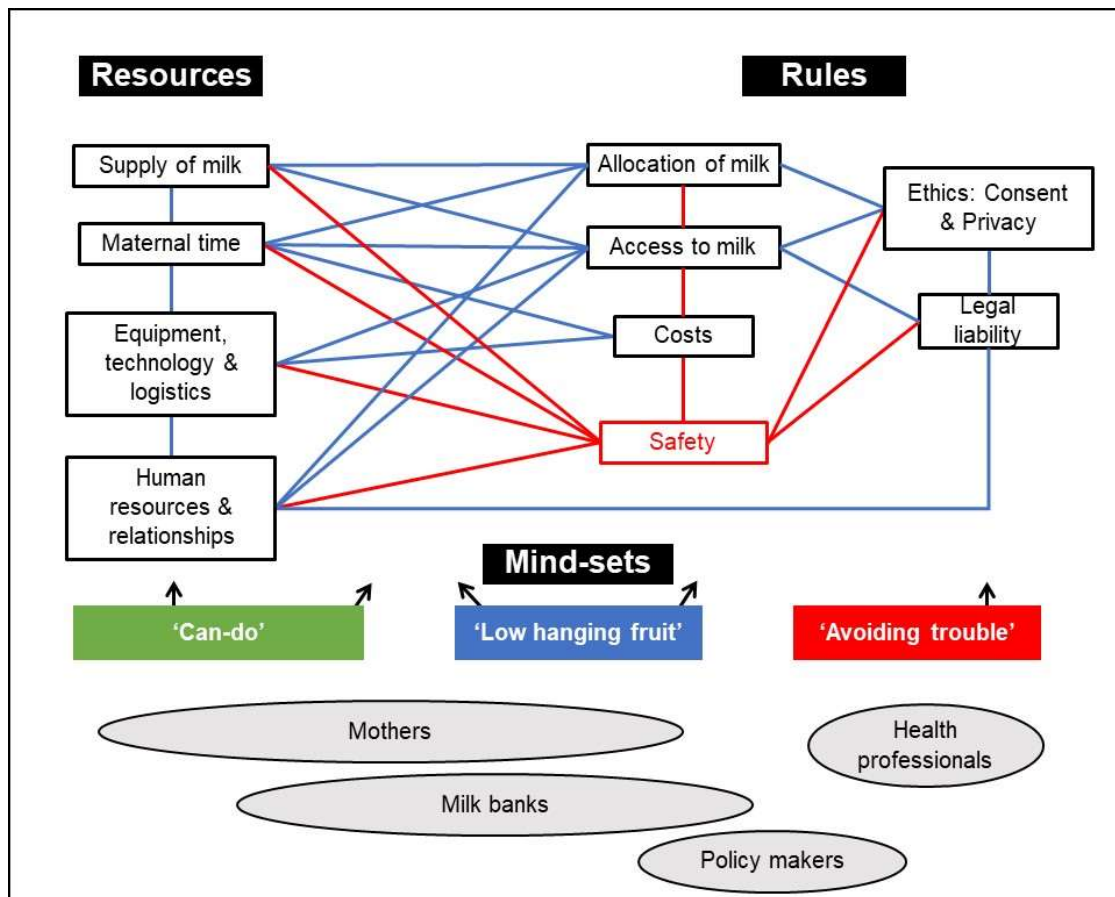


Figure 8 The resources, rules and mind-sets that shaped pathways for four actor groups (mothers, milk banks, health professionals and policy makers).

In all milk sharing sectors, mothers bore a large proportion of the costs of milk exchange and safety, which were additional to the costs of breastfeeding and caring for infants that were subsidized by the state (through paid parental leave, public health and maternity care).

In addition, power imbalances in milk exchange were addressed through rules for informed consent and respect for privacy. However, these rules also created broader problems in the management of power, by requiring anonymity and reducing transparency in milk banking, or limiting options for donor milk in health settings. On these issues, mothers lacked pathways to participate in decisions about milk sharing policy and governance and challenge medical power.

All actor pathways were shaped by rules about safety. The primary focus in safety was the risk of infectious disease but other risks (legal liability, business and social risks) restricted actor involvement with informal sharing. Arguably, risk averse institutions, health professionals and policy makers forced mothers to rely on alternative forms of legitimacy and support, driving informal and covert milk sharing practices. When polarized actor positions on risk were analysed in more detail, it

was shown that assessments of risk needed to be appropriate for different categories of infants, and informed by the practices of mothers. The analysis showed there was more agreement between actors about actual levels of risk and that differences arose from an actor's acceptance of risk. These differences in acceptance pointed to social and political reasons for a lack of pathways to use unpasteurized donor milk, indicated by health system failures to support breastfeeding and to restrict commercial power in infant feeding.

The data on pathways showed the intersections of actor agency with structures. These intersections invariably revealed structural barriers to breastfeeding, including siloed policymaking and commercial, institutional and research interests invested in CMFs and milk. There were few pathways to handle complexity and build coalitions of expertise around milk to strengthen its governance. The ways that actors responded to these various constraints depended on mind-sets, which explained how some of the least powerful actors addressed power and neglect in the regulatory regime for milk sharing. Mind-sets relevant to milk sharing were guided by efficient use of resources, pragmatism, and sharply different responses to risk. This open framework of resources, rules and mind-sets showed the dynamism of pathways, and how they were not necessarily tied to actor groups (Figure 8).

8.4.2 How pathways for milk sharing affected breastfeeding

The analysis showed that pathways for milk sharing in Australia affected breastfeeding in two ways: in the community, informal milk sharing supported breastfeeding because it was deeply connected to breastfeeding practices and culture, while in institutions, milk sharing was disconnected from breastfeeding and made it more likely to displace breastfeeding practices and policy (Table 10). Overall, pathways for milk sharing that supported breastfeeding were pathways that enabled and empowered breastfeeding mothers.

The analysis showed that mothers, and sympathetic health professionals, overcame their limited agency by using resources, rules and mind-sets to circumvent institutional power, and which embedded milk in knowledge, relationships and cultures of breastfeeding. In contrast, many health professionals and policy makers displayed a lack of agency in the face of institutional risk aversion, medicalization and commercial interests, and a powerlessness to resolve policy conflicts within milk sharing, leaving it disconnected from breastfeeding. The pathways of these actors, and those of milk banks, had tenuous connections to breastfeeding communities, and promoted the extraction of milk without investment in its production.

Importantly, the analysis showed that pathways were not just about the acquisition of milk, but about its governance in ways that maintained milk's symbolic meanings and relationships with

breastfeeding. These pragmatic, relational and political pathways tipped the triangulated balance of power in infant feeding, (described in chapter 1), towards or away from breastfeeding. Pathways to share milk were complex, costly and more ethically and legally difficult than pathways to use CMFs. Shared milk was under-promoted, over-regulated and less available, compared with CMFs.

Consequently, pathways for milk sharing that were disconnected from breastfeeding's physiological and sociocultural processes could easily displace breastfeeding, or mask inadequate breastfeeding protection, support and investment. Actors described the weaknesses in Australian breastfeeding policy and implementation, which, arguably, created the conditions that diminished milk sharing and favoured CMFs: inadequate breastfeeding support and health professional education led to a lack of milk sharing policy, which made milk sharing inaccessible and risky, leaving CMFs to fill the void. In this way, milk sharing was signal of policy failures in infant feeding rather than a symbol of success.

In this unstable infant feeding policy environment, the importation of milk threatened both domestic breastfeeding and milk sharing. Importation also distracted policymakers from investment in breastfeeding. Importation exposed weaknesses in Australia's legal frameworks for milk, designed around trade rather than the protection of domestic milk banking and breastfeeding capacity. Siloed policy approaches and mindsets of 'avoiding trouble' or picking 'low hanging fruit' failed to tackle these bigger issues: the governance structures that made milk a threat rather than a bridge to breastfeeding. Overall, pathways to share milk did not address political and structural barriers to breastfeeding. The next chapter examines how this regime was shaped by rewards for sharing milk.

Chapter 9. Results: Actor rewards for milk sharing

Chapter 9 examines the rewards derived for engaging in milk sharing and the processes that shaped these rewards for four actor groups. Rewards are defined as the 'benefits and payoffs that either had been realized or expected' and which provided 'positive feedback' to actors to sustain their action or position (218).¹¹⁷ As observed in Chapter 7, rewards overlapped with motivations when rewards were anticipated and operated as incentives. Rewards were tangible (for example, gifts) and intangible (for example, positive emotions) (summarised in Table 11). The principal tangible rewards of milk sharing for mothers and milk banks were the health of recipient infants and the ways that milk sharing supported breastfeeding. However, beyond the benefits of donor milk to NICUs,¹¹⁸ policy makers and some health professionals were uncertain about the wider value of milk sharing. At the time of the study, there were few financial rewards for any actors engaged in milk sharing in Australia. Emotional and social rewards were important for mothers who shared milk informally, and these rewards created the positive 'relational' context in which milk sharing supported breastfeeding and maternal mental health. The reasons for these limited rewards or 'slim pickings' are explored throughout the chapter. Actors described biological processes and sociocultural, policy and political economic factors that structured rewards (Table 12, p.206). These factors reinforced altruistic informal sharing but enabled the emergence of commercial interests in milk banking, revealing tensions between social and commercial power in infant feeding.

The first sections of this chapter describe the tangible and intangible rewards for actors, followed by a discussion of the factors that shaped them, and the explanatory power of rewards: as indicators of actor interests and behaviour but not the whole story. As previous chapters have shown, actor awareness, motivations and pathways also shape 'what actors do.'

¹¹⁷ The links between Motivations, Pathways and Rewards are illustrated by the observation that following an available pathway requires incentives and 'demonstration of its value' (219) p.678.

¹¹⁸ Neonatal intensive care units

Table 11 Rewards for engagement in milk sharing for four actor groups, and their effects on breastfeeding.

Rewards		Actor groups			
		Mothers	Milk Banks	Health Professionals	Policy Makers
Tangible	Infant health	Response of individual recipient infants	Response of recipient infants (in NICUs)	Response of individual recipient infants?	Uncertainty about effects on infant health (outside NICUs) at population scales
	Gifts	Incidental gifts	-	-	-
	Financial	Milk storage bags for donors	Reduced costs of NEC to NICUs	Insurance restricts fees for private lactation consultants	Cost savings to health system? Trade?
	Emotional	Relief, happiness, gratitude, satisfaction	Job satisfaction	Maternal mental health	-
Intangible	Social	Social support, connection, maternal identity, empowerment	-	Maternal mental health	-
How actor rewards for milk sharing affected breastfeeding					
Direct effects on breastfeeding		Supports breastfeeding, if provided with lactation support and social rewards.	PDHM supports breastfeeding, if provided with lactation support.	Donor milk supports breastfeeding, if provided with lactation support.	Uncertainty about rewards from donor milk or its relationship to breastfeeding outcomes.
Effects on competition between breastfeeding and CMFs		Health and psychosocial rewards and altruistic donation make milk sharing more competitive with CMF.	Without lactation support, PDHM displaces breastfeeding.	Without lactation support, penalties and limited rewards of milk sharing for health professionals favour CMFs	Limited financial rewards from milk sharing do not change competition between health and trade in infant feeding policy, which favours CMFs.

9.1 Tangible rewards

9.1.1 Health

The most important tangible reward of milk sharing was the health of infants. As described in the chapter on motivations, health practitioners reported evidence of the use of PDHM rather than CMF in NICUs as reducing infant morbidity and mortality from necrotizing enterocolitis (NEC) and some other medical conditions associated with prematurity. Among community participants, the effects of shared milk on the health of full-term infants were anecdotal. These benefits were not apparent to policy makers without systematic population-based data that covered health outcomes over the lifespan.

Mothers, milk banks and some health professionals reported individual recipient infants as having less illness, improved weight gain, more settled behaviour and achieving developmental milestones ('thriving', 'happy'):

'We've had babies that have had terrible eczema rashes and things, and then a week or two of breastmilk and it's completely gone. Babies covered because they're scratching themselves the whole time... awful. Unbelievable to see the difference, the change' (MB02, milk bank).

These outcomes reassured actors of the safety and value of milk sharing but relied on reporting pathways, for example clinical reports. In informal arrangements, ongoing contact between recipient and donor mothers was important to sustain long-term donation:

'Seeing the difference with [infant] when she started on my milk and she went from losing 13% in her body weight; gaining nothing, and then, within a week of being on my milk, was 20% up above her previous weight – just in a week. ...It was wonderful to see.... and they kept me up to date with her progress, and every other day would send through another photo' (MWAU, donor mother).

In addition to the response of infants, milk sharing supported breastfeeding. However, this support was conditional. Milk banks and mothers reported that donor milk supported breastfeeding physically and psychologically, by acknowledging the value of milk and breastfeeding and when accompanied by breastfeeding knowledge and skills:

'Having donor milk helped save our whole breastfeeding journey, really... I think psychologically it helped me to know that even if I couldn't give her a full supply that she was still having breast milk... I'm really glad that we've had that relationship and that bond. She's a very dedicated nurser now' (MWAR, recipient mother).

One milk bank described how mothers perceived PDHM as 'real, because it's mother's milk, ...the milk that their baby needs, it's healthy food,' whereas CMF was seen as 'defeatist' and undermined confidence (MB02 milk bank). To encourage breastfeeding, some NICU staff 'bent the rules' to extend the period of PDHM use beyond clinical guidelines (MB03, milk bank).

However, concerns persisted about donor milk displacing breastfeeding. Reports of displacement in informal arrangements were rare, but milk bank participants reported a wide range of breastfeeding outcomes in NICUs. These outcomes were potentially confounded by many factors (NICU levels, the health of recipient mothers and infants, the introduction of other medical practices). Of key importance was lactation support, with one observing a decrease in breastfeeding rates at discharge when cost cutting in the health system removed lactation consultants:

'I don't think it's got anything to do with the milk bank at all. If you look at the timing, we had huge amount of cuts about four years ago with the state government, and a lot of jobs were lost including a number of lactation consultants. So there's more to it' (MB03, milk bank).

Mothers claimed that milk sharing delivered wider public health and economic benefits to society ('decrease the healthcare budget,' EOF Admin-MVICQ). However, these rewards depended on how benefits, harms and evidence were framed in infant feeding by different actors, for example the economic costs of *not* breastfeeding.

'Having the option to donate milk and help another baby might support their breastfeeding to continue perhaps a little bit longer than what it might have. ...Having access to donor milk in the community setting isn't something that we're in a position to offer, at this time. Hopefully ... in the future, if women are supported with establishing breastfeeding in the early days, even if it's [with] just 100mls of donor milk that they need to get over that initial 24-48 hours, then that would have positive impacts on breastfeeding rates in the community' (MB05B, milk bank).

9.1.2 Gifts

Donors sometimes received small gifts from recipients as an expression of their gratitude ('for helping to nurture my child' MVICL, recipient mother). Recipient mothers routinely replaced milk storage bags, which functioned as 'currency' or 'etiquette.' Less frequently, mothers received flowers, treat foods, baby clothes, picture books or personal care products. Some gifts for longer-term donors were personalized or for their families:

'So I gave the lady who became our long-term donor... things like milk bags and some nipple ointment because she was pumping for us, so it seemed only fair to help with the costs of providing extra milk. Then I got a little necklace for my baby and ...the same for her baby... part of that whole 'milky siblings' kind of idea' (MWAR, recipient mother).

The closest to monetary gifts were shopping vouchers, but these were uncommon and, like other gifts, more acceptable if specifically for the donor's infant. Many donors refused or never received gifts and were concerned that gifts violated principles of altruism, felt vaguely manipulative or made milk unaffordable:

'I don't want mums to feel that they have to be going out and buying milk bags, and chocolates and flowers for all of their donors, and not every time that they receive milk either. ... And I feel like... the first time the milk bags were good, the second or third time I feel like there's maybe a bit of an obligation' (MVICT, donor mother).

9.1.3 Financial

For mothers, health professionals in NICUs and policy makers, improved health outcomes from donor milk delivered indirect financial rewards as 'costs saved,' for example from prevention of NEC, as described above.

The altruistic forms of milk sharing practiced in Australia provided few financial rewards for actors. Milk banks were paid for PDHM used in NICUs but limited to cost recovery, which was covered by the public health system. The sole milk bank that supplied the public used volunteer labour and required parents to pay a 'charitable donation' to cover the cost of PDHM. For health professionals in private practice who facilitated milk sharing, the cost of their services was covered in their consultation fee. Recipient families could not obtain reimbursement for these costs from health insurers (discussed in the chapter on pathways). The lack of financial incentives for privately sourced PDHM or lactation services was seen by health professionals as a structural limitation to the medical supervision of milk sharing in the community (MW01, MW05 health professionals).

Mothers who shared milk informally reported that payment for milk did not occur. One donor was offered money for her pumping time and equipment costs, which she refused (MVICK). Another mother described an unsuccessful attempt to sell milk on social media by a mother from a regional area, who was struggling financially while her infant received medical treatment in a city:

'We were a bit horrified... her child was in NICU, so they were having to pay for their accommodation, so she was trying to cover the costs of that by selling her milk' (MVICT, donor mother).

9.2 Intangible rewards

Strong positive emotional and social rewards reinforced actor engagement in milk sharing. For many recipient mothers, intense feelings of relief and happiness, combined with social support and connection, were reported to be transformative and empowering. Health professionals and milk banks who witnessed these feelings valued their beneficial effects on maternal mental health. Donors and milk bank participants described a high level of 'satisfaction' from their involvement with milk sharing, and in all forms of milk exchange, gratitude was an important reward.

9.2.1 Emotional rewards

Relief

Mothers struggling to breastfeed and anxious to provide an exclusive milk diet felt profound relief when they discovered milk sharing or had an offer of milk ('a weight off your shoulders...a lifeline')

MWAW, donor mother). Recipients using informal arrangements over a long period described the securing a stable supply of donor milk as 'a safety net' (MQLDY, recipient mother):

'But the relief was incredible to have that milk, rather than just pumping and never getting enough... And obviously that doesn't help, being stressed about not having enough, you're going to make even less. And my breaks at work were very limited... I was pumping extra throughout the night and during the day when I was at home with her to make enough for the day when I was at work, which was hard' (MWAQ, donor and recipient mother).

Mothers and milk banks observed the effect of relieving stress on the lactation of recipient mothers in many settings - homes, hospitals and workplaces (above):

'A lot of the time, it's just removing the stress and anxiety on the mother. Provide them with a few bottles of milk, and it just changes' (MB02, milk bank).

'She said that that had done enormous things for her mental health... taken the pressure off her... because she'd been expressing around the clock... she hadn't slept since her baby was born... And she mentioned that the night before she'd almost given in to the hospital because they were coming into her room and putting a consent form for formula in front of her and saying, 'You need to sign this' (MVICO, donor mother).

Happiness

In addition to relief, mothers, health professionals and milk banks recognized happiness, joy and celebration around milk sharing as powerful rewards for those involved:

'And everybody was happy. It's really rewarding, the donors desperately want to donate and the mothers receiving the milk are just overwhelmed. You know its mothers helping mothers' (MB05A, milk bank).

In informal arrangements, these feelings included love and bonds of attachment, including between donor and recipient mothers and each other's infants:

'I said, 'It's been traumatic, I need to give him breastmilk, is anyone able to help?' One call and I was inundated...I was overwhelmed. ...I had friends offer to start expressing, I had friends buy breast pumps ...it was pretty amazing. I felt so overwhelmed with love from all of these people' (MQLDW, recipient mother).

Gratitude

Expressing gratitude was important in informal milk sharing arrangements. For recipient mothers, gratitude sometimes seemed inadequate:

'Sitting there and expressing for I don't know how many hours a day... any cake or flower I can give you is nowhere close to the amount. Like you've given my baby life... so how can I repay you for that?' (MVICX, recipient mother).

For donors, 'simple thanks' was sufficient, but its omission was noticed. A lack of 'proper appreciation' (MVICZ) made the exchange feel like a demand that could discourage further donation. Recipient mothers acknowledged this and many never refused an offer of milk so as not to appear ungrateful. Milk banks understood the importance of gratitude and acknowledged the generosity of donors on their websites. However, donating milk to an institution could feel impersonal, 'like an exchange on the street' (MWAT, donor mother).

Satisfaction

For some mothers, donating milk informally and directly witnessing the effect of donor milk was more rewarding than donating to a milk bank:

'There's something very different about going around to a struggling mum's house and seeing what it means to them when you drop the milk in, compared to just dropping it into some facility' (MACTV, donor and recipient mother).

Donors felt good about helping others ('the warm fuzzies' MACTR, donor and recipient mother) and part of a supportive society:

'The good feeling is enough... it's funny how it actually has grown, it's almost like it snowballs. You do it once or twice and 'Oh, that feels nice,' then you continue doing it because you see the impacts of what you're doing' (MVICT, donor mother).

Similarly, milk bank staff in contact with mothers described relational rewards and job satisfaction:

'When I got into the position of recruiting and having a relationship with donors and still having my relationship with the mothers in the neonatal unit, struggling to feed their little ones, that was the greatest job ever. Because I felt like Robin Hood: I was stealing from the rich and giving it to the poor' (MB05A, milk bank).

Maternal identity

As outlined in the chapter on motivations, some mothers and milk banks described milk sharing as 'an endorsement of motherhood' (MB05A, milk bank) or 'healing' if it helped overcome trauma of a difficult pregnancy, birth, feeding or other postnatal experience for a donor or recipient mother:

'She said, 'I have a strong emotional connection to it, because it had been all that period around her baby being preemie'...and giving it away was a big emotional release, and letting go of that time as well' (MAWX, recipient mother).

For recipient mothers, sourcing donor milk felt like 'success' and 'counted' as breastfeeding (MQLDY, recipient mother), which could mitigate shame, distress, or 'devastation' at not being able to breastfeed as they wanted:

'I failed at direct breastfeeding...[but] I don't have any hang-ups at all towards that because I definitely think I've been very, very, very successful in giving him the best product available that I can source, which is the donor milk...starting from three months to get to eight months before we had to use any formula at all' (MACTW, recipient mother).

Empowerment

For some mothers, the combination of positive feelings, support and reconfigured maternal identity from milk sharing were empowering. In particular, mothers gained knowledge from cross-feeding that provided the 'confidence to dig my heels in' when health professionals were dismissive of breastfeeding problems (MACTV, donor and recipient):

'It really cleared up any lingering doubt that I'd done anything wrong with feeding... it really showed me it was him [infant], and it just wasn't possible, that I had not had the right support, skilled help with feeding at all' (MACTQ, donor mother).

Some mothers described feeling liberated by milk sharing, which helped drive advocacy for change in infant feeding:

'I became really passionate about women who wanted to use donor milk having access to it. So, I started talking a lot about it and breaking down those barriers, I suppose. Because I had those same barriers myself... I felt like I was liberated in some way... formula or artificial milk is so normalised... and it makes me really angry now to be on the other side of that and to be able to see it. So, I guess that's where the feelings come from and my passion' (MWAS, donor and recipient mother).

9.2.2 Social rewards

Social support

Mothers valued approval and practical support to share milk. Approval came from many sources: partners, peers, childcare workers, some health professionals and NGOs, but knowledge and encouragement was most often provided by experienced donors and recipients:

'I told her that it was my first time doing this, I really had no clue what I was doing. So she gave me a few tips and just shared with me a bit about her babies and that sort of thing...and because the original lady was really nurturing and guided me through everything, ... I guess that gave me the comfort that I can go through this, it's not a dodgy thing' (MVICX, recipient mother).

Families and partners were an important source of encouragement for donors and recipients to continue sharing milk and to be their 'champion' when others were 'grossed out' or suggested CMF (MVICX, recipient mother). Donors to milk banks encountered general approval, including from health professionals. Recipient mothers who shared milk informally received less support from health professionals, but valued this when it occurred:

'The maternal child health nurse was very supportive...respectful... She also suggested a local GP clinic ... she has been incredibly supportive of donor milk. She's like, 'It's a great idea, good on you for organising and doing it.'...they've not challenged it or been concerned about it or passed judgement' (MVICL, recipient mother).

Two recipient mothers (MACTW, MACTU) reported positive responses from health professionals with Muslim backgrounds:

'I was getting pretty sick of my experience, and I went out of my way to seek a Muslim doctor because I know that in Islam, in the Koran, it's about the baby's right to breastmilk... So I figured, having all this crappy advice and bad experiences, if I can find one doctor that is Islamic then maybe I'm going to have a bit more support, because it's not seen as such a disgusting, taboo thing...And yeah it was awesome...male doctor, very open to it' (MACTW, recipient mother).

Social connection

A powerful reward of informal milk sharing was friendship and a sense of social connection across time, place and cultures:

'Just the social side, the friendship, and the stories I've heard from women, of why they express or why they donate, has been a wonderful part of it.... I think the experience and knowledge that I've gained through those other women is just amazing. ...And then I made some of my best friends now through milk sharing, which is something that I'm extremely grateful for. And...it's nice, this is the way it was done, and is done in other cultures' (MVICV, recipient mother).

'I posted one day about the multicultural-ness of our experience of milk donations...it doesn't matter whose milk it is because it's all the same, but he's had Asian milk, he's had European milk, he's had Aboriginal Indigenous milk, ...it's been amazing. And I think that's the most beautiful thing, ...that we get together as women and it doesn't matter. It's a baby in need, and it's sharing that love and that's all that matters' (MWAX, recipient mother).

Separate to friendship was sense of 'cooperative mothering' (375) that contrasted with the isolation or alienation of other infant feeding experiences ('Asking the village' to 'share the rearing of children' MWAQ, donor and recipient mother):

'That sense of being connected to other women through this donation was important for me at the time because I was really isolated with [infant]. ... and it was a shared support... It was all through Facebook ...everyone posting supportive comments, it was just nice. It was my first sort of exposure to everyone being on board with the same thing and similar values' (MVICP, donor mother).

One donor thought that flows of information, advice and friendship around milk sharing made communities more cohesive ('networks a community' MWAW, donor mother). For mothers, milk sharing structures provided transformative, co-operative experiences, that contrasted with other experiences of competition and conflict in infant feeding:

'So having that involvement with my community, extended through milk sharing, gives me that sense of pride. ...looking after other mums and each other. We should be empowering each other, we shouldn't be tearing each other down' (MWAW, donor mother).

When examined across the regulatory regime for shared milk, rewards varied widely between actors but were skewed towards mothers. While the benefits of milk sharing to infant health and breastfeeding were critical for mothers and milk banks, these rewards were less clear to other actors. Emotional and social rewards were important for mothers but of limited significance to policy makers. Overall, there were very few financial rewards for health professionals.

The rewards above were defined by what actors considered important and what they noticed or was transparent. Rewards reflected what actors expected for themselves and others, what they valued and their capacity to capture it. Factors that limited or amplified some rewards are explored below.

9.3 Factors that shaped rewards

The material and social rewards of milk sharing were shaped by multiple issues: biological processes, and sociocultural, policy and politico-economic factors for infant feeding (Table 12). These factors

linked micro- and macro- scales of regulation for shared milk, in which women's bodies and social power intersected with global commercial power.

A dominant feature of milk sharing in Australia was the restriction of financial rewards, through altruistic donation and non-profit milk banking ('non-commercial' milk sharing). At first glance, these restrictions were strongly upheld by most actors. However, on further discussion, actors held nuanced positions that challenged non-commercial milk sharing in several ways. In support of their positions, actors described key concepts and issues concerning the value of milk, social goods and harms, the distribution of costs and benefits, competition with CMF and international trade in milk (Table 12). These concepts and issues demonstrated the importance of sociocultural values in shaping rewards, but that these values were conditional and vulnerable to policy that failed to protect weak actors from commercial interests.

9.3.1 Biological processes

Biological processes of lactation determine whether donor milk has a positive or negative effect on breastfeeding. Depending on the way milk is expressed and fed, donor milk affects physiological feedback and behavioural mechanisms that may stimulate milk production in donors and suppress it in recipient mothers. These biological responses are, in turn, influenced positively or negatively by 'spheres of individual, interpersonal, community, organizational and policy environments,' recognized in social-ecological models of breastfeeding (709).

In this study, donor milk supported breastfeeding when accompanied by encouragement and breastfeeding knowledge. In most NICUs, PDHM was provided with support from lactation consultants, whereas this support was lacking in health settings where policy omitted PDHM or prohibited the use of milk sourced informally. In the community, milk shared informally was provided by mothers who were highly successful at producing milk. Their milk, knowledge and skills were typically embedded in emotional and social rewards.

Table 12 Factors that shaped rewards for milk sharing for four actor groups.

Factors that shaped rewards		Actor groups			
		Mothers	Milk Banks	Health Professionals	Policy Makers
Biological	<i>Physiology of lactation</i>	Shared milk supports lactation if provided with lactation support.	PDHM* supports lactation of recipient mothers in NICUs** with lactation support.	-	-
Socio-cultural	<i>Norms and principles</i>	Norms for altruistic donation and fairness. Maternal, cultural and national identity.	-	Medical ethics and institutional norms for altruistic donation of other human tissues.	-
	<i>Social inequities</i>	Social inequities in capacity to breastfeed, donate and access shared milk.	Equity of access for NICUs to PDHM.	-	Limited political and policy attention to social inequities in breastfeeding and access to milk. Limited equity of access by NICUs to PDHM.
	<i>Social structures</i>	Relationships, communities and co-operative mothering support altruistic donation.	-	-	-
Policy	<i>Payment of donors</i>	Believed to be illegal and unlikely.	Restricted by legislation for human tissue in some States and Territories.	Restricted by legislation for human tissue in some States and Territories.	No legal restriction on importation of milk from donors paid in other countries.
	<i>Cost recovery vs profit-taking</i>	Cost recovery of maternal time unrealistic. Profit-taking by mothers immoral. Donors should share in any profits.	Ministerial exemptions allow cost recovery by milk banks. Legal uncertainties for commercial entities, importers.	Salary or professional fee.	Principles of free trade and deregulation Profits allowed if milk legally a food. Organization's position on profit from milk. Recovery of regulatory costs from entities.
Political economic	<i>Distribution of benefits and costs</i>	Donors bear costs. Altruistic donation makes milk more affordable for recipients and milk banks.	Altruistic donation reduces costs. Milk banks recover costs from health system. Recipients pay for PDHM outside NICUs.	Public vs private health sectors. Funding of health professionals with qualifications in lactation.	Free trade and individual choice in infant feeding limit public funding. Public funding for maternal health and Paid Parental Leave, but limited investment in breastfeeding and milk banks.
	<i>Gender equity</i>	Feminist principles of remuneration of women for their labour.	-	Gender discrimination in health policy and insurance cover for lactation services.	Gender discrimination in policies for work of lactation in homes and workplaces.
	<i>Commercial power</i>	Commercial power of CMF undermines breastfeeding. Donor milk competes with CMF. Profit from milk may increase investment in milk but exploit women.	Milk banks lack public funding. Rationalization of milk banks. Competition with imported milk and milk products. Emerging commercialization in milk banking.	Commercial power in health system and maternity care vs political power of health professions with interests in milk.	Commercial power of CMFs vs commercial power of milk on infant feeding policy. Principles of cost-efficiency and self-regulation weaken protection of breastfeeding, milk banks and prevention of exploitation.

9.3.2 Sociocultural factors

Many of the sociocultural factors that shaped actor motivations (chapter 7) also shaped rewards. These included human rights principles, and cultural norms and social meanings associated with milk, motherhood, helping, relationships and social connection. These sociocultural values placed a high social value on milk, maternal time, giving and access to milk but also supported non-commercial systems of milk sharing.

The relationships, friendship and feelings that accompanied informal exchanges of milk were barriers to commerce:

‘Well do you put a price on it? It's almost like do you put a price on love?’ (LC03 health professional).

Altruistic donation was also valued as a moral principle and an expression of national character ('the Australian way' MWAZ). Principles of fairness, namely, to make milk affordable for recipients and competitive with CMF, supported altruistic donation and cost recovery by milk banks. However, realizing these cultural values depended on societal structures ('The 'village' has changed... sometimes you have to pay' MWAQ, donor and recipient).

Social inequities also structured the capacity for altruism, illustrated by the circumstances of the mother attempting to sell her milk (above). Despite publicly funded maternity care and parental leave, several mothers and health professionals thought that informal milk sharing was beyond the reach of many disadvantaged women, for example mothers who were single, without a car or living in a shelter.

Accordingly, few actors supported the idea of donors selling milk and 'commercial' milk sharing. However, opinions varied over compensation and profit-taking. Some donors and health professionals thought that compensating donors was fair, might promote breastfeeding and improve the affordability of milk sharing for donors:

'I have great ethical difficulties ...if you pay somebody for milk. They may neglect their own infant, and I have heard of instances in America where the mother's own infant is on formula while she donates milk to a milk bank that pays her for it... One can pay [mothers] for their time, I guess, and parking and that sort of thing, but I don't see that as payment. I think that's probably just helping out a little bit (MB03, milk bank).

However, some donors thought it would be difficult to provide adequate remuneration for the work of pumping milk:

'Would I pump just for the money? No. ...it's just too much work to be honest... you're better to go and work at McDonalds, you're going to get a better return on your time, absolutely' (MWAY, donor mother).

Profiting from milk was more divisive. Some mothers and health professionals supported compensation or cost recovery but rejected profit-taking on moral and political grounds. However, if profits were made, most felt strongly that donors should share in those profits. Actors referred to US commercial milk banks as examples of unacceptable profit-taking. Others felt that profits would attract investment in milk, and that for-profit milk banks might improve access to donor milk and its acceptance. Actors who supported payment for milk considered price competition with CMF less important, which is supported by the use of PDHM in NICUs but not post-natal wards.

All actors raised concerns that financial incentives (payment to donors or profit by milk banks) risked social harms. These harms included the reduced safety or quality of milk, inappropriate allocation of milk, and the exploitation of women and infants, as highlighted in international trade in milk:

'I do not like the idea of payment. It's just like the blood banks. It opens things up to someone being manipulated or being taken advantage of...the donor...or perhaps her baby might go without, because her partner might want her to donate and get the money from that. I did see something about Ambrosia Milk [in] Cambodia. ...I think we also see in America with the Medolac people, that they were targeting people in very, very poor areas, the African American mums, ...I just don't think anyone should be paid for it. I think it's a gift' (MQLDX, donor and recipient mother).

The interplay of sociocultural and political economic factors appeared in complex positions on commercial milk sharing. One mother worked through this complexity when she heard about a new for-profit milk bank that proposed to pay donors for research into a new technology and sell processed milk to the public:

'If it meant that there was a place to go for mothers who needed breast milk, where they weren't having to put in all of this work to source milk, and drive all over the country ...I believe that that is a good thing. ...My concern came from the payment of the donors, and I just didn't like undermining that quality assurance... I suppose it's not a bad thing if it means that the mothers who are a little bit iffy about informal milk sharing are able to access human milk for their babies. This bigger picture, if more babies are being breastfed... ultimately is that the greater good?' (MVICT, donor mother).

9.3.3 Policy environments

Domestic policies supported non-commercial milk sharing. However, these policies varied between jurisdictions, and conflicted with international frameworks for free trade ('You can't stop trade' SACT11 and 13, policy makers). In jurisdictions that applied Human Tissue Acts to milk, the payment of donors was prohibited but milk banks could recover costs (Chapter 5). Many actors, including federal policy makers, were uncertain about the legality of selling milk and some milk banks had to provide reassurance that they did not pay donors:

'When I was talking to the NICUs they asked about whether our donors would be paid donors, and we said no. And they were all very positive with that.... I think people would just rather attract the altruistic volunteer non-remunerated donor' (MB05B, milk bank).

Non-commercial milk sharing was also supported by non-government actors. From their familiarity with altruistic donation of blood and other tissues in Australia, many health professionals found questions of payment or profit-taking around milk to be 'tricky' (LC02), 'uncomfortable' (MW02) and 'confronting' (MW03). Legal uncertainty around milk meant that the most restrictive rules available were applied. For example, NGOs and companies applied a 'blanket' prohibition on advertising milk or facilitating its sale. Similarly, mothers who believed that selling or procuring milk was illegal in their jurisdiction perpetuated this belief, and social media groups policed non-commercial milk sharing.

However, as discussed in Chapters 6, 7 and 8 on actor awareness, motivations and pathways, policy frameworks that supported non-commercial forms of milk sharing were challenged by international trade in human tissues. Despite WHO guidelines for altruistic tissue donation, policy makers in federal agencies were aware of Australian precedents for compensation of some reproductive tissues and the importation of plasma products from paid donors. Under international rules for free trade, governments had limited control over the importation of commercial milk products. Beyond managing safety,¹¹⁹ 'consumer values' were left to the market around matters of price, the ethics of donor payment, profit-taking, diversion of milk from infants, or exploitation. Policy makers described needing the pressure of public 'outrage' to seek pathways to restrict imports:

'It's really the...media test: if there was some kind of potential for public outrage, that conversation between the Department of Health and Australian Border Force/Home Affairs might see this kind of constraint being applied through implementation of the Customs Act.

¹¹⁹ Safety and suitability or efficacy, depending on the legal classification of the imported milk product as a food or therapeutic good.

But even in the absence of there being a barrier through the Imported Food Control Act or the Biosecurity Act, if there are prohibitions that exist at a state and territory level, it puts a barrier in the way of lawful importation and sale of these products' (SACT11, policy maker).

Overall, these regulatory restrictions on milk removed commercial rewards. In contrast, the commercial rewards of CMFs were clear. CMF's regulation as a food allowed profit-taking and advertising, facilitated by weak implementation of the WHO Code¹²⁰ (710) and subsidies (294):

'If I compare infant formula to donor milk, the donor milk doesn't come with incentives to continue buying, ...the convenience and the access. ...I'm seeing toddler milk ads like at least three to four times a day' (MVICT, donor mother).

Arguably, these disparities in rewards put donor milk as a disadvantage, in addition to constraints on awareness, motivations and pathways to use donor milk, as discussed in chapters 6- 8.

9.3.4 Political economic factors

The rewards of milk sharing were also structured by political economic frameworks that shaped who benefited and paid costs along 'supply chains' for milk (Figure 1 p.12) (240, 294). As shown above, these benefits and costs were shaped by disparities in commercial power between CMF and milk. All actor groups described the power of CMF companies to directly influence policy and shape debates in infant feeding (instrumental power) (255):

'So for us, with the last review, it was the lobbying from infant feeding formula companies... Infant Nutrition Council ...for the women who choose not to or cannot breastfeed, respecting that. And then obviously, on the other side, you have ABA, lactation consultants who are pushing for a much harder line in support of breastfeeding (SACT10, policy maker).

Some actors were concerned that commercial interests in CMF might also threaten milk banks, made vulnerable by a lack of public funding and policy:

'I'd like to see two milk banks in every state...However, the billions of dollars that happen in formula marketing, ...the insidious marketing that would occur, I can even see there would be some sponsorship of milk banking made by a formula company, ...I can absolutely see them sponsoring that. I can see them undermining it for sure: 'In like Flynn!'" (LC04, health professional).

¹²⁰ WHO International Code of Marketing of Breastmilk Substitutes 1981 and subsequent WHA resolutions; WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children 2017

In addition, milk banks exercised instrumental and discursive power in a three-way power struggle for legitimacy between CMF and other forms of donor milk:

‘What's out of hand is that ...[milk]'s got to be pasteurized and it's got to go through all of these processes, so you're actually making it less valuable. So now we're starting to build this whole industry around human donor milk...It's almost like we've had to go through milk banking so that we can so we can get people to accept that [unpasteurized] donor milk is okay' (LC03, health professional).

A few other actors were alert to this industrialization and commercial interests in donor milk. Neoliberal principles for small government and deregulation had left Australian milk banking as a 'cottage industry' (SDOH01) with little governance at the national level and a range of regulatory barriers at lower levels of government (11). These regulations enabled some milk banks to expand, while others were restricted. Arguably, these gaps in supply and governance created conditions for the emergence of semi-commercial and commercial milk banks with scale, resources and political power:

‘The discussions with the relevant Health Departments ...How you are going to regulate human milk in your state and what exemptions are required? ...I guess that's the benefit of having a government relations department within the Blood Service,¹²¹ which has all those relationships already’ (MB05B, milk bank).

Several milk bank participants saw the entry of Lifeblood Milk in the Australian market for PDHM as likely to result in the rationalization of milk banking. This raised concerns about transparency, a loss of local control and the lack of an overarching authority to ensure milk banking served public objectives for breastfeeding ('At the moment, the Red Cross, who knows who they answer to?' MW03, health professional). Others were not opposed to competition between milk banks, if it improved access to PDHM and delivered economic efficiencies:

‘Those milk banks might fold as Red Cross comes on-board. But I suspect that would be a relief more than an issue, because the health system is bearing the cost of running those and they're probably running at a loss. ... I think it would be a lot more efficient use of money and resources to use milk from Red Cross. I doubt very much the hospitals would be too concerned about that’ (SSA01, milk bank).

¹²¹ Later renamed Lifeblood Milk

However, arguments for economic efficiency also supported the importation of milk and milk products ('Why don't we just buy it in?' SDOH01, policy maker). Policy makers saw importation as 'opening the door' to commercial milk banking in Australia, in which supply and demand were driven by profit, rather than the medical needs of infants:

'So once we come to the point where we decide it's okay to bring in this product for neonates, it's the thin end of the wedge ...because if it's okay for our most vulnerable babies, then can't it be okay for ...whoever, just for convenience, wants to buy it?... There are other products that we are aware of in America that are more marketed at muscle builders, it's human milk in a capsule... So there is a potential for an explosion of products derived from human milk which have got nothing to do with babies' (SDOH01, policy maker).

When considering these scenarios, actors were most concerned about coercion and economic exploitation, especially of disadvantaged women in Australia and overseas, but public debate on these issues was limited (143). Commercialisation of milk was seen as potentially driving further inequities in access to milk:

'Is it going to drive that gap bigger? Like are the ones who are lower socioeconomic [status], going to ...have further reduced access, especially if it's commercialised? ...Are the lactation services going to be reallocated ...to these women who are of higher socioeconomic status who are producing excess [milk]?' (SACT10, policy maker).

However, some policy makers noted that all mothers were vulnerable to gender discrimination in economic and social policies that made breastfeeding unachievable in homes and workplaces, and which created a market for donor milk ('we want them back in work to boost the economy' SDOH01, policy maker). Mothers were aware of discriminatory policies that failed to recognize their lactation and care work as lost superannuation, inadequate Paid Parental Leave and lactation support and a lack of Medicare rebates for private lactation consultants. Feminist principles of gender equity and economic security supported payment of women to breastfeed and share milk.

'Well, what's milk worth? Is it \$300 million or \$3 billion it contributes to the economy? ... Women are thoroughly underpaid for their contributions to society, let alone under-respected.... I totally believe in women getting paid... if you are going to provide a service, you'd damn well better be paid for it properly' (MVICZ, donor and recipient mother).

While many mothers and health professionals in the study supported feminist principles to remunerate women (271), they distrusted free markets and capitalism to deliver fair outcomes ('Someone's going to get exploited in there because that's the way that capitalism works...and it will be the woman who supplied the milk' MW01, health professional).

'If it becomes part of business, then I feel it could be open to corruption and difficulty...
What's going to happen if we see the benefits of breastmilk as a commercial business? ...
Who's got the biggest dollar and where will it flow to?' (MW02, health professional).

In addition to distorting policy, capital was likely to invest in the fractionation of milk to develop more profitable products (as had occurred with blood, cow's milk and human milk fortifier), which risked wastage and diversion of milk from infants (SACT15). Rather than risk this plethora of harms, many mothers and health professionals wanted governments to improve support for breastfeeding and milk banks and restrict commercial power:

'And that's the role of government, to take a strong leadership policy and say ...we've reviewed the research, we support this on behalf of the country because we know this is best ...and we rise above special interests and money' (MWAZ, donor and recipient mother).

However, leadership on milk sharing required champions –senior health professionals and policy makers– but, as this chapter shows, for these actors there were few rewards. Without these champions and robust management of all forms of commercial power in the health system, commercial milk sharing remained a 'can of worms' (MB03, health professional) and morally hazardous:

'If I was donating for payment, especially if I was donating to a milk bank, I'd have ethical issues about the way that hospitals interfere with breastfeeding relationships in the first place, ...and financially benefiting from that, ...with me profiting from the way that institutions undermine breastfeeding... for babies that are born at term and then have formula pushed on them, for whatever reason... I wouldn't feel comfortable being part of that' (MVICP, donor mother).

Given these failures, altruistic informal milk sharing was a system that resisted commercial power and demonstrated the power of social rewards. The direct exchange of milk between donor and recipient enabled immediate feedback and emotional and social rewards that sustained a responsive, autonomous system of exchange.

9.4 Summary of analysis of rewards

9.4.1 How rewards regulated milk sharing

Actors obtained tangible and intangible rewards for engagement with milk sharing but these rewards varied between actors (Table 11 and Figure 9). The analysis revealed how rewards were generated and distributed between actors, indicating sites of social, institutional and commercial power within and outside the 'regulatory regime' for milk sharing (Table 12).

The principal material rewards for mothers and milk banks were positive outcomes for infant health and breastfeeding. In all forms of milk sharing, breastfeeding outcomes depended on the provision of skilled lactation support. For mothers who shared milk informally, this support was accompanied by powerful social rewards of feeling being supported, connected and empowered through milk sharing.

Emotional and social rewards also contributed to maternal mental health, which was valued by health professionals who worked closely with mothers. These social rewards relied on contact between donors and recipients in informal exchanges of milk and, consequently, were more abstract in anonymized donation through milk banks.

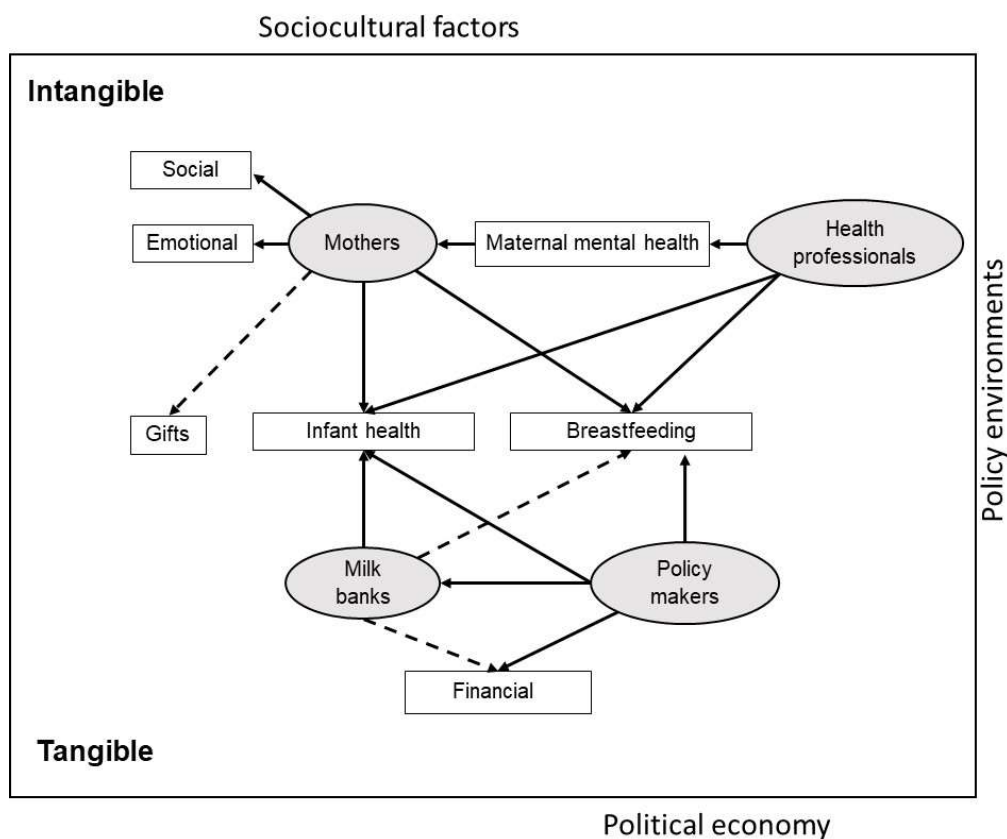


Figure 9 The rewards of milk sharing for four actor groups: mothers, health professionals, milk banks and policy makers.

A major feature of rewards for milk sharing in Australia was the lack of financial rewards. Most actors valued altruistic donation and non-profit milk banking and saw the potential commercialization of milk sharing as complex and harmful. Actors held a range of positions on cost recovery and profit-taking, that were shaped by sociocultural, policy and politico-economic frameworks. Non-commercial

milk sharing was supported by current policy, but this was not consistently applied, leaving gaps in law and governance of milk.

Policy makers recognized international trade in milk and the emerging commercialization of milk banks as key events or 'tipping points' likely to destabilise the current, fragile system of non-commercial rewards, the viability of Australian milk banks and the competitiveness of banked milk with CMF. Most actors raised concerns about negative consequences for the safety and equitable access to donor milk if commercial milk sharing occurred. However, these and other substantial, harmful outcomes (displacement of breastfeeding, fear, shame, stigmatization, costs borne by mothers and exploitation) were not accounted for in the AMPR model.

Actors called for government intervention and public funding to address wide disparities in commercial power between milk and CMF and protect local milk production and milk banking from competition with cheaper, centralized or imported milk. However, intervention to protect local milk production and banking was resisted by governments, influenced by neoliberal principles of deregulation that enabled free markets and individual 'choice' in infant feeding. Government failures to address the infant feeding system's unbalanced rewards, which tilted the 'playing field' in favour of CMFs and disadvantaged milk sharing, was one of the regulatory mechanisms that posed the greatest threat to breastfeeding, of all the regulatory mechanisms for milk sharing identified in this research.

Despite the moral and social value of altruism, and its contribution to the safety and affordability of milk for recipients, altruism came at a cost to donors, as described in chapter 8 on pathways. Some mothers and health professionals raised concerns that altruistic donation perpetuated gender discrimination against women. Milk banks in the public sector returned this social value to the public. However, for-profit milk banks potentially capitalized on this value and distributed it to those who could afford to pay, a system of rewards that sat uncomfortably with Australian values and socialized maternity care and parental support. However, in the face of inadequate government investment in these systems, some actors thought that commercial milk banks had a role in improving access to milk and milk products and promoting breastfeeding (if donors were paid).

When examined across the regulatory regime for milk, the rewards for other actors other than mothers and milk banks were scant (Figure 9). In addition, there was a lack of certainty and coherence in rewards. Arguably, these weak signals contributed to the ambivalence of health professionals and policy makers towards milk sharing. In policy processes, the intangible rewards for mothers were easily overlooked, for example in benefit-cost analyses based on monetized outcomes. Overall, this array of rewards provided disorganized feedback to actors in positions of authority and

reflected the conflicts in motivations and lack of policy integration around milk sharing, described in previous chapters. On the other hand, the direct emotional and social rewards for mothers sharing milk in the community reinforced the autonomous operation of the informal milk sharing sector and fuelled an alternative site of power.

9.4.2 How rewards for milk sharing affected breastfeeding

This rewards analysis has revealed who 'wins' and sites of power in the regulatory regime for milk. The tangible and intangible rewards of milk sharing were shaped by biological processes and tensions between sociocultural, policy and politico-economic frameworks. Across the whole regulatory regime for shared milk, rewards for actors were limited. Emotional and social rewards of informal sharing supported breastfeeding and were powerful for mothers, but few others, and therefore maintained the status quo in infant feeding policy. Apart from mothers and milk banks who witnessed the benefits of donor milk to infant health, most actors received weak or uncertain signals to support engagement with milk sharing, leading to regulatory neglect. This neglect created opportunities for commercial milk banking and trade, but these developments raised concerns about exploitation, and the negative influence of commercial interests in public policymaking. Overall, rewards were important, but not sufficient to explain the way milk was shared in Australia.

Chapter 10. Discussion and Conclusions

The aim of this research was to provide a deep understanding of the complex regulatory regime of human milk sharing in Australia. The lack of law on milk sharing may make it seem ‘unregulated’ but this thesis argues that the issues are more complex if a more nuanced view of ‘regulation’ is taken and that milk sharing is regulated by a range of mechanisms. This research sought to answer the question: *In what ways does the regulatory regime for milk sharing shape breastfeeding in Australia?*

The first section of this chapter briefly revisits the research problem and approach from regulatory, public health nutrition and social science perspectives. The second section provides an overview of the main findings and their meaning, from which three regulatory themes emerged, and interprets their relevance to the academic literature. Section three makes recommendations from this research. Section four discusses the limitations of this study and section five suggests directions for future investigation. The conclusions of this research are set out in section six.

10.1 Approaching the research problem

My research addresses a higher order research puzzle, namely what do we need to know to regulate well? My research investigates this question using the regulatory problem of milk sharing in Australia and how this shapes infant feeding. The example of milk sharing illustrates the need for pluralistic and interdisciplinary approaches to regulate well, while maintaining a clear focus on public health policy objectives.

10.1.1 The regulatory problem of milk sharing

As described in Chapter 1, health authorities promote breastfeeding as the optimal way to feed infants, but Australia has low rates of breastfeeding exclusivity and duration (19). At the same time, sales of CMFs continue to rise (711, 712), contributing to the burden of disease and costs to the health system (21, 30, 34).

Milk sharing developed as two sectors: highly medicalized milk banking providing PDHM¹²² to NICUs¹²³ for extremely premature infants, and supposedly ‘unregulated’ informal sharing by women in the community, facilitated by technological developments in breast pumps and the internet. Milk sharing raises medical and public health concerns about transmission of infectious disease, as well as

¹²² Pasteurized donor human milk

¹²³ Neonatal intensive care units

broader social issues about costs, ethics, trade in milk¹²⁴ and effects on breastfeeding, and a political economy where women are wedged between powerful interests in public health and commerce. These very different sectors and the varied settings for milk sharing present challenges to understanding the complex issue of how milk sharing is regulated and shapes breastfeeding in Australia.

The review of the literature examined these regulatory tensions from the three perspectives: regulatory scholarship, public health nutrition and the social sciences, which represented the broad knowledge systems in which milk sharing was described and problematized (Chapter 2). The review showed that there were no studies of the regulation of milk sharing that spanned both sectors, and limited research in Australia of milk sharing practices following the re-establishment of milk banking and the emergence of social media (62, 66, 83, 97, 264, 713). Uncertainty about the legal classification of milk as a food, human tissue or therapeutic good limited access to milk banks domestically (11) and internationally (88, 89, 214, 215, 231-237). On the other hand, informal milk sharing was a legal grey area, framed in studies as high risk and ‘unregulated’ (beyond the reach of the state) (195, 248). Legal analyses tended to marginalize breastfeeding, although some studies recognized that equitable access to milk relied, ultimately, on adequate policy for breastfeeding (89). Superimposed on this ambiguous legal landscape were ethical debates about the role of markets in the regulation of milk (90, 260, 268), and feminist critiques of altruistic donation (the ‘gift/commodity dichotomy’) (15, 90, 252, 256, 269, 271, 290). An emerging international trade in milk and the COVID-19 pandemic created ethical and logistic challenges for milk banking that encouraged global alliances and the standardisation of guidelines (130, 228-231, 237, 241, 243, 293, 305, 641, 714). However, milk banking agendas remained highly medicalized and marginalized mothers,¹²⁵ prompting calls for their representation (130, 241, 641). Another concern was that donor milk displaced breastfeeding by acting as a ‘substitute’ for breastfeeding policy and investment across all levels of governance, from individual to global levels (307, 326-328, 331).

The literature on public health nutrition described the pragmatic regulation of milk sharing through the management of donor milk risk, acceptability and supply but did not address wider issues of governance. Milk banks were regulated through institutional factors: operational guidelines, clinical decisions in NICUs, benefit-cost analyses of PDHM and concerns about displacement of a mother’s own milk (96, 327, 349, 365, 388, 432, 715, 716). Studies of milk banking in non-Anglophone countries showed the importance of integrating milk banking with health systems (214, 227, 502,

¹²⁴ In this thesis, milk refers to human milk/ breastmilk.

¹²⁵ For example, ‘consumer representation’ was not mandatory in the governance of HMBANA milk banks (238).

717, 718). In contrast, US studies showed a rapid but uncoordinated increase in PDHM use in hospitals, (390-392) and trials of its use in less acute settings (393-399, 470, 719, 720). Despite this expansion, access to PDHM was inequitable and the effects of donor milk on breastfeeding were highly context-specific, depending on infant and maternal medical conditions and lactation support (284, 503, 508, 718, 721-726).

The public health nutrition literature on informal milk sharing had a regulatory focus on mothers' practices and attitudes towards risk, given their high rates of awareness of informal sharing and substantial levels of practice in the USA (280, 367). In Australia, the prevalence was unknown but qualitative studies of altruistic informal sharing practices (62, 80, 97, 364) showed similarities with international studies, which were dominated by research in North America (220, 278, 279, 447, 465). The attitudes of Australian and international health authorities and media reports towards informal sharing were poorly informed about risk management practices by mothers in altruistic exchanges (220) and focused instead on a single US study of contaminated milk sold via the internet, (249, 250, 276, 440). Mothers were highly motivated to provide all infants with exclusive milk diets, manage surplus milk and help other mothers, but their capacity to realize these goals was shaped by logistic barriers to milk banks, access to supportive health professionals and philosophical positions (220, 370-372). The limited involvement of health professionals in informal milk sharing was due to legal liability, inadequate breastfeeding education and 'backlash from colleagues' (220, 276, 279, 454). The role of other actor groups was unclear, with one historical study showing that legal and resource constraints prevented engagement with milk sharing by a key NGO for breastfeeding (78).

Overall, the key finding of the literature review was the need for a more integrated and relevant framework for addressing problems of good governance. The literature showed inadequate frameworks for understanding how the regulation of milk sharing meshed with the structural factors that shaped breastfeeding, despite calls for milk banking to be incorporated into breastfeeding policy (241, 307, 327, 328). Consequently, of the effects of donor milk in health settings (470, 503) and the community on breastfeeding were inconclusive (449, 451). This represented a crucial policy problem of failures to address (and measure) the factors essential to breastfeeding, for example consistent definitions of lactation support and institutional and social barriers (506-508, 510, 717, 718).

The social sciences literature added an understanding of the ways milk sharing was regulated through milk's social meanings. These meanings were shaped by constructions of motherhood and gendered power, that reflected the dominance of studies in WEIRD¹²⁶ societies, which framed milk as

¹²⁶ Western, Educated, Industrialized, Rich and Democratic

‘yucky’ (‘abject’) and milk sharing as deviant (447). Western stigmatization of milk sharing had historical associations with class exploitation, morality, disease transmission and infant deaths from wet-nursing and HIV (69, 727, 728), which promoted the medical control of milk banking. Historical processes of commodification and de-commodification (194, 692) and medicalization (349, 729) and de-medicalization (461), explain the emergence of milk banking and informal sharing sectors in their current form in Europe and the USA. In countries with traditions of cross-feeding, milk sharing was more accepted but cultural and religious rules about milk kinship restricted milk banking (266, 487-490). Arguably, these broad social developments had different trajectories in Australia, where milk banking was delayed and had less hegemonic power over altruistic informal sharing, which was normalized in communities, shaped by multiculturalism and semi-institutionalized on maternity wards until the 1990s (62, 66, 70, 78, 80, 264, 491, 713).

These intersecting strands of knowledge showed the legal and social complexity of milk sharing globally and in Australia, and limited existing frameworks for understanding of how its regulation fitted with public policy and women’s objectives for breastfeeding. To address these gaps, localized research was needed across multiple levels of governance, actor groups and settings, grounded in the experiences of mothers, which is what this study did.

10.1.2 The research approach

This research investigated how the regulation and governance of milk sharing shaped public health objectives for breastfeeding, using Australia as a case study. Australia was an ideal location because of its federal system of government, range of legal structures and diverse milk sharing practices. This work required inter-disciplinary knowledge and research methods from the fields of regulation and governance, public health and infant nutrition, with expertise in breastfeeding.

To investigate the conditions under which the regulation of milk sharing shaped breastfeeding, the research drew on theories of nodal governance (526, 527) which recognized multiple sites of power involved in different types of milk sharing, and the autonomy of mothers to share milk independently of the state. Institutional framing of milk sharing was examined using a document analysis of laws and policies concerned with milk sharing at multiple levels of governance (Chapter 4), and their application in health and community settings using data from key informant interviews of four actor groups (mothers who shared milk, milk banks, health professionals and policy makers from government and non-government organizations). These actor groups, and their associated institutions, were hypothesised as nodes of power.

Table 13 How the research questions were addressed by the analytical methods, regulatory themes and key findings.

Research questions	Analytical methods	Regulatory Themes	Key Findings
<i>How is milk sharing regulated in Australia?</i>			
How do institutions frame milk sharing?	Document analysis of legal structures. Letters to government agencies.	Legitimacy - Legal - Social/biological - Systems of knowledge	Milk sharing is not integrated in breastfeeding policy. Milk sharing outside a milk bank is illegitimate (unsafe, unregulated, obscure or deviant). Milk can be alienated from mothers and infants and their interests. Systems of knowledge held by breastfeeding mothers not valued e.g. feelings, embodiment. Risks not assessed relative to CMFs.
What are the conditions under which milk sharing occurred?	Key informant interviews. Analysis of actor awareness, motivations, pathways and rewards (AMPR framework)	Resistance Object of Regulation - Product - Process - System	Product focuses on safety, displaces donor, diverts milk from infant feeding Processes include physiological and sociocultural aspects of milk sharing and breastfeeding. Systems support safe, affordable, relational milk sharing as legitimate part of breastfeeding.
How does the regulatory regime of actors institutions and ideas shape the way milk was shared?	Synthesis of analyses of legal structures and actor behaviour. Nodal governance.	Power 	Mothers excluded from policy development and governance of milk sharing. Self-regulation enables consolidation of power in milk banking. Limited protection of milk as complex, complete infant food. Market logic enables domestic capacity to be threatened by importation.
<i>How does the regulation of milk sharing shape breastfeeding?</i>			
	Synthesis of themes.	Systems of governance 'Milk Catchments'	Current regulatory regime for milk sharing risks displacement of breastfeeding, by separating milk from breastfeeding relationships, knowledge and support. Governance of milk sharing to support breastfeeding requires structures that enable mothers to control milk.

Within this model of nodal governance, the analysis of how power was exercised drew on theories of organizational behavioural change (218, 219), to understand the factors that shaped actor awareness, motivations, pathways and rewards (AMPR) (Chapters 5-8). In combination, nodal governance and AMPR provided an open analytical framework to understand the nature and direction of power and how individual agency intersected with structural factors to constrain or enable milk sharing.

The study investigated the regulation of diverse forms of milk sharing in health settings and the community for the period 2011-2018, in States and Territories with and without milk banks. The research question was divided into two parts. The first investigated how milk sharing was regulated, using three sub-questions: (1) how institutions framed milk sharing; (2) the conditions under which milk sharing occurred, and (3) how the regulatory regime shaped the way milk was shared. The second part of the primary research question, namely how the regulation of milk sharing shaped breastfeeding, was challenging. These questions were answered by synthesizing qualitative data from the document study and interviews (Table 13).

10.2 Summary of key findings and contribution to the academic literature

Based on the literature review, it was expected that milk banking and informal milk sharing operated as isolated sectors. It was unclear how each sector's laws and policies, ethics and social norms combined to help or hinder breastfeeding. However, my findings show that divisions between milk sharing sectors are more nuanced in Australia. Regulation at the micro-level, through actor behaviour (AMPR), provided insights into macro-level regulatory processes. As described below, these processes were found to centre around four regulatory themes: the framing of legitimacy, resistance, the object of regulation and configurations of power through nodal governance (Figure 10). These findings showed how contested legitimacy and systems of knowledge explained resistance to regulating milk sharing as a product rather than a system. For milk sharing to support breastfeeding, regulators need to address actor resistance by recognizing the ways that legal, social and biological legitimacy support systems rather than products, and various forms of power in infant feeding.

The following sections show how my research complements and adds to the academic literature on regulation, a case study in the field of public health nutrition, and empirical data to studies of milk sharing in the social sciences. The conclusion of the research offers a conceptual framework to understand how these fields of scholarship frame legitimacy, resistance, objects of regulation and power (Figure 10).

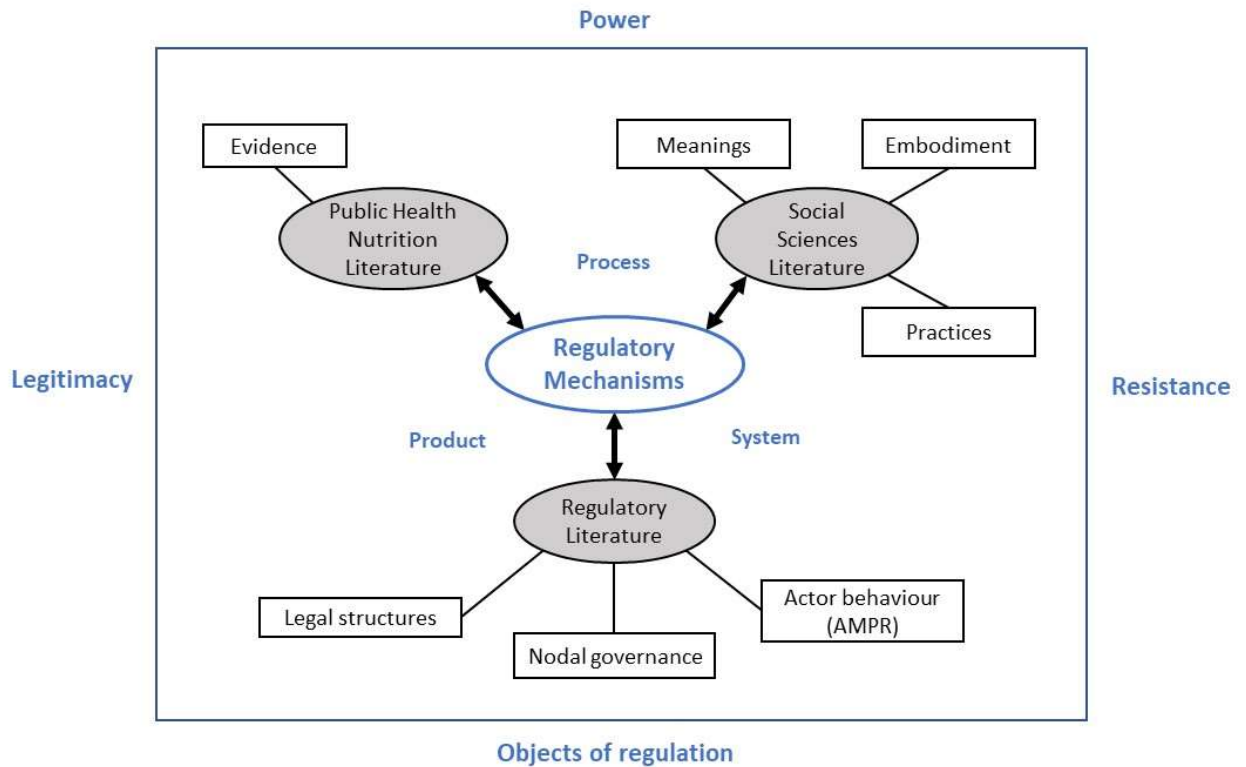


Figure 10 Relationships between the regulatory mechanisms (legitimacy, resistance, objects of regulation and power) in three fields (regulatory, public health nutrition and social sciences) and key topics in these fields.

My research also provides an approach to the methodological problem of linking micro- and macro-levels of governance by combining analyses of actor behaviour (AMPR) (218, 219) and nodal governance (526, 527). This analytical framework challenged assumptions about the extent to which milk banking was ‘regulated’ and informal sharing was ‘unregulated’ by showing structural interdependencies and the importance of social and biological rules. These complex physiological, psychosocial and relational factors enrich the analysis of legal structures, which are the focus of the regulatory literature. These affective and embodied elements are important to an understanding of regulation as dynamic processes of resistance (698) and transformation, of actors and institutions (730).

10.2.1 Legal structures and factors that shape actor behaviour

Australian health institutions framed milk sharing as obscure, deviant and risky unless it was medically supervised. A lack of clarity about the legal classification of milk added to this obscurity, and framed milk as not warranting special protection, beyond the requirements of food and human

tissues. Policies and institutional norms shaped perceptions of separate milk sharing sectors: a 'regulated' milk banking sector and an 'unregulated' informal sector, with few policies for medically supervised donation of unpasteurized milk. Policy for PDHM framed it as scarce, costly and only of clinical benefit for extremely premature infants. Outside NICUs, policies for supplementation omitted donor milk, in contrast to WHO recommendations that prioritized milk from a healthy donor over CMFs. These dissonant messages about milk were exacerbated by NGOs important to breastfeeding, whose policies distanced them from milk sharing outside milk banks.

My research showed that the agency of mothers to share milk and act collaboratively blurred distinctions between milk sharing sectors. Mothers and their milk moved between sectors: PDHM was sometimes allocated to infants in the community and unpasteurized donor milk was used in health settings covertly or occasionally with medical supervision. Sectors also overlapped because they were supported by common structural factors which underpinned safety, including universal access to health care. However, laws and policies restricted access to milk banks and medically-supervised milk sharing, leaving unmet demand and surplus milk with nowhere to go. These gaps were acknowledged by some health professionals and milk bank staff and contributed to ambivalence about sectors and risks for different categories of infants.

Regulatory incoherence

My study of legal structures confirmed that Australia's fragmented laws for human tissue and food created uncertainty and a lack of coherent governance in milk sharing, and left milk sharing unintegrated with breastfeeding and World Health Organization policy. At the national and sub-national levels of governance, food laws managed some aspects of safety but enabled trade and lacked mechanisms to deal with ethical issues. Ethical issues were managed at the State/Territory level through the application of human tissue laws, which prohibited the sale and advertising of milk. However, inconsistent application of these laws limited milk sharing's potential to promote breastfeeding and shifted costs onto mothers, while milk banks could recover costs (641).^{127,128,129} At the national border, the federal classification of milk as a food provided other countries with market access to Australia but this was hindered post-border by human tissue laws. Overall, this regulatory burden limited the establishment of milk banks but a lack of national governance left them self-governing and with inadequate public funding. Informal sharing can be seen as a response to these

¹²⁷ Further to my findings presented in Chapter 2, jurisdictions where human tissue laws apply to milk are the ACT, TAS, VIC, WA and NT and Food Acts apply in VIC, TAS and SA (641) p. 78.

¹²⁸ However, WHO recommendations allow for the compensation of donors for their costs (242)

¹²⁹ The commercialization of donor milk by milk banks or a contracted supplier is allowed if consent from donors is obtained in Sections 13.2.1.(a) and 13.2.5 (c) (iii) (641).

problems, as a form of 'grassroots governance' (731), but is hampered by being framed as 'legal but illicit' (278) (p158). In contrast, CMFs had the advantages of clear legal classification (as a food), and an international regulatory system that enabled its promotion, trade and profit at global scales (58, 59, 732) .

A second source of regulatory incoherence arose from conflicting policy objectives for nutrition and infection control. Policies for infection control framed unpasteurized milk as a dangerous bodily fluid, which was inconsistent with the promotion of breastfeeding as safe, optimal infant nutrition and guidance on milk handling in households and workplaces.

A third source of incoherence was the lack of integration of policies for milk banking and infant feeding. Outside NICUs, donor milk was not an accepted supplementation option and guidelines were not readily available. Mothers who sourced milk informally encountered a deeply alienating paradox: institutions warned about risk but refused to mitigate it ('wilful blindness' or 'washing their hands').

Overall, these legal structures challenged orthodoxies in tissue donation and infant nutrition. Legal gaps failed to protect human rights to milk, as part of breastfeeding, or protect milk as a complete infant food with unique bioactive properties important to infant health. My findings show that the regulation of milk requires more than a knowledge of legal rules but an understanding of governance, the 'play of the game' that shapes how milk competes with CMFs and supports or displaces breastfeeding. In reality, milk sharing is handled in health settings according to the 'street-level' regulation of health professionals (733), whose decisions were shaped by their breastfeeding knowledge and various institutional and social norms, as shown in my analysis of actor behaviour.

My analysis of Australian legal structures adds to international studies that show a range of legal and policy frameworks for milk (88-90, 213, 214, 231-233). Few countries apply Australia's hybrid legal classifications for food and human tissue to milk, but this finding agrees with a Canadian study, in which the regulation of milk resembled a therapeutic good, human tissue and food, according to the way it was handled in different settings (232). This layering of regulation contributes to dissonant messages about milk, for example health system advice to discard milk via the sewer, when this would be inconceivable to mothers who routinely handle their milk in kitchens (666). Overall, my findings showed that current legal classifications for milk framed it as a product isolated from breastfeeding.

Actor behaviour: more than motivations

The analysis of actor behaviour revealed how legal structures operated in practice and the institutional cultures and other factors that regulated milk sharing in health and community settings. The AMPR analytical framework teased out principles from pragmatism and showed that actor motivations were insufficient to explain behaviour, highlighting the importance of awareness, pathways and rewards. The analysis of awareness showed that actor knowledge of milk sharing and breastfeeding could not be assumed, even among milk banking staff and health professionals, and that personal experience was an important source of power in the regulation of milk sharing. The invisibility of milk sharing meant that mothers lacked a voice in policy making and research agendas for infant feeding issues outside milk banks.

The analysis of actor motivations revealed sources of agreement and conflict between actors. The study confirmed the multiple motivations of mothers described in the literature, of upholding exclusive milk diets, helping and not wasting milk. In contrast, milk banks were driven by the stringent demands of NICUs to prevent NEC.¹³⁰ Many health professionals sympathised with mothers but were positioned as gatekeepers, with limited knowledge of milk banking and sharing or caught between conflicting policies for infant nutrition and infection control, without pathways to manage legal liability, in agreement with previous research (444, 734). Policy makers were also risk averse and restricted by the narrow objectives of their organizations.

Pathways were central to the analysis of regulation: they exposed the weaknesses and strengths of infant feeding systems and the agency of actors in different settings. Small skirmishes and larger conflicts over rules showed failures of legitimate pathways to feed infants optimally and the capacity of actors to create alternative pathways. The capacity of mothers to share milk was shaped by their material and social resources, policy and social rules and assessments of safety. These resources included maternal time, relationships and social media, as mothers juggled the biological, embodied time-sensitive demands of lactation and infants. Mothers managed safety in a range of ways, using scientific information and trust, underpinned by their experience of antenatal care. Equally, models of maternity care shaped trust between health professionals and mothers. For milk banks, health professionals and policy makers, pathways were highly constrained by legal structures, policy silos and funding. For example, NICUs wanting to use PDHM needed additional lactation support, which added to its costs (593). At the national level, policy makers responsible for the importation of milk lacked pathways (and awareness) to manage ethics or impacts on breastfeeding. Governance was

¹³⁰ Necrotizing enterocolitis

hampered by limited transparency, consultation and alliances. In the face of these obstacles, actor and institutional 'mind-sets' were important to overcoming limitations, through collaborations or leveraging existing resources.

In Australia, financial rewards from milk sharing were highly restricted and the most important rewards were biological and social. All actors supported altruistic donation, a finding that validates previous empirical research in Australia and internationally (83, 274-278, 370, 371). These values aligned with human tissue laws, but their inconsistent application left openings for trade by third parties. For mothers and health professionals, the main rewards were the health of infants and psychosocial benefits for mothers, which were abstracted when milk donation was anonymous, as required by milk banks. In contrast, informal sharing, with direct contact between donor and recipient mothers, provided relational rewards and the exchange of information that supported breastfeeding. Sharing milk locally felt empowering to mothers and communities: they owned the problem and the solution. However, milk sharing sometimes created problems for actors. Some mothers and health professionals experienced abuse or stigmatization around informal milk sharing, which drove it underground and limited medical oversight. These 'rewards' provided feedback to reinforce particular motivations and pathways. However, not all actor groups perceived these signals. Policy makers were often removed from the rewards of other actors, and driven by organizational motivations and rewards, for example the tangible rewards of trade rather than breastfeeding.

10.2.2 Power: nodal governance

The analysis of legal structures explains institutional power but this is insufficient to explain actor behaviour, while an analysis of actor behaviour is restricted by its focus on individual agency. Nodal governance was used to analyse the less visible, distal mechanisms of power that regulated milk sharing through multiple 'sites of capacity, knowledge and resources' (522). Compared with the map of nodal governance hypothesised at the start of this thesis (Chapter 3), the empirical data in my research showed that nodes did not map neatly to actor groups and that not all nodes were equal. For example, health professionals held widely divergent positions on risk. Instead, the governance of milk sharing involved competing interests and tensions between four overarching 'superstructural' nodes (526) of biocultural, medical, commercial and patriarchal power (Figure 11). Nodal mapping shed light on the 'biopolitics' and the 'regulatory logics' and discursive power of nodes, how they framed issues and reproduced or challenged institutional and societal norms (735). The lived experiences of actors in my research showed these regulatory logics in practice, at different levels of government.

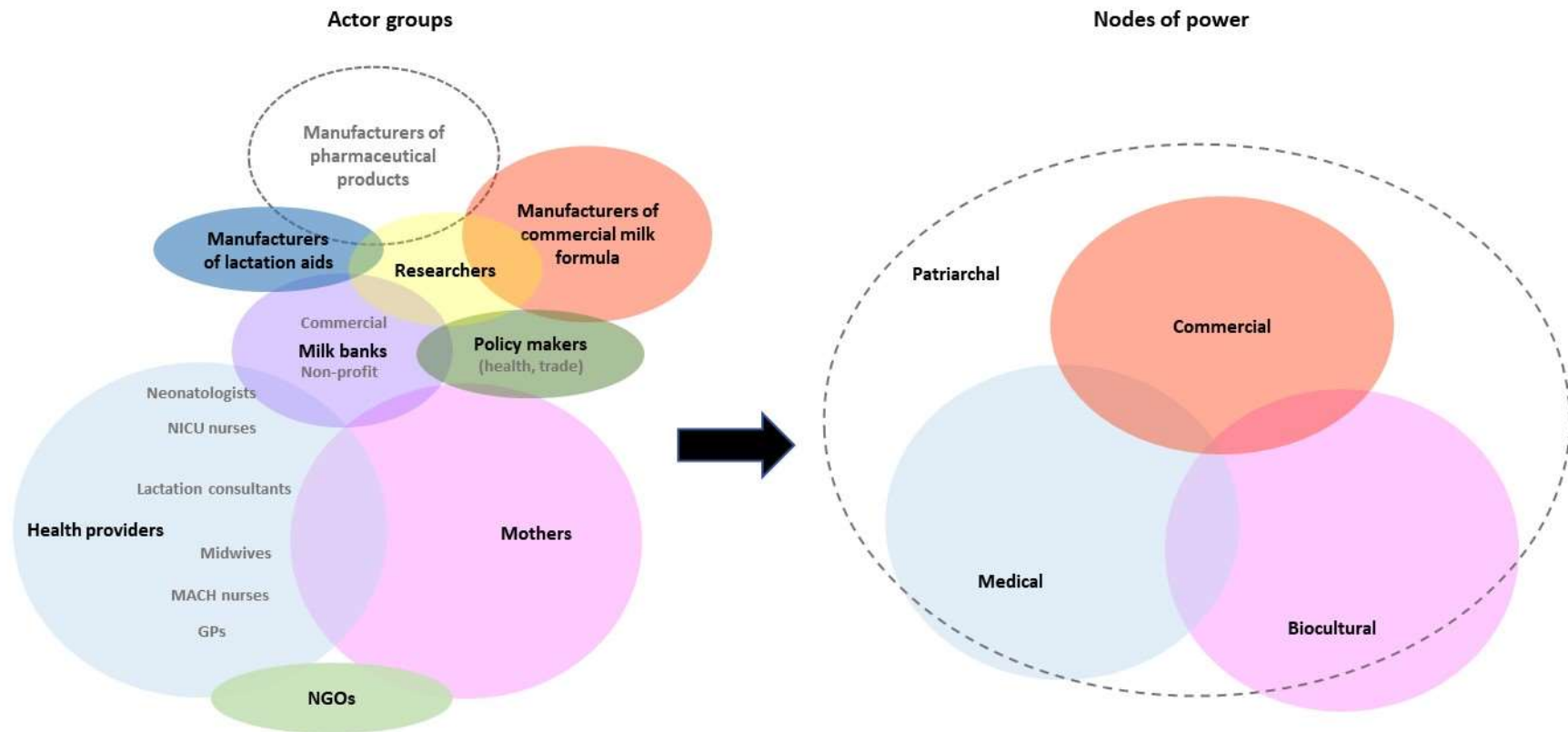


Figure 11 The shift in concepts of regulation in this thesis from governance by actor groups to governance through nodes of power.

My research adds to a limited number of studies of nodal governance in public health, at the global level (526, 735-737) and in Australia (738-740), with an analysis at national and subnational levels in an emerging field of infant nutrition. My approach made original contributions to this regulatory field, by applying nodal governance to milk sharing and combining analyses of nodal governance and actor behaviour. This approach explained how weak actors (mothers) resisted powerful actors, like milk banks and medical authorities, and enabled investigation of 'a system where mothers exercise independent control' (208).

Biocultural power

The central node of power in milk sharing was the biocultural power to produce and share milk. This node consisted of mothers, their bodies and breastfeeding knowledge and sociocultural systems. Health professionals, researchers and others who supported mothers and infants enact rights to breastfeeding and exclusive milk diets contributed to this node. Mothers were the biological powerhouse and regulatory units of milk production (and demand), but their power was diffuse, distributed and qualified. This meant that maternal power was aggregated rather than organized, and had limited political clout, as shown by decades of stasis in breastfeeding policy implementation.

Milk sharing expressed an alternative form of power, which aimed to meet short-term needs for infant nutrition, rather than institutional reform. While milk banks were supported by health institutions, the structures that enabled informal milk sharing were less tangible.

The relationships and social media that provided mothers with collective capacity were loose and impermanent. This alternative form of power tapped into social solidarity, as described in the literature on altruistic tissue donation (260) and other studies of informal sharing (278, 461). For some mothers, a sense of social cohesion was personally transformative (an 'alternative mode of being') (276) (p.173) and a shift to a kinder, more interdependent society, in agreement with scholars who recognized milk sharing as 'cooperative parenting' (467) that recast breastfeeding as a 'creative (inter)corporeal act' (363). Similarly, studies of milk banking show that recipient mothers felt sustained by an 'imagined community' (266).

Other scholars of informal sharing have debated the degree to which it engages with 'the politics of breastfeeding' (15) and disrupts the policies and institutional norms that support the use of CMFs (371). Some researchers considered informal milk sharing apolitical for its lack of objectives for societal or institutional change, describing its non-hierarchical structures as 'networks of biointimacy' (288) or 'bio-communities of practice' (276), with collective action coincidental to pursuit of a human milk diet and 'powered by a politics of pragmatics' (279). Carter and Reyes-Foster (276) concluded

that milk sharing was politicizing only when its participants advocated for policy reform beyond milk exchange. In contrast, Falls (278) believed that informal sharing had political intent to change social norms rather than institutions through 'microactivism.' She described informal milk sharing structures as 'heterarchical counternetworks' (278) p.152 enacting the politics of 'quiet encroachment,' drawing on concepts of everyday empowerment by Bayat (741) .

My findings support an intermediate position: the political power of informal milk sharing was limited by short-term feeding objectives and its covert nature, but it provided some mothers with an experience of collective power and helped shift the policies of some health services and NGOs. In addition to these small wins, some mothers and health professionals openly engaged in discussions with mothers, the media and colleagues to raise awareness of milk sharing. However, these gains were not uniform and sometimes backfired. Some health authorities responded by narrowing policy definitions for breastfeeding by the biological mother (593, 610) or emphasised risk in their guidelines (629) and resorted to legal waivers, as advised (253). These responses did not address the reality of mothers' needs or systemic breastfeeding failures, and only enabled CMF to displace breastfeeding. This institutional abandonment of mothers resulted in their 'retreat to Facebook' rather than advocacy. Yet institutional actors expected mothers to act politically: one health professional declared that new mothers on a post-natal ward wanting to use donor milk rather than CMF could appeal to the Human Rights Commission or lobby their local politician.

At the macro-level, the biocultural node engaged with political and economic systems that produced inequities in breastfeeding, with milk overproduction by some mothers and deficits for others, creating donor milk supply and demand. My research provided empirical evidence of the workings of this political economic system at lower levels of governance, but actors also understood how the bigger picture produced barriers to breastfeeding. The failure of governments to protect breastfeeding, mothers and infants from commercial interests was central to legitimacy and led mothers to question or circumvent health authorities. By investigating diverse forms of milk sharing, my analysis identified an important characteristic of nodal governance, which was the power to control milk. Once milk left the control of mothers and other actors in the biocultural node, it was subject to medical and commercial interests, as discussed in the following sections.

Medical power

A second node of power in the governance of milk sharing was medical power, exercised through milk banks, health institutions, laws and policies and affiliated actors (health professionals, policy makers in health agencies and facilities and NGOs). Medical power served medical interests. My research showed that these interests were fractured by conflicting objectives and siloed institutional

cultures, for example, conflicts between infection and nutrition, public health and the specific needs of NICUs. Medical power was not monolithic but included dissenting voices within and between medical disciplines and models of maternity and paediatric care (Fig.2), as noted by Bond (445). Milk banks occupied an uneasy position in the health system, which required them to 'battle for legitimacy' and the supply of milk (189), and distance themselves from informal sharing, while some mothers and health professionals resisted the rhetoric of milk banking as the only safe way to share milk.

Milk banks transformed milk's value and acceptability through the medicalization of safety and trust and relegated mothers to roles as compliant suppliers or consumers (289, 349). Consequently, mothers who shared milk informally engaged with medical power in ways that were complex, 'at the intersection of compliance and defiance' (276). They leveraged scientific information and sought the help of health professionals, but rejected the ways medical institutions reproduced Western social norms of motherhood, individualism and exclusive maternal breastfeeding, in agreement with other studies (276, 278, 279, 461). My research adds evidence that health professionals (and NGOs) wielded power in institutional settings but were unpredictable gatekeepers, constrained by legal liability, institutional cultures and limited collaborations. Importantly, the inadequate education of health professionals in breastfeeding limited their power (220, 276, 278, 361, 364, 413, 448, 742), and made personal experiences of breastfeeding an important disrupter of medical power (220, 274, 454). Milk banking's role in the politics of breastfeeding was limited by its narrow focus on NICUs and governance that weakened alliances, as noted by (371). In contrast, governance that integrated the sector with communities engaged more directly with the politics of breastfeeding (292), while models that fully integrated milk banking and breastfeeding policy and services had coherence and political power at national and international levels, for example in Scotland and Brazil (214, 215, 371, 500).

My analysis showed that the hegemony of milk banking in Australia was shaped by self-regulation and legal structures that enabled consolidation rather than localized governance through community-affiliated milk banks. The dominance of Lifeblood Milk was derived from its affiliation with Australia's monopoly blood bank, and its resources and political influence. This milk bank made important contributions to the evidence base and accountability of milk banking through scientific studies that supported policy for PDHM concerning standards, safety and access, demand and outcomes (393, 431, 432, 508, 743). However, this influence also enabled Lifeblood Milk to shape policy (432, 744) and funding (684).

Countering medical hierarchical power were deliberative processes. Some state health departments consulted specific mothers, for example parents of premature infants about milk bank research priorities (745) or the feasibility of a local milk bank (113). However, benefit-cost analyses dominated policy making, which focused on the needs of NICUs and discounted benefits to the community with potential to support breastfeeding. In general, the governance of Australian milk banks remained opaque, buried in hospital administrative processes or lacking transparency. For example, there was no public consultation for the development of Australia's milk banking guidelines (641). Similar issues have been raised by scholars in the USA, concerned that governance problems in milk banking, (consolidation, commercialization and inadequate representation of mothers), may threaten informal sharing (89, 278, 279).

This lack of transparency in milk banking made it unclear where medical and potential commercial interests overlapped. Greater public scrutiny and debate is required about milk banks and their role in research and product development and influence on policy making for infant and young child feeding, for example through potential associations with CMF manufacturers or other commercial actors.

Commercial power

A third node consisted of commercial power and included organizations and milk banks with commercial objectives, namely profit and trade. These actors included government agencies and health professionals interested in accessing milk or milk products from commercial milk banks or companies that profited from donor milk, milk fortifiers, milk processing technologies and data on milk (132, 135, 746). Commercial nodes responded to the 'regulatory logic' and language of markets and included actors that profited indirectly from milk, for example researchers in milk science (747, 748), health professionals and semi-commercialized milk banks (144). The language of markets pervades the literature of bioeconomies, in which trust and nurture in milk sharing were commodified as a 'bio-intimate economy of care' (288) or 'care work' (289).

Conflicts of interest may arise between these actors and objectives for breastfeeding, blurring the boundaries between medical and commercial power around milk. For example, in the USA, Cambodia and India, commercial milk banks have been criticised for exploiting disadvantaged communities (130, 143, 240, 749, 750). Conflicts may also arise through associations between actors in other nodes and for-profit entities that divert milk from infant feeding, for example ingredients for novel CMF and biopharmaceutical products, such as antibodies to the SARS-COV2 virus (751, 752). Importantly, Australia's largest non-profit milk bank, Lifeblood Milk (753), has potential links through its parent non-profit organization, which supplies one of the world's largest biopharmaceutical

companies for plasma products, CSL Behring (754, 755), whose power and objectives diverge widely from those of actors focused on breastfeeding..

The commercial node also included sub-nodes that overlapped with the biocultural node, for example businesses that provided breastfeeding support services and lactation aids. For example, an international breast pump manufacturer was a sponsor of the Australian Breastfeeding Association (756) and another's philanthropic foundation funded academic positions in Lactology (757). The commercial node also included private sector lactation consultants and health insurers, whose role in milk sharing is emerging. For example, some Australian health insurers covered the cost of a lactation consultant (but not breast pumps as in the USA).¹³¹ The distorting effects of commercial objectives on breastfeeding are indicated by suggestions that the marketing of milk products and lactation equipment should be restricted through the WHO Code¹³² (130, 330, 331, 759).

Overall, the commercial actor with the greatest power and influence on breastfeeding was the CMF industry (58, 59, 255, 516, 760). This influence was observed at national and subnational levels of governance by actors in my research, and policy makers confirmed the weak and missing consumer voices in the global food regulatory forums charged with regulating CMFs, a problem articulated by Buthe and Harris (761). The power of CMF companies extends to control of knowledge of milk through milk science research, funding and forums, health professional education (762), sponsorship of health professional associations (763) and the capacity to lobby politicians, shape policy agendas and weaken marketing controls (255, 732). Importantly, knowledge of milk composition serves commercial interests in several ways, through the development of food standards (764), novel ingredients (765) and marketing strategies for CMFs (766, 767). To this end, one US CMF claimed to operate the 'largest breast milk bank in the world' (768). It is not clear whether donors to these milk banks and research programs understood how their milk and its data 'fed' the political economy of infant and young child feeding, which undermined breastfeeding.

Patriarchal power

The intersection of biocultural, medical and commercial nodes explained tensions and overlaps in interests that governed milk sharing. However, these three nodes did not explain the persistent need to share milk covertly, the suppression of awareness of milk sharing across institutions and the community and the harshness of penalties. These manifestations of power targeted women and required the addition of a fourth superstructural node, of patriarchal power, that encompassed all

¹³¹ In the USA, health insurers are legally required to cover the purchase cost of breast pumps under the Patient Protection and Affordable Care Act (758).

¹³² WHO International Code of Marketing of Breastmilk Substitutes

others. As described in the section on biocultural power, patriarchal power controlled women's bodies and identity through legal structures and the social meanings of milk, based on idealized motherhood, gendered constructions of risk and neoliberal concepts of individualism (519, 769). However, participants in my research were quick to point out how these ideas were modified in Australia by structural and cultural factors, which reinforced collectivism and the safety of milk sharing.

The patriarchal node explained why the biocultural node, despite being a source of empowerment, lacked political power. Patriarchal structures explained women's lack of voice and self-censorship, weak allies, omission in policy making and dispossession in milk banking. According to (276) (p. 51), the obscurity of milk sharing was symptomatic of the erasure of mothers' bodies from all infant feeding and represented 'the lack of value placed on women and the feeding of infants' (371). These concerns reflect the wider invisibility and devaluing of maternal work, discussed by feminist economists (210, 269, 770). The structural and cultural mechanisms of patriarchal power permeated the experiences of actors, and their cumulative effect was revealed in their narratives. One donor's story included her (male) relative's description of milk donors as 'stray women,' the surprise of her (male) doctor that women wanted to share milk, her experiences of models of maternity care that crippled breastfeeding and the abuse and financial penalties (no superannuation) for extended breastfeeding.

Overall, the analysis of nodal governance showed how mothers, through informal milk sharing, challenged medicalized, commercial and patriarchal power that maintained the status quo in infant feeding. However, the limited political power of milk sharing and its weak institutional support meant that their effects on breastfeeding were uncertain, while structures that protected markets in CMFs remained intact. My research shows how these forms of power combined to limit the agency of mothers, restrict pathways to manage safety and drive all forms of milk sharing out of the public domain to operate as an 'obscured organization,' (771). Consistent with the regulatory theories of Foucault, which (771) applied to a lack of awareness about milk banking, my data showed that mothers and health professionals were complicit in this obscurity and remain 'below the radar,' a finding common to other studies of milk sharing (62, 97, 169, 220, 276, 278, 279, 361, 364, 413, 444, 445, 447, 448, 465, 696). Regulators need to recognize these power dynamics as the strategies of less powerful actors to use 'hidden forms' of power and 'claimed spaces,' while more powerful actors, like milk banks, are able to exploit the 'closed spaces' of policy making (772).

In summary, the regulation of milk sharing requires an understanding of laws and policies, the conditions under which women breastfed and the behaviours of multiple actors and sub-groups that

served nodes of power with disparate interests in infant feeding. Incoherence of legal and institutional framing around milk sharing and its separation from breastfeeding fostered diverse forms of milk sharing across health and community settings with the potential to affect breastfeeding positively and negatively. Understanding this potential requires more than a description of regulatory mechanisms and power, explored in the next section through several regulatory principles or themes.

10.2.3 Regulatory themes

Three regulatory themes emerged from my empirical data: legitimacy, resistance and the object of regulation. These meta-concepts are about who controls the bodies of women and infants and their milk. These concepts help answer the second, more complex part of the research question: how did the regulatory conditions for milk sharing shape breastfeeding? These concepts, and their contribution to the academic literature, are discussed below and form the basis of new governing structures for milk sharing, recommended in section 3 of this chapter.

Legitimacy

Legal, ethical and sociological theories of justice and power propose that the concept of legitimacy arises from legal power and also moral authority, based on fairness and good outcomes (773, 774). In my research, legitimacy emerged from the data in relation to fair processes in policy making and social interaction. This procedural fairness was observed through good governance, transparency and accountability in the way power, ethics and privacy were handled in milk banking and personal exchanges of milk. My findings showed how legitimacy in milk sharing was constructed legally, socially and also biologically, through embodiment. These different forms of legitimacy privileged various systems of knowledge. The next sections describe how these forms of legitimacy and knowledge structured milk sharing sectors and limited their integration with breastfeeding.

Legal legitimacy

In milk sharing, the legal authority of the state operated through laws and policies concerning milk, ethics and markets. In addition, legal legitimacy was derived from the welfare state and public health system, which supported donor health and the capacity to share milk. My findings showed that the legal legitimacy of milk banking was driven by NICUs and their acceptance of PDHM as standard care in policy and practice for premature infants, following trends in the USA and Europe (310, 313, 745, 775, 776), while guidance on PDHM use outside NICUs is emerging (287). In Australia, use of PDHM lagged these trends (358, 385). Institutional adoption of PDHM was supported by evidence of clinical and economic outcomes (220, 333), which depended on local contexts, for example background rates of NEC, which are low in Australia (777, 778), and lactation support.

However, the legal legitimacy of milk sharing in general was undermined by its obscurity in policy and a lack of policy coherence. Although milk banks and medically-supervised donation were legitimate, health professionals rarely discussed donor milk as an option (outside NICUs) and this omission framed it as deviant. Milk banks, health services and NGOs maintained legal and medical legitimacy by distancing themselves from informal sharing, framing the latter as unsafe and not part of breastfeeding (286). This institutional position contrasted with the attitudes of mothers who saw informal sharing as a solution and part of breastfeeding. In search of a legal authority, many mothers and health professionals referred to WHO policy for infant feeding (7) and human rights frameworks, and learnt to 'navigate competing authoritative claims' (286).

My findings show that legal legitimacy required knowledge of local policy and practice. For example, an international review of position statements on milk sharing concluded that Australian NGOs supported milk sharing through informed decision making (220) but my research showed they were little used, with few health professionals or mothers knowing of them (435, 455), while some mothers were alienated by the policy of the Australian Breastfeeding Association (204, 670, 779). These gaps delegitimized informal sharing and contributed to the difficulties of forming alliances between milk sharing and breastfeeding advocates. By vacating the field, these powerful advocates of breastfeeding left milk sharing exposed to the interests of actors less committed to breastfeeding.

Informal milk sharing was framed as illegitimate based on its representation as high risk. However, the literature increasingly supported the position that most altruistic informal sharing arrangements carried a low and manageable level of risk (220, 429, 430), with most diseases of concern well controlled in Australia.¹³³ Recent studies by an Australian milk bank also validated the health status of donors screened with an online questionnaire (431, 432). While these results cannot be extrapolated to informal arrangements, they support the strategies many mothers used to manage safety, as reported in other studies (97, 361, 364). Limited research in other high income countries supported the safety of altruistic donation (220, 429, 430) over commercial exchanges (249, 250, 426, 438).

The legal legitimacy of milk sharing also depended on the end use of milk. Australian policy for PDHM for specific medical categories of infants de-legitimized its use for other infants. However, my findings showed that, in practice, PDHM use was less rigid, and unpasteurized donor milk was used in health settings, while some medically-supervised exchanges of unpasteurized milk occurred in the community. This flexibility is confirmed by other research (387, 411) and media reports (216).

¹³³ With the exception of HTLV for some Indigenous populations, as discussed in Chapter 7 on actor pathways.

However, Australia lacked systematic services for medically supervised sharing in the community, which are available in some countries (97, 415). The idea of milk sharing as a spectrum of practices represents a shift in legitimacy, as shown by calls in the literature for a more balanced appraisal of unpasteurized donor milk (410) and reframing informal milk sharing as a continuation of milk banking (409), so that policy recognises ‘a range of donated human milks sourced and processed in different ways to meet the needs of clearly defined end users’ (241).

Social and biological sources of legitimacy

Despite uncertainties around its legal legitimacy, milk sharing was found to have social and biological legitimacy. The social legitimacy of milk sharing was based on moral principles of respect and fairness, derived from human rights,¹³⁴ and social norms about infant care, relationships, maternal and civic identity, helping and reciprocity. Institutions that did not uphold these principles prompted the need for an alternative authority, for example trusted relationships: a sister who offered her colostrum had more moral authority than the hospital that prohibited its use. In common with studies in the USA, milk sharing narratives typically described ‘ignoring,’ ‘sidestepping’ or ‘replacing’ authority (279) (p. 116).

My findings showed that milk sharing challenged the bioethics of human tissues donation. Summarizing these challenges, Shaw (256) described how milk sharing’s gendered power relations were not well accommodated in medical and bioethical frameworks or their underlying liberal, utilitarian or communitarian principles. In my research, these complexities manifested across settings and levels of governance, showing the need for a unique and contextualized set of ethics for milk sharing, and appropriate legal structures. An ethical issue of fundamental importance to actors was the prevention of exploitation. However, perspectives on exploitation were nuanced, and ranged from views about micro-level interpersonal power imbalances to macro-level political economic power. Mothers and health professionals did not consider milk banking and informal milk sharing in Australia to be exploitative, based on their experience of altruistic practices, a position that may reflect the socioeconomic advantages of participants. However, mothers were acutely aware of the vulnerability of mothers and infants.

Social legitimacy depended on the conditions under which milk was produced and distributed, and the alignment of these conditions with moral principles. These conditions reflected how political and social power intersected with lactating bodies. My data showed that milk sharing had social

¹³⁴ For example, human rights to food, health and bodily autonomy and freedom from exploitation, enshrined in various UN Human Rights Treaties, but which have limited legal protection in Australian law.

legitimacy when it upheld the rights of women and infants to breastfeed, which were enshrined in United Nations treaties but not implemented in full in Australia, as shown in my analyses of legal structures (Chapter 4) and actor pathways (Chapter 7). Of the array of rights that uphold breastfeeding, specific rights, for example the right to food, have particular potency when applied to milk sharing. The anthropologist Penny Van Esterik described breastfeeding as enacting rights to food through the conjoined rights of infants and mothers 'to food,' 'be fed' and 'to feed' (780). The right 'to feed' recognizes the social role of providing food to others, and its importance to maternal identity and status. Milk sharing extends the right 'to feed' by valuing of social processes of 'kinship, care and ongoing ethical and political transformation' (781) (p.187). Importantly, these relational processes include relationships between mothers, which engage sociocultural systems of breastfeeding support. According to Long (80) and Palmquist (467), cross-feeding and cooperative child raising by extended families in some cultures challenge the moral legitimacy and 'naturalness' of exclusive maternal breastfeeding in Western societies. My findings showed that this cultural complexity was difficult to accommodate in legal and market-based frameworks, which neglected relational processes, as noted by other researchers (89, 90, 256, 268).

Milk sharing's social legitimacy also depended on good outcomes, which prioritized infants over outcomes for mothers. Some milk banks considered, as part of their social licence, the health of donors and the risk of milk overproduction, (782) and acknowledged wider public health objectives, but their role in supporting breastfeeding was limited in Australia. My findings showed that milk sharing had psychosocial benefits for recipient mothers, in agreement with other research (287, 328, 363, 374-378, 380, 381, 783). However, mothers and health professionals also encountered shame, disapproval and institutional stigmatization around milk sharing (375, 413). These outcomes depended on many factors, including the sensitivity of how milk was offered. For example, health professionals described the need for 'conversations' with mothers about donor milk and models of maternity care that built trust. Similarly, mothers sharing milk informally described the time and effort required to communicate their stories. These investments of time delivered rewards but came at a cost. The logistic and emotional toll of milk sharing emphasised the moral importance of efficient, pragmatic and safe pathways. To have legitimacy, principles needed to attend to the lived experiences of women, as acknowledged in the philosophical traditions of 'pragmatist feminism' (784).

An important part of the social legitimacy of milk sharing was the fair redistribution of milk ('from the haves to the have nots'). Milk redistribution may reproduce 'systems of dominance' based on socio-political identity ('race, class, culture, religion, gender and sexualities') (284), but my research

provides limited insights on this issue. In Australia, equitable access to PDHM was restricted by geography (358, 386). This structural barrier may penalize Indigenous infants disproportionately,¹³⁵ but differs from inequitable access by poor, black and Hispanic populations in the USA that stems from a lack of access to health insurance (390, 395, 401, 416-420). In my research, families with diverse gender identities and structures were supported to obtain donor milk by informal milk sharing networks, directed donation protocols and health professionals. This contrasts with reports in the literature of child protection agencies restricting access to PDHM for families with surrogacy, adoption and fostering arrangements (421, 422). In these families, fear of child removal was a powerful threat that promoted covert milk sharing (279). This threat was also experienced by biological mothers in my research and other studies (278, 279, 375, 413, 454). Most donors made judgements about the 'worthiness' of recipients based on relationships, infant and maternal medical conditions and the effort of recipient mothers to breastfeed, as noted in other studies (277, 286, 449), while other donors allocated milk on a 'first come first served' basis. In contrast, in the context of Australia's Medicare system, milk banks had greater capacity to redistribute milk equitably, from advantaged donors to the disadvantaged recipient groups overrepresented in public hospital NICUs.

In my analysis, inequities in informal milk sharing were shaped by legal structures, ethical frameworks, actor motivations and practices and who had resources to donate and access milk. Legal and social norms for altruistic donation meant that donors bore substantial costs, despite some public funding of their health costs and time. The cost of PDHM to recipients in public NICUs was covered by the health system while families paid for PDHM used in the community. In general, mothers and health professionals thought fair access to milk was more important than fair donation. These actors balked at third parties profiting from unpaid donors, which casts doubt on the social legitimacy of Australia's milk banking guidelines, which mandate unpaid donation but allow milk to be commercialized (641). These sentiments align with those of some Marxist-feminist scholars and feminist economists who consider not paying milk donors a misogynistic turn of exploitative capitalism (240, 294).

The social legitimacy of milk sharing also relied on good governance. Some mothers questioned the transparency and accountability of milk banks: 'wasting' milk was a breach of social licence and risked donors allocating their milk elsewhere. Transparency was important in debates about the importation of milk. Some mothers, health professionals and policy makers considered it unethical to

¹³⁵ For example, inadequate PDHM availability to NICUs in the Northern Territory means that Indigenous infants are penalized disproportionately because Northern Territory births account for about 1% of all births in Australia but 8.6% births to mothers who identify as Indigenous, and Indigenous infants are more likely to be premature and of low birth weight and require NICU care (785).

export milk from communities or countries in which infants died because of inadequate breastfeeding or not pay impoverished donors, reflecting the need for global ethical standards for milk (293). In the literature, bioethicists also suggest that it is exploitative to leverage communitarian values, especially when donation is gendered and taps into maternal identity (474). However, all milk banks appeal to communitarian values (287). The issue is whether these appeals were for public good or private gain and transparent (90).

In addition, legitimacy was shaped by biology. Biological legitimacy was based on the dynamic physiological drivers of lactation, the physical capacity of maternal bodies, infant health and the material properties of milk. Embodiment also intersected with maternal 'identity, community and generosity' ((256) p.84) and the embodiment of infants. However, embodiment was removed or abstracted by legal and ethical rules that decontextualized milk, for example through anonymized donation or commodification. Disembodiment was motivated by privacy principles, market logic (268) and anxiety in Western societies about 'female bodily fluids and female sexuality' ((256) p.84).

Biological legitimacy was self-evident to mothers and other actors with embodied experience of breastfeeding. However, the biological basis of lactation and its physiological feedback mechanisms of demand and supply were not accommodated well in legal frameworks for food and human tissue. Embodiment also received scant attention from feminists wary of essentialism and biology as a source of gender oppression. A countervailing feminism recognized lactation and breastfeeding as part of women's reproductive rights (786), and celebrated lactating bodies as sites of ambivalence, vulnerability and liberation (414, 519, 769, 787-790). As described in the analysis of nodal governance, some mothers saw milk sharing as a collective form of female biological power, whose legitimacy was material and relational, based on their embodied intention and work to produce milk to meet the embodied needs of infants.

Legitimate systems of knowledge

Recognition of biological processes in milk sharing raised questions about legitimate systems of knowledge. Legal, social and biological legitimacy depend on different types of knowledge, which are ranked or privileged by actors (454). Legal structures and health policies value objective data over subjective experience, but medicalized systems of knowledge can exclude 'essential contextual pieces of the neonatal feeding 'jigsaw'' (454) (p. 128) and neglect women's endocrine disorders that drive milk sharing. For example, in my research, cross-feeding sometimes provided information about an infant's latch problem, which was dismissed by some health professionals and valued by others.

Milk sharing was regulated to a large extent by knowledge that was psychological, relational and embodied and difficult to quantify. Relational knowledge contributed to safety and the 'known donor' was part of hospital protocols for directed donation. All forms of milk sharing relied on feelings: the donor's empathy and civic values and the recipient mother's anger, shame, trust, relief or gratitude. These findings agree with the social sciences literature, which recognize intense feelings associated with breastfeeding, ranging from distress (791) to pleasure (460, 781, 792, 793), and that feelings rather than 'rationality' may drive milk sharing (377, 789). These data challenge the 'fiction' of rationality removed from embodiment and test the rejection of biological determinism by some strands of feminism (794). In my research, one donor felt a 'visceral' desire to cross-feed a stranger's crying baby on a tram, while another felt 'violated' by an ex-partner handling her milk. However, this emotional knowledge was suppressed. Female health professionals and policy makers recognized relational and embodied knowledge in personal anecdotes of breastfeeding or milk sharing but then discounted it, reflecting the cognitive dissonance around these topics.

Systems of knowledge clashed when policy did not accommodate embodiment and time, in women's life stages of reproduction, lactation and employment and the body clocks of infants (374, 792). Arguably, integrating relational and embodied knowledge of breastfeeding into milk sharing reduces displacement of breastfeeding across levels of governance. If milk is separated from breastfeeding knowledge, it must be re-inserted, for example by a lactation consultant, at great cost.

My research showed that mothers shared milk using multiple forms of knowledge, which included science, experience, embodiment and relationships. This transdisciplinary interchange was noted in early commentaries on milk sharing as holding promise for 'dialogue and exchange of practical experiences' and 'synergy' between informal sharing and milk banking (189, 208, 454). The legitimacy of diverse knowledge systems is recognized in theories of regulatory pluralism (795) and critical theory, in which gendered and racial oppression is a result of embodiment (796, 797). Recognizing embodiment legitimizes diverse experiences of gender, power, class and race, described by Donna Haraway as 'situated knowledges' (798). In a study of mothers with lactation insufficiency, beleaguered by the 'cyborgification' of their bodies by pumps and other technologies, (363) proposed that the body is something to 'think with' rather than just think about. These 'thinking bodies' need to be part of the governance of milk sharing.

Resistance

Resistance is central to an analysis of power relations in regulation. Milk sharing signals resistance to the current system of infant feeding. Mothers expressed resistance in several directions: towards CMF, medicalization, commercialization and social norms of motherhood and family. These targets

were shaped by resistance between other actors and various interests at the macro-level, as described in the section on nodal governance (2.1.3). These dynamics flag opportunities for regulators to probe tensions about legitimacy and improve governance.

In combination, milk banking and informal milk sharing resisted the enormous pressure to use CMF in the health system and society. However, informal milk sharing resisted the medical control of milk (461). This resistance was nuanced: while mothers and health professionals recognized the need for milk banks for vulnerable infants, they questioned the appropriateness of pasteurization in all situations, and some questioned their governance, as described in the previous section on legitimacy.

Resistance to commercialization was also complex. Many mothers and health professionals resisted the commercialization of donor milk, the distortion of infant feeding policy by commercial power and neoliberal narratives of individualism. Informal sharing, with its short 'supply chain' between donors and recipients, resisted the fragmentation of breastfeeding into products and services. Mothers resisted 'treating people like commodities' (794), understanding that 'profit ...depends on the dispossession of donor' (268) (p. 187). These motivations, and the capacity to resist, were manifestations of biocultural power and recast altruistic informal milk sharing as a political act (461).

Altruism was more than a rejection of commodification. It was also a way to make milk affordable as a food, which was often required daily in large volumes, unlike other donated tissues. This intention resisted portrayals of altruism as the mere performance of maternal identity ('moral motherwork') (286). This nuanced altruism rejected donor payment as the only means of realizing women's rights to breastfeed, as proposed by US feminist legal scholars (89, 90, 252, 271). Instead, it emphasised the need for local solutions to achieving these rights, grounded in 'everyday ethics' (283), including respect for cultures of cross-feeding and milk kinship. Health professions differed widely in their cultural understanding of the ways mothers resisted narrow Western institutional and social norms of exclusive motherhood and breastfeeding and patriarchal control (284, 769). More broadly, milk sharing resisted blaming individual mothers and supported the promotion of sharing as a norm of a good society. These multiple forms of resistance have been described in US studies of informal sharing (276, 278, 279, 461).

Resistance had implications for regulators. Covert milk sharing was a form of 'game playing,' required to circumvent rather than confront authority, and which represented 'disengagement' from the health system (698). However, disengagement was rarely absolute. Mothers may have resisted medical control but did not abandon medical knowledge. These 'motivational postures' of resistance, game playing and disengagement are recognized in regulatory scholarship as a 'complex signalling

system that authorities can read and respond to' (698). Milk sharing was a signal of system-level failures to support breastfeeding or enable access to milk banks. Attention to resistance revealed misalignment between legal structures and actor motivations and rewards, which included strong principles and feelings: a sense of betrayal, abandonment or punishment when health professionals used legal waivers or called Child Protection Services. Such institutional responses alienated breastfeeding's most skilled and motivated proponents. In designing regulation, policy makers need to avoid alienating mothers, who control the production of milk.

Object of regulation

My empirical findings and analysis of legitimacy and resistance show the importance of the object of regulation in milk sharing. This section shows the different ways that legal structures and actor behaviour focused on a product, process or system, and the implications of this regulatory focus for breastfeeding.

Regulating a product

My research showed that milk was regulated as a product in law and policy and in the way milk was treated by various actors. Legally and practically, milk was treated as a tangible form of private property that was separate (alienated) from the mother's body, and under her exclusive control and ownership until transferred to another individual or entity. Legal and ethical debate centred on the intangible rights and relationships associated with milk, for example restrictions on its sale and the interests of infants in milk. The literature on public health nutrition treats milk as a product in its focus on infant diets and milk efficacy, safety, costs and access (220). These studies also tend to objectify mothers, as separate from milk and sociocultural systems of breastfeeding. This framing neglects cross-feeding, other than its role in emergencies, in which the limitations of products become apparent (223, 324, 799-802).

My analysis showed that regulating milk as a product had several problems. Firstly, regulating products narrowed the focus of regulation to product safety and trade. Safety in milk sharing needs to be appropriate to the health of donors and recipients, the health system, and the properties of milk. Arguably, requirements for premature infants were not always applicable to healthy, full term infants in the community. A focus on milk as a disembodied product (457) enables commercialization and trade, which are facilitated by standardization for composition and safety (for example, requirements for pasteurization). Standardization makes products more interchangeable, blurring the differences between expressed milk, various milk-derived products¹³⁶ and CMFs that contain

¹³⁶ These products include pasteurized and freeze-dried milk and laboratory grown cell-cultured 'milks'

synthetic human milk ingredients. These products may be promoted as near-equivalent to milk and displace breastfeeding (330, 803), requiring their inclusion in the WHO Code¹³⁷ (143), adding to the cognitive and regulatory burden on milk.

Exchanges of milk as a product, whether by donation or trade, decontextualize milk and discount the conditions of its production and consumption. These include the conditions of maternal time and labour and disparities in gendered and socioeconomic power. Policymaking processes that treat milk as a product, for example benefit-cost analyses, emphasise price, supply and efficiency. For example, under current legal frameworks, one policy maker in my research contemplated whether it was more efficient economically to import donor milk from India than support milk banking in Australia. This was a similar decision-making process to that which rejected a proposal for a local milk bank in the ACT as it was cheaper to use PDHM from Sydney (113).

Secondly, regulating a product undervalues the properties of milk. Laws that classify milk as a food and/or human tissue do not recognize the complexity of milk as a complete food and a bioactive substance necessary for immunological protection and normal infant development. Arguably, the multiple functions of milk need to be protected with a unique legal classification. This need is pressing, as illustrated by a proposed US law to classify ‘donor human milk that has undergone any bioburden reduction process’ as a special category of CMF (330), a rude conceptual reversal of framing, which potentially captures informal milk sharing within the international food regulatory system.

Thirdly, regulating milk as a product risks its diversion from infants. According to one policy maker, regulating milk as a therapeutic good may encourage its fractionation into components for profit and divert it from infant feeding. There is a moral argument against mining milk and diverting it from the infant food system when most infants are not fed an exclusive milk diet.

Finally, regulating milk as a product encourages markets in milk, and markets lack accountability. Markets in milk may improve the economic security of some poor women and provide an incentive to breastfeed. However, markets tend to externalize costs, for example the wellbeing of the donor and her infant, investments in breastfeeding and relationships of care. Consequently, markets permit the continued failure of structural reforms and policies to support women’s reproductive work. Mothers in my study preferred to socialize the costs of milk sharing, given that society reaped the benefits of improved infant diets. Arguably, framing milk as a product distanced recipients from

¹³⁷ WHO International Code of Marketing of Breastmilk Substitutes

donors, removing the sociocultural dimensions of breastfeeding and increasing the potential to displace it.

Regulating a process

My research confirmed that actors with a knowledge of breastfeeding understood it as a dynamic physiological and relational processes between the mother and her infant and wider society, which milk sharing can support or disrupt. Milk sharing regulated as a process is more likely to support breastfeeding than displace it. Regulation that recognizes these processes embraces embodiment. For example, NICUs recognize that policy for PDHM should require lactation support. However, NICU design and staff also need to ensure that it is not more convenient to use PDHM than locate the mother.

Distinctions between product and process are well-recognized in anthropological and sociological studies which describe the knowledge, care and relational processes necessary for breastfeeding (211, 460, 803). Legal frameworks that remove these sociocultural processes threaten breastfeeding as a biocultural system. However, without recognition of embodied processes, regulators are unlikely to understand the disembodiment that occurs through pumping milk, tube or bottle feeding, payment or anonymity (268, 790, 803, 804). Disembodied processes ignore the legal, social and medical conditions that promote milk expression rather than breastfeeding. In contrast, breastfeeding is supported by sharing that retains embodiment and social connections, for example through cross-feeding or methods to feed donor milk at the breast (363) and forging communitarian values.

Arguably, when social processes are ignored, milk sharing has greater potential to exploit communities. This issue arose when Australian milk banks were unable to guarantee that pasteurized milk was returned to its donor community or state. Similarly, communal interests were not protected by policy that protected individuals, for example informed consent. Communal interests were expressed by mothers who felt that donor payment would separate donors and recipients rather than unify them through common interests in infant and maternal wellbeing. This sense of solidarity was forged by reciprocity and inclusion, for example, including mothers who used donor milk in breastfeeding events.

Regulating a system

This study found that the regulation of milk sharing was more complex than products and processes and required a systems approach. A system captured the exercise of power across multiple levels of governance and between actor- and macro-level interests, and the alignment and conflicts, synergies and friction in motivations, pathways and rewards that shaped legitimacy and resistance. Systems

help identify gaps in governance. For example, milk sharing in Australia lacked structures to debate legitimacy and manage resistance. A system, by design, requires inclusion and transparency and helps redefine 'surplus,' 'wastage,' equitable distribution and the externalization of costs in milk sharing.

Importantly, from the viewpoint of public health, the governance of a system orients attention from solving problems to the generation of public goods ('the generative dispositions of a system') (217). Regulating milk sharing as a part of a breastfeeding system, rather than as a product, offers greater potential to achieve public health outcomes. A systems approach may redefine milk banks as 'units at the service of direct breastfeeding,' rather than providers of products (Israel-Ballard cited in (500) p.284). For example, Brazil embeds milk banking in an institution of health professionals, research and education centred on breastfeeding support (João Aprigio, cited in (500) p.284) that has been shown to promote breastfeeding (501). Systems approaches to breastfeeding, based on social ecological models, are well established in the health and food policy literature (294, 517, 805), and include 'first food systems' (806) and their policy environments (807). However, such models do not include milk sharing. If breastfeeding is the system objective, then milk sharing requires policy and practices integrated with breastfeeding. This requires regulating milk as part of breastfeeding by retaining relationships around milk and not splitting milk from its ties to breastfeeding knowledge and skills. A system-level integration of milk sharing with breastfeeding would need to foster collaborations and socialized approaches to managing risk and costs, making it easier to realize equitable outcomes. In such a system, it would be unthinkable to import milk without evaluating its effect on breastfeeding and consulting mothers in the exporting and destination countries.

An important disposition of a system is its politics, specifically whether the current regulatory system for milk sharing was empowering or disempowering of various actors and interests. It is only at the system level that wider ethical and social justice outcomes become apparent. Rather than being merely an exchange of products, all forms of milk sharing involved relationships and values, among them social solidarity and empowerment. As observed by Sadan (808), 'social practices which encourage solidarity, social integration, support of the vulnerable, compassion and empathy, are rare.' My research identified the legal, material and social conditions that engendered solidarity, which included feelings of belonging, trust and 'commitment to shared goals' (808) and empowered mothers to provide alternatives to milk banking and CMF. In doing so, mothers used the language of solidarity and saw altruistic donation as the lynchpin of a system that prevented coercion and upheld human dignity and social cohesion, which kept milk safe, affordable and price competitive with CMF.

In summary, these three regulatory themes – legitimacy, resistance and object of regulation – help understand how the current regulation of milk sharing restricts its potential to support breastfeeding. Contests about milk sharing’s legitimacy shape multiple forms of resistance, exacerbated by a focus on regulating products and processes rather than systems. Conflicting legal and social rules lag evidence of milk’s importance and alienate mothers and milk from systems that sustain breastfeeding. The current regime also fails to provide governance structures that bridge all forms of milk sharing within breastfeeding systems. These gaps reveal a deep neglect of mothers and infants and of milk sharing’s potential contribution to society.

10.3 Recommendations

The evidence presented in this thesis shows that breastfeeding is not well supported by the current regulation of milk sharing. The following recommendations aim to address legitimacy, resistance and objects of regulation in the regulatory regime for milk sharing in ways that strengthen breastfeeding systems. In addition, it is important to address power relations in milk sharing with a new governance structure that serves the interests of infants and communities in milk.

Recommendation 1: Improve the legitimacy of milk sharing

Legitimacy requires policy that prioritizes the use of milk for infant feeding and embeds milk sharing in breastfeeding. Strengthening the legal and social legitimacy of milk sharing should remove the need for covert practices. Health professionals and organizations need greater awareness of milk sharing and pathways to manage medical oversight and legal liability. These pathways require a unique legal classification for milk, inclusion of milk sharing options in breastfeeding policy, appropriate harm minimization approaches using existing guidelines and health professional education.

Recommendation 2: Remove the need for resistance

The root causes of actor alienation and conflict around infant feeding should be addressed by the full implementation of the structural reforms in the 2019 Australian National Breastfeeding Strategy (579). Specific resistance to milk sharing from concern about infection requires actor motivations to be aligned under public health objectives for equitable breastfeeding that enable safe milk exchange. These objectives reinforce the need to invest in maternal health and breastfeeding through public health and universal health systems, and the use of existing guidelines for safe informal milk sharing.

Removing resistance between milk banks and informal sharing sectors requires reframing them as a spectrum of services catering to infants and mothers with different levels of vulnerability to infection and other harms. Along this spectrum, synergies can be achieved by embedding milk sharing in

communities, so that local breastfeeding knowledge and relationships are strengthened between donors, recipients and health professionals.

Good governance is essential to reducing resistance and requires transparency, so that donor and recipient mothers are informed of milk's origin and use. Resistance to commercial influence in milk sharing requires mandating non-profit milk banking and sharing. This requires public funding of milk banks and research in milk to remove links with commercial interests that undermine breastfeeding.

Recommendation 3: Regulate milk sharing as part of breastfeeding systems

Addressing the object of regulation means that laws, policies and governance arrangements should regulate milk sharing as part of breastfeeding systems, rather than regulating milk as a product. This means that any regulation of milk sharing should have as its objective the support of breastfeeding relationships and sociocultural knowledge. This approach prevents milk from being alienated from mothers and lactation support and encourages relational (non-anonymized) donation and feeding donor milk 'at the breast'. It prevents the diversion of milk from infants and its fractionation into products. The good governance of milk sharing in breastfeeding systems, rather than the regulation of milk as a product, provides mothers with a political voice that engages more effectively with commercial and medicalized power (milk banks and health professionals).

Regulating milk sharing within breastfeeding systems ensures that research is in the service of breastfeeding women rather than product development. This would direct research to the causes of inadequate breastfeeding and lactation, including women's physiological and endocrine disorders and their social, environmental and commercial determinants. Research on milk would support low cost technologies and logistics that met actor needs for pragmatic, efficient and risk-appropriate management and ethical processes.

10.4 Limitations

This research has a number of limitations. Recruitment of participants for interviews used opportunistic and snowballing techniques to sample diversity in milk sharing practices and actors who were difficult to reach. Data collected on the socioeconomic status, location and language of participant mothers (but not their racial, gender or religious identity) showed that they were broadly representative of the general population in these characteristics. Actor attitudes and practices concerning ethics and safety are specific to the conditions under which milk was shared at the time, including media reports of controversial issues associated with milk sharing. These conditions may change, for example, with investment in public health or antenatal care or new disease risks (190).

My research examined a limited number of actor groups who were most closely engaged in milk sharing. However, there were no participants who were mothers of premature infants receiving PDHM or mothers whose infant had died, although mothers, milk banks and health professionals described milk sharing experiences that involved these mothers. I did not include actors at the international level of governance, which was underdeveloped at the time of the study, or actors with commercial interests in milk and milk banking, despite attempts to do so. Other missing actors with commercial interests relevant to the governance of milk sharing include health insurers, researchers and manufacturers of breast pumps and lactation aids (331), novel milk products and CMFs.

The AMPR analytical framework used in my analysis (218, 219), is based on the theory of planned behaviour (535). The latter has been applied to breastfeeding and donation to milk banks (374) mostly to investigate motivations, which are included and extended by analyses of awareness, pathways and rewards in the AMPR model. However, a limitation of the AMPR model, is its conceptualization of rewards as positive, which ignores the regulatory role of negative outcomes or 'penalties.' As discussed in this chapter, penalties such as stigma and guilt need to be acknowledged to understand legitimacy and resistance.

My analysis of governance acknowledges complexity but falls short of a full 'systems approach' (809). Systems models have been applied to breastfeeding, for example as a 'Complex Adaptive Health System' (810). A more developed conceptualization of complex systems include processes of governance ('policies, connections and boundaries, power and control dynamics, system regulations, values and norms and system interdependencies') (811). My research included some, but not all, of these features.

10.5 Future research

The regulation of milk sharing is more than a complex field of interdisciplinary scholarship. Today's regulatory decisions about milk chart the course for future systems of infant feeding towards breastfeeding, infant health, good governance and planetary health. This thesis examined some of the factors that shape milk sharing and breastfeeding, but gaps in knowledge and understanding remain, and new research questions and policy challenges are emerging.

More quantitative research is needed on the prevalence, safety and sustainability of cross-feeding and donor milk use in health settings and the community, linked to current surveys of infant feeding and socioeconomic and health data. Research to quantify the safety of milk shared altruistically may adopt the approach of Perrin et al (442), and extend it by linking data on milk to risk management practices and donor and infant health outcomes.

Further research is needed on the governance of milk sharing in three areas: the role of health professionals, the political economy of milk sharing, and legal and social measures that support 'alternative' economies (812). More empirical research is required of mothers who receive payment for milk and families who pay for it. Innovative research is needed on governance structures and compensation systems (262, 813) that resist commercial influence and enhance the collective power of mothers over the conditions under which breastfeeding, and milk sharing, occur. This research is needed to address complex problems and prevent further planetary degradation.

Building on the study's recommendations, the current regulatory regime governing milk sharing needs an alternative to governance by markets and a means to 'mobilize the knowledge and capacity' of weak actors through 'simple institutions' at macro and micro levels of governance (217, 739). Governance structures for milk sharing at local and national levels are needed that counter commercial power in infant feeding and prevent the alienation of milk from mothers, infants and communities. This requires some form of deliberative decision-making and collective governance by mothers, for example cooperatives, that need further investigation.

10.6 Conclusion

The ways that infants are fed, and mothers are treated, are crucial issues for the health of individuals, societies and the planet. This thesis set out to investigate the regulation of milk sharing and its implications for breastfeeding. From my empirical findings, I show that Australia is at a critical point in the regulation of milk sharing, with limited capacity to govern commercial power in the public interest. I make the case for a new way to govern milk sharing, in which milk is inalienable from infants and mothers are empowered to control all aspects of milk production, distribution and use. These principles require governance that makes mothers the subjects of regulation rather than its objects.

My research shows that milk sharing is not just an example of a complex regulatory problem but an example of a complex solution. Informal milk sharing is not the poor cousin of milk banking, but an example of local collective capacity, of 'weak actors' overcoming global commercial power, institutional indifference and gender discrimination. Milk sharing, as a regulatory topic, probes the boundaries of governance, the 'regulated' and the 'unregulated,' legitimacy and the objects of regulation. These constructs link the micro- and macro-level governance of women's lactating bodies as sites of production, resistance and power to the biopolitics of infant feeding at the global level, and, potentially, the biopharmaceutical industry. My research shows that milk sharing is empowering when its regulation includes mothers' voices in ways that respect individual autonomy but uphold

collective interests. Without these twin objectives, milk sharing risks reproducing social inequities in infant feeding.

The regulatory challenge is to implement pragmatic pathways to balance autonomy and social justice. Structures are needed that build localized and national collaborative capacity and make mothers central in the governance of milk, a shift that is essential to resist the market structures that favour CMF. This new ordering of social relations around milk brings full circle the ancient wisdom of cross-feeding, through varied histories of wet-nursing, to the current reality of human and planetary interdependency.

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Appendix 1. Literature review search terms

Databases:

Ovid MEDLINE® ALL 1946 to March 22, 2023

APA PsychInfor1806 to March Week 2 2023

Search terms:

TITLE-ABS-KEY(("milk bank*" OR "milk donat*" OR "donor milk" OR "donor breastmilk" OR "donor breast milk" OR "donor breast-milk" OR "donor human milk" OR "informal milk sharing" OR "milk sharing" OR "shar* milk" OR "wet nurs*" OR "wet-nurs*") AND (policy OR regulat* OR law OR guid* OR legal OR legislat* OR standard*)) AND PUBYEAR > 1999 AND (LIMIT-TO (LANGUAGE,"English"))

Appendix 2. Ethics approval

Approval for the study from the ANU Human Research Ethics Committee

aries@anu.edu.au

Thu 23/06/2016 11:42

Libby Salmon

Human.Ethics.Officer@anu.edu.au;Sharon Friel

Dear Dr Libby Salmon,

Protocol: 2016/036

Human milk sharing in Australia

I am pleased to advise you that your Human Ethics application received approval by the Chair of the Asia & Pacific DERC on the 23/06/2016.

For your information:

1. Under the NHMRC/AVCC National Statement on Ethical Conduct in Human Research we are required to follow up research that we have approved. Once a year (or sooner for short projects) we shall request a brief report on any ethical issues which may have arisen during your research or whether it proceeded according to the plan outlined in the above protocol.
 2. Please notify the committee of any changes to your protocol in the course of your research, and when you complete or cease working on the project.
 3. Please notify the Committee immediately if any unforeseen events occur that might affect continued ethical acceptability of the research work.
 4. Please advise the HREC if you receive any complaints about the research work.
 5. The validity of the current approval is five years' maximum from the date shown approved. For longer projects you are required to seek renewed approval from the Committee.
- All the best with your research,

Human Ethics Officer
Research Integrity & Compliance
Research Services Division
Level 2, Birch Building 36
Science Road, ANU
The Australian National University
Acton ACT 2601
T: 6125-3427

E: human.ethics.officer@anu.edu.au W: <https://services.anu.edu.au/research-support/ethics-integrity>

Approval from the Australian Breastfeeding Association to advertise the study

Fri 17/06/2016, 15:40

Hi Libby,

Your research project *Human Milk Sharing in Australia* has been approved by ABA.

Wherever and whenever you promote your research you should include the statement **ABA Research Approval Number 2016-9**.

Please:

- amend your application via the webform when ethics approval has been granted and
- once you have ethics approval, write a blurb inviting women to participate in your research which I will get uploaded to the ABA Forum at <http://forum.breastfeeding.asn.au/viewforum.php?f=14&sid=2e9c3b50f5e35d17f7568bf64cd2a09f>

Also, please remember that as part of the ABA research policy you have agreed to the following re publications:

Publication

All researchers whose requests are approved under this policy are encouraged to submit a synopsis/report of their research to Breastfeeding Review for consideration of publication. Research into ABA or the services offered by ABA will only be approved where it is intended to be published in Breastfeeding Review or another ABA publication.

Where approval is granted in accordance with this policy:

- ABA must be appropriately acknowledged in all research publications and presentations
- A copy of the research publication that involved ABA members, staff or resources must be sent to the Breastfeeding Information and Research team.

Regards

Susan Tawia

Manager Breastfeeding Information and Research BSc PhD Dip Ed Dip Breastfeeding Management Cert IV TAE

Australian Breastfeeding Association

1818 Malvern Rd, Malvern East, VIC 3145

P: 03 9885 0855

www.breastfeeding.asn.au | susan.tawia@breastfeeding.asn.au

Office days: Monday to Friday 9.00am to 5.00pm

Breastfeeding Helpline: 1800 686 268

Information for participants

Participant Information Sheet

Thank you for your interest in this study.

Researcher:

My name is Libby Salmon. I am a PhD scholar at the Australian National University, within the School of Regulation and Global Governance, College of Asia and the Pacific. The research described below is part of my study.

Project Title: Human milk sharing in Australia

General Outline of the Project:

Description and Methodology:

In Australia, over 90% of mothers attempt breastfeeding but many struggle to continue. When a mother cannot provide enough breastmilk for her baby, expressed breastmilk is sometimes available from another mother. A few hospitals have milk banks, but milk sharing also occurs between mothers in the community, through social networks and the internet. Milk sharing also includes direct breastfeeding of another mother's child (sometimes called wet-nursing and 'cross-nursing').

The purpose of this research is to understand how breast milk is shared and contributes to infant feeding in Australia. Through interviews with mothers who have shared breastmilk, health professionals, policy makers, non-government organizations, commercial groups and others with interests in infant feeding, I aim to inform parents and health policy makers about the practices, motivations and beliefs surrounding shared breastmilk and breastfeeding in Australia, and their effects on infant feeding decisions.

Participants:

I expect to conduct interviews with 40 mothers of children born in Australia since March 2011 who have shared breastfeeding or breastmilk, or attempted these activities, and 30 health professionals, policy makers and others with interests in infant feeding. As the number of interviews is limited, not all interested parties can be interviewed.

Use of Data and Feedback:

The data collected during interviews will be used in my PhD and could be published in my PhD thesis, academic journals and books. It could also be presented at academic conferences. If you are interested in the outcomes of the project, I will be happy to provide you with feedback about the research at a later stage, after the interview, if you send me a request by email to the address provided in the contacts section below.

Participant Involvement:

Voluntary Participation & Withdrawal:

Your participation in the project will involve taking part in an interview. The aim of the interview is to find out (1) your experience, understanding and opinion about: (a) the ways that breastfeeding or breastmilk are shared in Australia (b), what helps or hinders these practices, (c) and how they might affect infant feeding outcomes; (2) what influences your views about these practices, and (3) your role and responsibilities with regard to infant feeding.

Your participation in the project is **voluntary** and you may, without negative consequences, refuse to answer a question. You can also decline to take part or withdraw from the research without providing an explanation at any time until the work is prepared for publication by contacting me by email. If you withdraw, your data will be destroyed and not used.

What does participation in the research entail?

In the face-to-face interview you will be asked about your experience, understanding and opinions about sharing breastfeeding or breastmilk and your role in relation to infant feeding.

Location and Duration:

The interview will take up to one hour to complete, at a place and time that is convenient to you.

Risks:

Some participants may feel uncomfortable when they reflect on aspects of milk sharing or infant feeding or their associated roles. If you feel this way, you may stop or discontinue the interview or withdraw from the study or seek support from the services listed after the contact section below.

Benefits:

It is unlikely that the outcomes of this research will benefit you personally. It is hoped that this study will benefit the Australian community through an improved understanding of how milk sharing contributes to infant feeding. As breastfeeding women continue to express and store milk, we expect this knowledge will enhance policy development in infant and maternal health.

Exclusion criteria:

Participant Limitation:

You must be at least 18 years old and fluent in English to participate.

Confidentiality:

Confidentiality: This research is carried out in accordance with the provisions of the Commonwealth Privacy Act 1988 and the Australian Privacy Principles Guidelines (both accessible at: www.comlaw.gov.au). Your name will not be used. You have the option to participate in the research without an attribution or with the use of a pseudonym. In any publication of the research, your comments will be assigned to a category (e.g. health professional #, health policy maker #) unless you prefer that no attribution be made. Where I quote from you or present your views in publications this will be done anonymously. If you agree to the interview being audio-recorded, all recordings will be erased after transcription of the interview.

In collecting your personal information within this research, the Australian National University (ANU) must comply with the Privacy Act 1988. The ANU Privacy Policy is available at https://policies.anu.edu.au/ppi/document/ANUP_010007 and it contains information about how a person can:

Access or seek correction to their personal information;

Complain about a breach of an Australian Privacy Principle by ANU, and how ANU will handle the complaint.

Data Storage:

Where:

Only I and my academic supervisor will have access to the data. During travel, consent forms and data will be stored securely. Upon return from field work, I will keep all recordings, transcripts, notes and consent forms secure in a locked filing cabinet in my office. Electronic information will be saved in a password-protected file at all times. Audio recordings and interview transcripts will be kept in a locked cabinet, safe or password-protected file.

How long: In accordance with Australian National University policies, information gathered for this project will be retained for at least 5 years following publication.

Handling of Data following the required storage period:

At the end of the storage period above, transcripts for this project will be archived in a de-identified format for future research by me and my academic supervisor.

Queries and Concerns:

Contact Details for More Information:

For further information or other queries about the study, please feel free to contact me or the Chair of my PhD panel, Professor Sharon Friel.

Libby Salmon PhD Scholar School of Regulation and Global Governance (RegNet) College of Asia and the Pacific The Australian National University, ACT 0200 T: +61 2 6125 0126 E: libby.salmon@anu.edu.au	Sharon Friel Director and Professor of Health Equity School of Regulation and Global Governance (RegNet) College of Asia and the Pacific The Australian National University, ACT 0200 T: +61 2 6125 2150 E: sharon.friel@anu.edu.au
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Contact Details if in Distress: If any of the questions that you are asked feel stressful you can discuss them anonymously with a counsellor on the Australian Breastfeeding Association's free 24 hour Breastfeeding Helpline by telephoning 1800 686 268, or contact your family doctor.

Ethics Committee Clearance:

The ethical aspects of this research have been approved by the ANU Human Research Ethics Committee (Protocol 2016/036) and the Australian Breastfeeding Association (ABA Research Approval Number: 2016-9). If you have any concerns or complaints about how this research has been conducted, please contact:

Ethics Manager
The ANU Human Research Ethics Committee
The Australian National University
Telephone: +61 2 6125 3427
Email: Human.Ethics.Officer@anu.edu.au

Appendix 3. Study of legal structures

Letter to Departments of Health seeking information on the legal structures that regulated human milk.

Sent to Commonwealth and all state and territory jurisdictions.

[Date] [To: Name Position Address] Regulation of human milk Dear I am a PhD candidate at the Australian National University studying the contribution of human milk sharing to infant feeding in Australia. My work is focused on the social and legal regulation of human milk that is shared through milk banks or by less formal arrangements in the community. As indicated in Annexure 1 – Background, my thesis investigates human milk sharing from the perspectives of mothers who share milk, as well as health professionals and policy makers. I am seeking your assistance to clarify regulatory arrangements for human milk sharing in your jurisdiction. A 2014 Commonwealth discussion paper ‘Donor Human Milk Banking in Australia’ highlighted the uncertainty of the classification of human milk as a food, human tissue, therapeutic good or some other product. [1] The paper did not address the sharing of human milk in the community, which has since become more common and debated, in local media [2-4] and internationally [5-7]. The website for the Australian Government’s Organ and Tissue Authority provides links to some of the relevant legislation in Australia as shown at Annexure 2. Could you please advise whether there are any additional legislative provisions that apply in your jurisdiction to the sharing of human milk - either through milk banks, or informally in the community? My research will address several regulatory questions as set out at Annexure 3. These are important issues to resolve as part of infant feeding policy. I would be most grateful for any assistance you could provide or the contact details of a person in your Department with which to discuss these matters further. Sincerely Libby Salmon PhD Candidate Centre for Health Equity and Governance RegNet School of Regulation and Global Governance Research approved by ANU Human Research Ethics Committee (Protocol 2016/036) and the Australian Breastfeeding Association (ABA Research Approval Number 2016-9).
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(Letter to Departments of Health to request an interview continued)

Annexure 1 – Background

Milk sharing occurs when a mother cannot provide enough of her own breastmilk for her baby, either temporarily or permanently. In infant feeding policy, milk sharing is endorsed by the WHO Global Strategy on Infant and Young Child Feeding 2003, which states that donor milk may be provided by a healthy wet-nurse or a milk bank as an alternative to the use of breastmilk substitutes (7).

Australia's National Breastfeeding Strategy 2010-15 highlighted the importance of milk banks (575), and four jurisdictions have milk banks that provide pasteurized milk from screened and tested donors for babies that are typically hospitalized and unwell (96). In the community, human milk may also be shared through exchanges between mothers of fresh, chilled or frozen expressed milk or arrangements to share breastfeeding (wet-nursing or cross-nursing). Such arrangements are typically made face-to-face between relatives or close friends, or may be facilitated by the internet or social media (274).

Internationally, concern about the safety of sharing human outside milk banks has resulted in warnings from health authorities. In Australia, prospective donors and recipients of milk are advised to consult medical practitioners by the Australian College of Midwives (670), the Australian Breastfeeding Association (669) and the Victorian Department of Health and Human Services (814).

However it can be argued that in Australia, community milk sharing occurs under varying degrees of medical supervision. Universal health coverage for maternity care, ensures that donor mothers receive routine antenatal screening and testing for infectious diseases that may be transmitted through human milk.¹³⁸ This testing ensures that mothers are sufficiently healthy to breastfeed their own child. The majority of Australian breastfeeding mothers also express and store their milk for their own baby at some stage (160), using guidelines provided during post-natal hospital stays, medical authorities (10, 815) and breastfeeding support organizations (662). Health professionals may also be more directly involved in milk sharing arrangements.

Further issues are the legality of trade in human milk and human milk products and the legal and ethical position of health professionals who may be approached by parents seeking human milk.

(Letter to Departments of Health to request an interview continued)

Annexure 2 – [Organ and Tissue authority links](#) for Commonwealth and State Legislation

[Commonwealth](#)

[Australian Organ and Tissue Donation And Transplantation Authority Act 2008](#)

[Australian Capital Territory](#)

[Transplantation and Anatomy Act 1978](#)

[New South Wales](#)

[Human Tissue Act 1983](#)

[Queensland](#)

[Transplantation and Anatomy Act 1979](#)

[Northern Territory](#)

[Transplantation and Anatomy Act](#)

[South Australia](#)

[Transplantation and Anatomy Act 1983](#)

[Tasmania](#)

[Human Tissue Act 1985](#)

[Victoria](#)

[Human Tissue Act 1982](#)

[Western Australia](#)

[Human Tissue and Transplant Act 1982](#)

¹³⁸ Human Immunodeficiency Virus (HIV), Hepatitis B and C viruses, Human T-lymphotropic virus (HTLV) 1 and 2, Variant Creutzfeldt-Jakob disease (vCJD), cytomegalovirus (CMV) and syphilis.

(Letter to Departments of Health to request an interview continued)

Annexure 3 – Questions on regulatory issues regarding human milk sharing

1. What is the legal classification of human milk in each jurisdiction?
 - a. Please refer to the legislation, departmental or Ministerial determination or other regulatory measure used to answer these questions.
2. What is the appropriate classification of human milk for each type of milk sharing illustrated in Table 1?

Table 1. Example situations in which human milk is shared with different levels of medical supervision* of the donor and recipient baby in different settings.

		Recipient baby		
		Medically supervised*		Not medically supervised
		Hospital	Community	Community
Donor	Medically supervised*	a. Milk bank associated with hospital	b. Milk bank in community, or midwife or lactation consultant knows donor and recipient	c. Lactation consultant or midwife manages a list of approved donors
	Not medically supervised	d. Friend provides milk for hospitalized baby e.g. with approval of paediatrician	e. Friend provides milk for baby in care of community health professional e.g. GP, MACH nurse	f. Peer-peer community milk sharing

*Medical supervision refers to being a client of a registered health service provider, for example a midwife, general practitioner, paediatrician, family services/maternal and child health nurse or lactation consultant qualified by the International Board of Lactation Consultant Examiners (IBLCE).

3. How does the legal classification of milk vary with the level of medical supervision of the recipient baby and donor or setting in the example scenarios summarized in Table 1:
 - a. The recipient baby and the donor are under some form of medical supervision, e.g. a hospitalized baby in a Neonatal Intensive Care Unit receives pasteurized milk from a human milk bank associated with a hospital (that uses screened and tested donors).
 - b. The recipient baby is not hospitalized but both she and the donor are under some form of medical supervision, for example a private midwife who provides post-natal care in the community and who knows both the donor and recipient.
 - c. The recipient baby is not hospitalized and a public health service or a private midwife or lactation consultant manages a list of eligible donors, for example the human milk donor was, within the previous 3 months, tested with negative results for HIV, Hepatitis B and C and syphilis under the supervision of a medical practitioner.
 - d. The recipient baby is in a private hospital and a private patient of a paediatrician who approves the provision of milk by a close friend of the mother.
 - e. The recipient baby is in the community under the care of a general practitioner who approves the provision of milk by a close friend of the mother.
 - f. The recipient baby is in the community and receives milk from a close friend of the mother.
4. Are there any restrictions in trade in human milk or processed human milk (chilled, frozen, pasteurized or otherwise treated) or human milk components or products?
 - a. Under what conditions can
 - i. human milk be sold or bought,
 - ii. a donor or processing facility (e.g. a milk banks) be eligible for reimbursement for expenses?

5. What, if any, are the legal, ethical or other implications for the administrators or users of social media and internet sites that:
 - a. facilitate connection between potential milk donors and recipient mothers.
 - b. host advertisements for human milk donors or recipients which refer to:
 - i. no payment or reward for human milk.
 - ii. payment or reward for human milk.
6. Under what legislation and conditions can breastfeeding services (wet-nursing or cross-feeding) be
 - i. conducted legally
 - ii. sold or purchased
 - iii. eligible for reimbursement of expenses?
7. What human milk banks are in operation and/or planned for each jurisdiction?
 - a. In each jurisdiction can parents access banked human milk for unwell, hospitalized babies receiving medical treatment in a hospital that does not have a milk bank?
 - b. If so, how is the milk supplied?
 - c. If so, which babies are eligible?
8. Which policies, legal instruments, regulations and guidelines apply to the operation of milk banks in each jurisdiction?
9. To assess the likelihood of transmission of infectious diseases relevant to milk sharing, please provide for each jurisdiction:
 - a. The rate of coverage of antenatal care for mothers in particular those who subsequently breastfeed their own children?
 - b. The rate of breastfeeding at 1, 3 and 5 and 12 months post-partum
 - c. The latest data on the prevalence of infection with HIV, Hepatitis B and C, HTLV 1 and 2, CMV or syphilis¹³⁹ of:
 - i. pregnant women,
 - ii. mothers at the time of birth, and at 1, 3, 5 and 12 months post-partum
 - iii. lactating mothers at 1, 3 and 5 and 12 months post-partum
10. What guidelines are available for health professionals to advise mothers on the safe sharing of human milk and breastfeeding in the community (i.e. not through a milk bank)?
11. What, if any, are the legal, ethical or other implications for health professionals (e.g. midwife, paediatrician, general physician, qualified lactation consultant, family services/maternal and child health nurse) who:
 - i. suggest that a mother asks a breastfeeding friend to supply milk or breastfeed her baby
 - ii. facilitates connection between potential milk donors and recipient mothers?

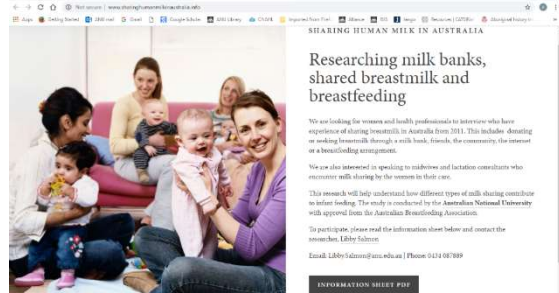
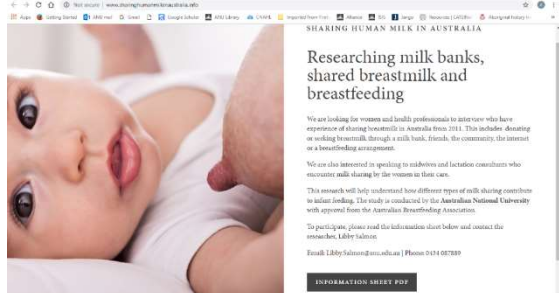
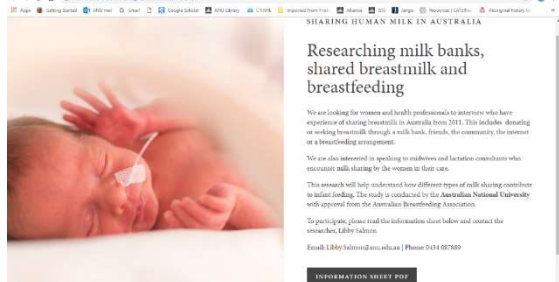
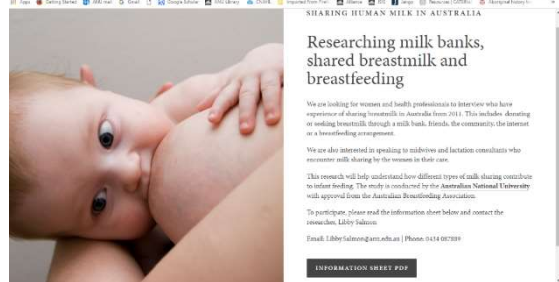
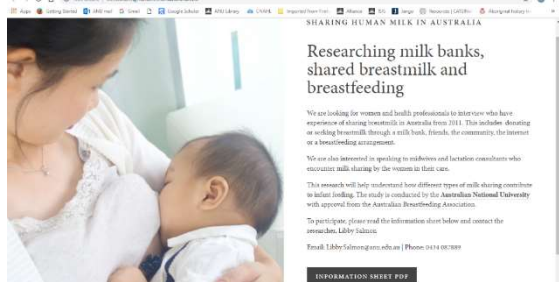
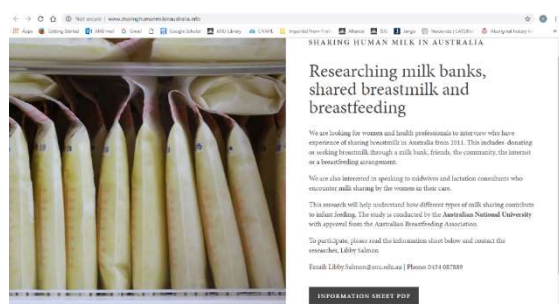
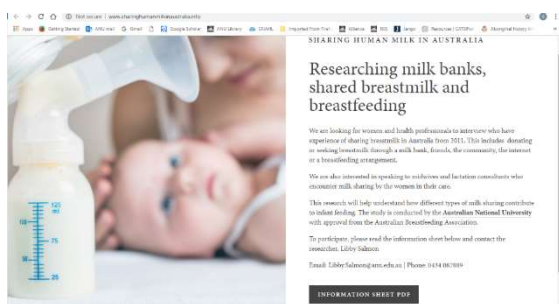
¹³⁹ Human Immunodeficiency Virus (HIV), Hepatitis B and C viruses, Human T-lymphotropic virus (HTLV) 1 and 2, Variant Creutzfeldt-Jakob disease (vCJD), cytomegalovirus (CMV) and syphilis.

Appendix 4. Study of mothers who shared milk

Web page to advertise the research

A web page titled 'Sharing human milk in Australia' was created to advertise the study of milk sharing to mothers and health professionals and provide access to the information sheet for research participants as a PDF to download. <http://www.sharinghumanmilkinaustralia.info/>. Designed in Squarespace software July 2016.

Screenshot of web page with rotating images to illustrate diverse types of milk sharing (milk banks, expressed milk and cross-feeding) and population groups.



Advertisement on Australian Breastfeeding Association (ABA) Research Forum

The following text was posted on the ABA web site Research Forum from 1 July 2016 30 June 2017 (<http://forum.breastfeeding.asn.au/viewforum.php?f=14&sid=65598768f082c67f78f18a209dc00249>).

“Research on sharing breastmilk and breastfeeding

We are looking for women to participate in interviews to understand how breastmilk and breastfeeding are shared and contribute to infant feeding in Australia.

Each interview will focus on your experience of providing or using breastmilk through milk banks, social groups, the internet or by sharing breastfeeding. At the end of the interview you will be asked to complete a short survey about you and your household. The interview and survey will take about 1 hour to complete.

The study has been approved by the Australian Breastfeeding Association (ABA Research Approval Number: 2016-9) and the Australian National University Human Ethics Committee (Protocol: 2016/036).

To take part in the study you need to be aged 18 years or over and to have given birth in Australia since March 2011 and shared breastmilk or breastfeeding. To acknowledge your help, you will be offered a \$20 shopping voucher at the time of the interview.

For more information or to participate in this study please contact Libby Salmon at the Australian National University by email at Libby.Salmon@anu.edu.au or phone 0434 087889.”

Appendix 5. Study of health professionals

Email to LCA NZ Board for assistance to interview members

Fw: Research request - Sharing Human Milk in Australia –what is the role of lactation consultants?

Libby Salmon

Tue 04/12/2018 13:57

To:

2 attachments (219 KB)

LCA NZ survey request-Background_Salmon_20180504.docx; 2016-036_Salmon_Information-Sheet-resubmitted_modified-HPs_ABA.pdf;

Dear

This is an email to you in my capacity as a PhD candidate, separate to my role in XXXX. I caught up with you briefly at the LCA NZ conference in Adelaide in October about my research on human milk sharing.

I am interested in understanding the role of lactation consultants in human milk sharing, defined as shared breastfeeding or expressed breastmilk, through milk banks and informal arrangements.

Given earlier problems with communication (below), I have changed my study design from a survey and am seeking the assistance of the LCA NZ Board to:

Interview the LCA NZ President, or relevant board member, about the organization's official position about the role of lactation consultants in milk sharing and use of human milk, including policy development and regulatory activity on these topics.

Interview a small sample of LCA NZ members about their opinions and experience of milk sharing in their professional roles since April 2011.

I need to select a small sample of about 10 LCA NZ members from those interested in this topic. I am seeking a diversity of views and experiences - positive, neutral and negative.

Interviews would be confidential and conducted face-to-face in January-February 2019, at a location convenient to the participant.

Background information on the study is attached (and the previous background to the survey).

Hopefully this is a much simpler request than my earlier one for assistance with a survey, and that the Board and LCA NZ members are interested in research on the role and regulation of milk sharing in infant feeding in Australia.

I realize it is close to the end of the year but would be grateful if you could let me know the feasibility of this request and the possible timelines for a formal request to the LCA NZ Board.

I am happy to discuss by phone if that is easier - my mobile is 0434 087889.

Kind regards

Libby

Libby Salmon BVSc MVS

PhD candidate

Centre for Health Equity and Governance

School of Regulation and Global Governance (RegNet)

The Australian National University

Email to board of Australian College of Midwives to request assistance with research

Research on Human Milk Sharing in Australia- The Perspectives of Midwives

Libby Salmon

Wed 23/01/2019 17:45

@midwives.org.au>;

2 attachments (347 KB)

2016-036_Salmon_Information-Sheet-resubmitted_modifed-HPs_ABA.pdf; ACM -Ad for interviews on milk sharing.docx;

Dear

Thank you for taking the time today to talk about my research on sharing human milk. I am located in the Centre for Health Equity and Governance at The School of Regulation and Global Governance at the Australian National University in Canberra. Background information on my PhD project is attached, with details of ethics approval.

Earlier work in this project with women who shared breastmilk pointed to the importance of midwives and other health professionals in how breastmilk is "regulated" socially and legally. As discussed, last year I sought ACM's assistance to publicise a survey of midwives planned for late 2018, and ACM kindly published an article in Australian Midwifery News (emails below).

My project design has now changed and I would like to interview a small sample of 10 midwives for my project.

I am seeking the assistance of ACM to send an email to its members to advertise the study and ask midwives to contact me if they are interested in participating.

The suggested text of the advertisement is below.

Please don't hesitate to contact me with any questions about the study by email or phone (0434 087889).

Many thanks for your assistance,

Libby

The suggested text of the advertisement below (and attached in a Word document):

What are Midwives' experiences and views about sharing breastmilk?

My name is Libby Salmon and I am a PhD student at the Australian National University researching [breastmilk sharing in Australia](#). Earlier work in this study with mothers pointed to the importance of midwives and other health professionals in shaping women's attitudes and practices around milk sharing.

I would like to interview midwives about their encounters with breastmilk sharing in their work. This includes use by women in the midwife's care of breastmilk banks or shared expressed breastmilk or cross-feeding through informal arrangements.

I am particularly interested in how midwives view different types of breastmilk sharing, from positive to negative, and how they handle issues about milk sharing in health facilities, private practice or the community.

Background information on the study is attached. Briefly:

- Individual face-to-face **interviews** would be conducted by me at a location convenient to you.
- Interviews take about 1 hour, and are strictly confidential (audio recorded, with permission).
- This study has been approved by the ANU Human Research Ethics Committee.

Eligibility to participate:

- Someone in your professional care shared milk after 1 April 2011.
- You were a registered midwife in Australia at the time.
- You speak English and are located in Queensland, New South Wales, Victoria or the ACT.
- You are available for an interview in March-April 2019.

Next steps:

If you are interested or have any questions, please send me an email at Libby.Salmon@anu.edu.au

In your reply please outline briefly:

- The type/s of breast milk sharing or issue you encountered
- Your role (Clinician, Administrator, Teacher/educator, Researcher)
- Your work setting (hospital postnatal ward, neonatal care, community, private practice, policy, other...)
- Your location for interview (nearest suburb/town/city)

This information will assist selection of participants. Unfortunately resources do not allow everyone to be interviewed. Feel free to share this information with other midwives.

I look forward to hearing from you!

Libby

Libby Salmon BVSc MVS

PhD candidate

Centre for Health Equity and Governance

School of Regulation and Global Governance (RegNet)

The Australian National University

Canberra ACT 0200

E libby.salmon@anu.edu.au | T 0434087889 | W Libby Salmon

Research: Sharing Human Milk in Australia

www.sharinghumanmilkinaustralia.info

Advertisement in Australian College of Midwives e-newsletter March 2019

What are Midwives' experiences and views about sharing breastmilk?

I am seeking midwives to interview about their encounters with breastmilk sharing in their work.

This study is part of my PhD research on [breastmilk sharing in Australia](http://www.sharinghumanmilkinaustralia.info), which highlights the role of midwives in shaping women's views and practices towards sharing breastmilk and cross-feeding.

Eligibility:

- Someone in your professional care shared breastmilk or cross-fed after 1 April 2011.
- At the time, you were a registered midwife in Australia in the ACT, NSW, Victoria or Queensland.
- You are available for an interview in March-April 2019.

What's involved:

- Individual, confidential face-to-face interviews (~1 hour) at a time and location convenient to you.
- Study approved by the Australian National University Human Research Ethics Committee.

Interested?

Contact Libby.Salmon@anu.edu.au or Mobile **0434 087889** and outline the milk sharing event/s, your type of work, setting and location.

Background information at <http://www.sharinghumanmilkinaustralia.info/>

Please share this study - I look forward to hearing from you!

Libby Salmon



Appendix 6. Interview questions

Questions for mothers who shared milk

Semi-structured interviews were prepared on the following questions about Experience, Awareness, Motivations, Rewards, Pathways and Breastfeeding outcomes.

“Breastmilk can be shared in many ways. For example, when a mother provides her breastmilk for someone else’s child, or when a mother feeds her baby another mother’s breastmilk. Breastmilk can also be shared directly through breastfeeding.

For convenience, 'milk' refers to breastmilk here.”

1. Experience:

- 1.1. Can you start by telling me about your milk-sharing journey?
- 1.2. What was that like?
- 1.3. Can you tell me what was going on for you with feeding your baby at that time?
- 1.4. Can you tell me who was involved in milk sharing?
- 1.5. What contact did you have with the people you shared milk with?
- 1.6. Can you tell me about any groups or organizations involved?
- 1.7. If so, what was it like to deal with them?
- 1.8. Tell me how you go about sharing milk.

2. Awareness:

- 2.1. Can you tell me how you first heard about sharing milk?
- 2.2. What were the options available to you for sharing milk?
- 2.3. When you decided to share milk, what were the key issues for you?
- 2.4. Can you tell me how you managed these issues?
- 2.5. Once you decided to share milk, what were the things you had to learn to get started to share milk?
- 2.6. How did you learn this?
- 2.7. Can you tell me what you think about milk banks and why parents might seek milk from one? (if milk banks not mentioned)
- 2.8. Can you tell me what you think about informal milk sharing and why parents might seek milk this way? (if informal milk sharing not mentioned)

3. Motivations

- 3.1. Tell me what motivated you to share milk. How did this change over time?
- 3.2. Can you tell me if anyone or an event influenced you to share milk?

4. Rewards

- 4.1. I would like to explore the pros and cons of milk sharing and how it affected you
- 4.2. Can you tell me about any positive things that occurred for you because of milk sharing?
- 4.3. Can you tell me about any negative things that occurred for you because of milk sharing?
- 4.4. Can you tell me about any positive thoughts and feelings you had about milk sharing at the time?
- 4.5. Can you tell me about any negative thoughts and feelings you had about milk sharing at the time?
- 4.6. Could you describe any positive effects on your family from sharing milk?
- 4.7. Could you describe any negative effects on your family from sharing milk?

- 4.8. Could you describe any ways in which your milk sharing affected your community?
- 4.9. Can you tell me what do you think about gifts or payment for breastmilk?

5. Pathways

- 5.1. I would like to find out about the ways milk sharing was made easier or difficult for you
- 5.2. What helped you to share milk?
- 5.3. What equipment did you use to share milk?
- 5.4. What facilities or services did you need to use to share milk?
- 5.5. What personal characteristics do you think were important for you to share milk?
- 5.6. Who has been the most helpful in milk sharing?
- 5.7. Has any group or organisation been helpful in sharing milk?
- 5.8. What hindered milk sharing for you?
- 5.9. Why was the way you shared milk best for you over other options?
- 5.10. What were the biggest restrictions on how you shared milk?
- 5.11. How did you decide who to share milk with?
- 5.12. Is there anyone you would NOT share milk with?
- 5.13. Were there any controls on how the shared milk was used?
- 5.14. In general, who do you think should be able to use breastmilk?
- 5.15. Is there anyone who should not be allowed to use breastmilk?
- 5.16. Who have you told about your milk sharing experience?
- 5.17. Is there anyone you would NOT tell about your milk sharing experience?
- 5.18. Whose business is it whether you share milk? Why?
- 5.19. Can you tell me about any legal issues about sharing milk that you have encountered?

6. Breastfeeding

- 6.1. I would like to find out how you think milk sharing might affect breastfeeding
- 6.2. Can you tell me about any ways that your milk sharing experience affected breastfeeding your child?
- 6.3. If you had another child, how do you think your milk sharing experience might affect your intention to breastfeed?
- 6.4. If you had another child, how do you think your milk sharing experience might affect your ability to breastfeed?

7. Overall

- 7.1. What advice about milk sharing would you give to a pregnant woman expecting her first baby?
- 7.2. Is there anything else you'd like to mention about milk sharing?

Online survey to collect demographic data from women interviewed

Electronic survey to collect demographic data from participants in the study of women who shared milk (N=48). After each interview, an email was sent to the participant containing a web link to the survey front page, a password to enter the survey and a unique code that enabled each participant's survey and interview data to be linked. Hosted on Survey Monkey software and password protected (i.e. not available to wider public). Paper copies of the survey were also made available.



THE AUSTRALIAN NATIONAL UNIVERSITY

Sharing Human Milk in Australia - Mothers

Welcome

Thank you for participating in this research on milk banking, shared breastmilk and breastfeeding. Your feedback is important.

This survey seeks information, in addition to the interview, about some of your personal and household details.

- The survey takes about 5 minutes to complete.
- If you do not understand a question, please ask the researcher to clarify.
- You do not have to answer any questions and you can withdraw from the study at any time, without negative consequences.
- If you feel uncomfortable or upset by any of the questions you can stop or discontinue the survey.
- You may choose to give reasons at the end of the survey, or refer to support services provided on the Information Sheet.

This research has been approved by the Australian National University Research Ethics Committee (Protocol 2016/36) and the Australian Breastfeeding Association (Research Approval Number: 2016-9).

If you have any concerns or complaints please contact:

Ethics Manager
 The ANU Human Research Ethics Committee
 The Australian National University
 Telephone: +61 2 6125 3247
 Email: Human.Ethics.Officer@anu.edu.au

1

1. Please enter your interview code []
2. Your age in years? [18-24; 25-29; 30-34; 35-39; 40-44; 45 or older]
3. What is your current marital status? [Married or in de facto relationship; Separated or divorced; Single; Other (please specify)]
4. How many biological children have you had in your lifetime? []
5. What is the highest level of education you have completed? [Left school before Year 10; Year 10; Year 12; Certificate IV; Diploma or Advance Diploma; Associate Degree; Bachelor's Degree; Master's Degree or PhD; Other (please specify)]
6. What was your status in the paid labour force at 2 months before the birth of your child (relevant to the latest milk sharing experience)? [Full time (usually 37 hours per week); Part time (usually less than 37 hours per week); Unemployed (i.e. not working more than one hour per week, and actively looking for paid work, and available to start work); Not in the paid labour force; Other (please specify)].
7. What parental leave did you use in the first 12 months after the birth of your child (relevant to your main milk sharing experience)? [Paid Parental Leave Scheme (PPL); Employer-provided parental Leave- Paid; Employer-provided parental Leave- Unpaid; Personal Leave- paid; Personal Leave –Unpaid; No leave taken; No leave available; Other (please specify)]
8. Your postcode []
9. How many children aged under 15 years currently live in your household? []
10. How many adults (people aged 18 years or older) currently live in your household?
11. How much total combine money did all members of your household earn in 2015? (This includes money from jobs; net income from business, farm, or rent; pensions; dividends; interest; social security payments, and any other money income received by members of your HOUSEHOLD that are EIGHTEEN (18) years of age or older. Please report total amount of money earned –do not subtract the amount you paid in taxes or any deductions on your tax return) [Less than \$20,000; \$20,000 to \$34,999; \$35,000 to \$49,999; \$50,000 to \$74,999; \$75,000 to \$99,999; \$100,000 to \$149,999; \$150,000 or more)
12. In which country were you born? [Australia; England; New Zealand; India; Italy; Vietnam; Philippines; South Africa; Scotland; Malaysia; Other (please specify)]
13. Which language do you mainly speak at home? [English; Mandarin; Italian; Arabic; Cantonese; Greek; Vietnamese; Spanish; Hindi; Tagalog; Other (please specify)]
14. Are you a current member of the Australian Breastfeeding Association (ABA)? [Yes; No, but a member previously; Never been a member; Don't know; Other (please specify)]
15. Is there anything you would like to clarify or say about the questionnaire or interview? []

Thank you for your contribution to this research.

Interview questions for milk bank staff

Background

1. Your role in this milk bank
2. Details of the milk bank's operations:
 - a. How long has the milk bank been open?
 - b. Numbers and types of staff?
 - c. How many litres of milk has it processed?
 - d. How many donors?
 - e. How many recipient babies?
 - f. What criteria are used to prioritize recipients?
 - g. How is milk utilized?
 - i. What proportion of donated milk is fed to babies or discarded?

Role of milk banks

3. In your opinion, what is the role of a milk bank?
 - a. Who should have access to milk banks?
4. In your opinion, what demand is there for banked human milk?
 - a. How much of this demand is met?
 - b. What helps/hinders meeting this demand?
5. Is there a wider role for milk banking in infant feeding?
 - a. What is the effect, if any, of milk banking on breastfeeding?

Legal regulation

6. What legislation applies to this milk bank?
 - a. What hospital-level policies apply?
7. What guidelines/standards are used?
8. What legal regulation or other controls are needed for milk banks?
9. What associations or networks are needed for milk banking in Australia?

Governance of milk banks

10. How are the operations of the milk bank managed?
11. What are the milk bank's measures of performance?
12. Who should be involved in milk banking?
 - a. What qualifications are required for milk bank operations?
 - b. What oversight is required, and who should provide this?
 - c. How should milk banks be 'marketed'?
 - d. Who should advocate for milk banks?
13. What relationships does this milk bank have with other milk banks and tertiary NICUs in Australia?

Funding

14. What funding arrangements would support milk bank establishment and maintenance?
15. What are the major costs of donor milk (as fed)?
 - a. How are costs affected by:
 - i. Operations of donor screening, donor testing, milk testing, milk processing, storage and record keeping?
 - ii. Staff? Equipment? Premises?
16. How is banked milk valued?
17. What are the issues associated with payment for milk in Australia?

Constraints/facilitators

18. What helped and hindered establishing the milk bank?
19. What capacity is there for expansion of milk banking?
20. How does the milk bank balance the need for safety and efficacy?
 - a. Are there alternatives to the use of Holder pasteurization?
21. If milk supplies were abundant,

- a. How might that change the value of banked milk?
 - b. Would the milk bank supply non-hospitalized babies?
 - i. If so, what criteria would be used?
- 22. What level of awareness and knowledge of milk banks by health professionals and the community are required?
 - a. What is the role of social media and the internet in creating awareness and demand for milk banks?
- 23. What potential harms and benefits are there from sharing milk outside milk banks in Australia?
- 24. What is the relationship between milk banks and those involved in sharing milk outside milk banks?
- 25. In your opinion, what are the opportunities and threats to milk banking in Australia?

Questions for policy makers

Definitions:

“Milk” -breastmilk or human milk.

“Milk sharing” -the use of milk banks and informal arrangements to share expressed milk or breastfeeding.

1. Please describe your position title, qualifications and work relevant to milk sharing or infant feeding.
2. What is your understanding of current milk sharing practices in Australia?
3. What issues of relevance to your agency and position, if any, have arisen with respect to milk sharing?
 - a. How were these issues raised?
4. How is shared milk, as a product, classified legally by your agency (if at all)?
5. How is milk sharing, as an activity, classified legally by your agency (if at all)?
6. How is shared milk addressed by your agency (if at all)?
 - a. What are these positions, policies or other regulatory measures?
 - b. What are the objectives of these policies?
 - c. Who are the targets of these policies?
 - d. How binding are these policies?
 - e. How effective are these policies?
 - f. Which stakeholders should be involved in policy development for shared milk?
7. What are these policies or regulatory measures based on? (principles, mechanisms, evidence, other policies, other agency positions)
8. In what ways does policy making for shared milk align with or deviate from policy making for breastfeeding, infant formula or bottle feeding?
9. How are these policies and processes affected by:
 - a. Demand for milk through milk banks or informal arrangements?
 - b. Commercial markets for milk?
 - c. Imported milk?
 - d. Development of products from milk?
10. What should pregnant and breastfeeding women know about milk sharing?
11. What should health professionals know and do about milk sharing (if anything)?
12. What is the legal liability of health professionals and lay individuals involved in milk sharing?
13. What opportunities and threats to your agency are posed by milk banking and milk sharing?
14. In your view, in what ways might milk sharing affect breastfeeding?

Questions for health professionals

Please describe your current:

1. Qualifications, (dates)
2. Position (midwife (MW)/lactation consultant (LC)/both)
 - a. How long in position?
3. Current employer (facility, community; public, private sector)
4. Location of work (metro/regional/rural/remote; state/territory)
5. Job description (clinical, administrative, research, other)
6. Clients - the issues they bring to you, area they are from, SES
7. Own
 - a. infant feeding history, if relevant
 - b. personal experience of milk sharing in your own feeding experience, family or social networks – (use of milk banks, shared breastmilk or cross-feeding)
8. **In general,**
 - a. What do you think are the Pros and Cons of milk sharing?
 - i. (Benefits -nutritional, health, social, social capital/harms, risks, costs)
 - b. On balance, would you say is your overall position towards each different type of milk sharing?
 - i. milk banks
 - ii. informal sharing of expressed breastmilk (IMS)
 - iii. shared breastfeeding or cross-feeding CF
 - c. What are your main reasons here?

Thinking about the period from 2011 onwards,

9. **In your work as a MW or LC, have you encountered MB, IMS, or CF?**
 - a. What happened?
 - i. Who, what, when, where, why, how?
 - ii. Ages of infants?
 - iii. How often does this happen?
 - iv. Amount of CF (number of feeds) or Volumes of milk involved?
 - v. Any cultural, linguistic factors associated with the MS event (families or other HPs/staff)
 - b. What was your role here?
 - c. For the mothers and infants involved, what were the:
 - i. Positive outcomes of the event?
 - ii. Negative outcomes or adverse events?
 1. In what ways did they manage these?
 - d. For you as a health professional, what were the:
 - i. Positive outcomes of the event?
 1. In what ways did you allow or facilitate these?
 - ii. Negative outcomes or adverse events?
 1. In what ways did you manage these?
 2. What were your major concerns here?
 - iii. Safety issues, if any, you were aware of?
 1. What did you do to address these issues, if anything?
 2. What types of information, if any, do you use to manage safety?
 3. What level of donor screening and testing was required? (any why)
 4. What level of milk processing, if any, do they require? (and why)
 5. What criteria do you use to:
 - a. Assess a baby's need for shared milk?
 - b. Allocate shared milk (if limited)
 - iv. What professional ethical and legal issues arose?
 1. What Policy or Guidelines were available or did you use?

- a. How did you interpret these e.g. Clinical indications for shared milk vs supplementation
 2. Who knew about the milk sharing event?
 - a. Who would you tell about it?
 - b. Who would you not tell about it? (and why)
 3. Were there any other outcomes or consequences, positive or negative, in your workplace or with your colleagues or employer about this MS event?
 4. What are the awareness, attitudes and policies of your employer to different types of milk sharing?
 5. How should different types of milk sharing be handled by your workplace?
 - a. What needs to happen to achieve this?
10. **For your profession** (as a midwife or lactation consultant), what is the
 - a. Professional scope of practice with respect to MB, IMS, CF?
 - b. What, if any, competencies are required for MB, IMS, CF?
 - c. What does your professional peak body (ACM or ILCA/LCANZ) say about milk sharing?
 - d. What should your professional association do with respect to milk sharing, if anything?
 - e. What training about MB, IMS, CF
 - i. Is available to you
 - ii. Have you undertaken?
 - iii. Do you need?
 - f. What services around informal milk sharing or cross feeding (*outside a milk bank*) do you oversight or engage in?
 - i. Milk sharing (type)
 - ii. What remuneration is there for you?
 - iii. What costs?
 - iv. Professional indemnity insurance coverage?
 - v. What are the legal issues arise, if any, if you:
 1. Advertise a need for milk?
 2. Advertise a surplus of milk to provide to someone else?
 3. Handle, be involved with or are aware of gifts, compensation or monetary payment to a donor for her:
 - a. Milk
 - b. Cross feeding (i.e. wet nursing)
 - c. Pump
 - d. Electricity, petrol or milk storage bags
 - e. Time and skill?
 4. Handle, be involved with or are aware of payment by a recipient?
 5. Charge a fee for oversight of milk sharing e.g. organizing and interpreting donor screening and testing, contacting donors and recipients, transporting milk, provide advice on its use?
 6. Provide information on:
 - a. Milk banks
 - b. Other sources of shared breastmilk?
 - c. Pasteurizing or heat treating shared breastmilk?
 7. What rules, policies or laws apply here?
11. **With respect to shared milk as a product**, what are your views about:
 - a. Payment of health professionals for any associated services they provide (MW, LC, GP, pathology, milk bank employee)?
 - b. Compensation or payment of donors?
 - i. What are the issues?
 - ii. Who should compensate or pay? (recipients, donors, third parties, medical insurers, society)?
 - iii. What should this cover? (donor's cost of milk production, skill, time, pumping, handling, storage (milk bags/containers, freezer, electricity, esky), transport, processing,

- distribution /transport, donor screening, donor testing, recipient screening (criteria?), record-keeping, HP services and fees,
- iv. If so, how much should they pay? (\$ per litre)
- v. If so, should someone (donor or third party) profit from the sale of breastmilk or breastmilk products?

- c. How should donor milk or CF be positioned as a feeding option relative to:
 - 1. Breastfeeding support
 - 2. Infant formula
- d. How should donor milk or CF be positioned in terms of cost relative to:
 - 1. Breastfeeding support
 - 2. Infant formula
- e. What do pregnant women and families need to know about types of milk sharing?

12. Opportunities and threats

- a. What do you think are the major factors that influence mums to share milk (in different ways)?
- b. What do you think are the major factors that encourage or discourage mums to share milk (in different ways)?
- c. Who do mums talk to about milk sharing?
 - i. Do mums ask you for advice about milk sharing?
 - ii. Do mums disclose to you their own experiences of milk sharing?
- d. What is the supply of milk:
 - i. What is the demand for milk?
 - ii. Do you think there is enough milk to share to meet demand?
 - 1. What would change this (increase or decrease the amount shared?)
 - 2. How many mums have pumps (and use them)?
 - 3. How much milk do mums store in their freezers?
 - 4. What factors influence mums to pump and store milk?
 - 5. Are current guidelines on milk storage times appropriate?
 - iii. Who has surplus breastmilk
 - 1. Among your clients?
 - 2. In your community?
 - 3. Wider population? (state/Australia) (equity)?
 - iv. Who needs donor breastmilk
 - 1. Among your clients?
 - 2. In your community?
 - 3. Wider population? (equity)?
 - v. Who gets access to shared breastmilk:
 - 1. Among your clients?
 - 2. In your community?
 - 3. Wider population? (equity)?
- e. In general, how do you think mums in your community view different types of milk sharing?
 - i. In general, what do you think are mums' expectations about access to milk banks?
 - ii. What factors influence mums to donate milk?
 - iii. What have you seen about different types of milk sharing in the media?
 - 1. What messages did they provide about the acceptability, safety, access of each type?

- 13. In your opinion, what are the **overall effects** (pros/cons) of each type – MB, IMS, CF?
 - i. What is the effect of milk sharing, if any, **on breastfeeding**?
 - 1. For individual mums
 - 2. At a population scale

14. Any other comments

- a. Anything else you would like to tell me about or comment on milk sharing?

Appendix 7. Demographic data from the study of mothers

Where possible, survey questions were based on definitions for demographic characteristics from the Australian Bureau of Statistics (ABS). The definition of income used the definition of gross household income from the Survey of Household Income and Wealth (816). To help participants answer this question, bands of income were provided. Seven bands were chosen after examining changes in cut-offs for quintile and percentile distributions of gross household income over previous ABS surveys and then rounding.

Participant Characteristics	Number	%
	(N=48)	
Age group (years)		
18-24	2	4%
25-29	11	23%
30-34	12	25%
35-39	18	38%
40-44	5	10%
Number of biological children		
1	17	35%
2	22	92%
3	7	44%
4	2	17%
Residence		
ACT	10	21%
NSW	2	4%
NT	1	2%
QLD	6	13%
VIC	17	35%
WA	12	25%
Country of birth (N=37)		
Australia	29	78%
Canada	2	5%
Ireland	1	3%
Japan	1	3%
Malaysia	1	3%
New Zealand	1	3%
Sri Lanka	1	3%
USA	1	3%
Language spoken at home		
English	48	100%
Marital status		
Married or in a defacto relationship	45	94%
Single	3	6%

Participant Characteristics (cont'd)	Number	%
Number of adults in household		
1	3	6%
2	42	88%
3	1	2%
4	2	4%
Highest level of education attained		
Year 10	2	4%
Year 12	3	6%
Certificate I-IV	4	8%
Diploma or Advanced Diploma	4	8%
Bachelor's Degree	25	52%
Master's Degree or PhD	10	21%
Paid work status at 2 months prior to the birth of the child relevant to milk sharing experience		
Full time (usually 37 hours per week)	18	38%
Part time (usually less than 37 hours per week)	21	44%
Not in the paid labour force	7	15%
Other (please specify)	1	2%
n.a.	1	2%
Household income		
Less than \$20,000	1	2%
\$20,000 to \$34,999	1	2%
\$35,000 to \$49,999	3	6%
\$50,000 to \$74,999	7	15%
\$75,000 to \$99,999	6	13%
\$100,000 to \$149,999	21	44%
\$150,000 or more	8	17%
n.a.	1	2%
Membership of Australian Breastfeeding Association		
Yes, current	15	31%
No, but a member previously	11	23%
Never been a member	19	40%
n.a.	3	6%

Appendix 8. Milk sharing practices of mothers studied

The milk sharing practices of participants in the study of mothers (N=48). EBM= expressed breastmilk.

ID	Classification as donor or recipient or both	Type of milk sharing (EBM in informal arrangement, cross-feeding or milk bank)	Age of mother's child when milk first shared	Age of other mother's child when milk first shared	Donor-recipient relationship	No. mothers in milk sharing network	No. times milk shared	Reason for sharing milk
1	Donor	Cross-feeding	4-6 mo	0-3 mo	Family or relative	1	1	Emergency
2	Donor and recipient	EBM and cross-feeding	0-3 mo	0-3 mo	Friends, acquaintances and strangers	3-5	>20	Other
3	Recipient	EBM	0-3 mo	4-6 mo	Family or relative	1	1	Emergency
4	Donor	EBM	7-9 mo	0-3 mo	Close friend/s	1	2-5	Low breastmilk supply
5	Donor and recipient	EBM and cross-feeding	0-3 mo	0-3 mo	Close friend/s	3-5	11-15	Other
6	Donor and recipient	EBM and cross-feeding	0-3 mo	4-6 mo	Family or relative	2	>20	Low breastmilk supply
7	Recipient	EBM and cross-feeding	0-3 mo	4-6 mo	Friends, acquaintances and strangers	>20	>20	Low breastmilk supply
8	Donor	EBM	4-6 mo	n.a.	Acquaintances and strangers	2	2-5	Excess EBM
9	Recipient	EBM	0-3 mo	n.a.	Acquaintances and strangers	6-10	>20	Other
10	Donor	EBM	0-3 mo	n.a.	Stranger/s	1	>20	Other
11	Donor	EBM	4-6 mo	n.a.	Friends, acquaintances and strangers	>20	2-5	Other
12	Donor	EBM	0-3 mo	0-3 mo	Friends, acquaintances and strangers	3-5	2-5	Other
13	Recipient	EBM	0-3 mo	n.a.	Family, friends and acquaintances	>20	>20	Other
14	Donor	EBM and milk bank	4-6 mo	n.a.	Friends, acquaintances and strangers	>20	6-10	Excess EBM
15	Recipient	EBM and milk bank	0-3 mo	4-6 mo	Friends, acquaintances and strangers	>20	11-15	Emergency
16	Recipient	EBM	0-3 mo	0-3 mo	Friends, acquaintances and strangers	11-20	>20	Low breastmilk supply
17	Donor and recipient	EBM	0-3 mo	7-9 mo	Friends, acquaintances and strangers	3-5	>20	Low breastmilk supply
18	Recipient	EBM	0-3 mo	0-3 mo	Family, friends, acquaintances and strangers	>20	>20	Low breastmilk supply
19	Donor	EBM and milk bank	4-6 mo	0-3 mo	Friends, acquaintances and strangers	>20	>20	Excess EBM

Appendices

ID	Classification as donor or recipient or both	Type of milk sharing (EBM in informal arrangement, cross-feeding or milk bank)	Age of mother's child when milk first shared	Age of other mother's child when milk first shared	Donor-recipient relationship	No. mothers in milk sharing network	No. times milk shared	Reason for sharing milk
20	Donor and recipient	EBM and cross-feeding	0-3 mo	0-3 mo	Friends, acquaintances and strangers	3-5	6-10	Excess EBM
21	Donor	EBM	10-12 mo	n.a.	Stranger/s	11-20	>20	Excess EBM
22	Recipient	EBM	0-3 mo	n.a.	Acquaintances and strangers	6-10	>20	Low breastmilk supply
23	Donor and recipient	EBM and cross-feeding	0-3 mo	0-3 mo	Stranger/s	>20	2-5	Excess EBM
24	Donor	EBM	0-3 mo	0-3 mo	Stranger/s	>20	2-5	Excess EBM
25	Donor	EBM	7-9 mo	0-3 mo	Stranger/s	1	1	Other
26	Donor	EBM	0-3 mo	0-3 mo	Acquaintances and strangers	3-5	>20	Emergency
27	Donor and recipient	EBM and cross-feeding	0-3 mo	n.a.	Friends, acquaintances and strangers	2	2-5	Low breastmilk supply
28	Recipient	EBM	4-6 mo	n.a.	Acquaintances and strangers	>20	>20	Medication
29	Donor	EBM	0-3 mo	0-3 mo	Stranger/s	2	2-5	Excess EBM
30	Donor	EBM	4-6 mo	0-3 mo	Friends, acquaintances and strangers	3-5	>20	Excess EBM
31	Donor and recipient	EBM	4-6 mo	4-6 mo	Acquaintance/s	3-5	6-10	Emergency
32	Recipient	EBM	0-3 mo	10-12 mo	Family, friends, acquaintances and strangers	>20	>20	Low breastmilk supply
33	Donor	EBM	0-3 mo	0-3 mo	Stranger/s	3-5	>20	Low breastmilk supply
34	Recipient	EBM	4-6 mo	4-6 mo	Stranger/s	n.a.	>20	Low breastmilk supply
35	Donor	EBM	4-6 mo	4-6 mo	Stranger/s	6-10	>20	Excess EBM
36	Donor and recipient	EBM and cross-feeding	0-3 mo	>12 mo	Friends, acquaintances and strangers	>20	2-5	Other
37	Donor	EBM	4-6 mo	n.a.	Friends, acquaintances and strangers	2	11-15	Other
38	Donor	EBM and milk bank and cross-feeding	0-3 mo	n.a.	Friends, acquaintances and strangers	>20	6-10	Other
39	Donor and recipient	EBM	0-3 mo	4-6 mo	Stranger/s	1	2-5	Other
40	Recipient	EBM	0-3 mo	n.a.	Friends, acquaintances and strangers	3-5	>20	Low breastmilk supply
41	Donor and recipient	EBM and cross-feeding	4-6 mo	n.a.	Friends, acquaintances and strangers	3-5	>20	Low breastmilk supply
42	Donor	EBM and milk bank	0-3 mo	n.a.	Friends, acquaintances and strangers	n.a.	6-10	Excess EBM

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ID	Classification as donor or recipient or both	Type of milk sharing (EBM in informal arrangement, cross-feeding or milk bank)	Age of mother's child when milk first shared	Age of other mother's child when milk first shared	Donor-recipient relationship	No. mothers in milk sharing network	No. times milk shared	Reason for sharing milk
43	Donor	EBM	0-3 mo	n.a.	Stranger/s	6-10	6-10	Excess EBM
44	Donor	EBM	4-6 mo	0-3 mo	Stranger/s	1	2-5	Low breastmilk supply
45	Donor	EBM	4-6 mo	0-3 mo	Family, friends, acquaintances and strangers	3-5	n.a.	Excess EBM
46	Recipient	EBM and cross-feeding	0-3 mo	>12 mo	Friends, acquaintances and strangers	>20	>20	Low breastmilk supply
47	Donor	EBM	0-3 mo	n.a.	Stranger/s	3-5	>20	Excess EBM
48	Donor and recipient	EBM	0-3 mo	n.a.	Close friend/s	3-5	2-5	Low breastmilk supply