Progressing policy and regulation of milk banking and milk sharing

– ANBS actions

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I'd like to begin by acknowledging the Traditional Owners of the land on which we meet, the Ngunnawal people, and pay my respects to their elders past, present and emerging.

Shared breastfeeding is an ancient practice in all cultures and persists to this day. I'm going to talk to you briefly about policy action for milk banks and milk sharing within the Australian National Breastfeeding Strategy. But first, some background on what's driving milk sharing, the risks and benefits and emerging governance issues relevant to making policy in this area.

This presentation includes additional material not covered due to the time available in the seminar. Please note the references at the end and feel free to contact me with any questions.

"**MILK BANK TO SAVE BABIES**"
Sydney Morning Herald
Tues 17 June **1941**
(Trove)

- What has changed?

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In 1941 Australia's first milk bank opened at George V Hospital (for Mothers and Babies) in Sydney, after a nurse was sent to the USA in 1936 to study milk bank techniques. In the article she states that demand from other maternity hospitals was not known.
What has changed in milk banking policy between then and now? Well, not much... For the rest of the century, milk sharing persisted as cross-feeding and milk donation on post-natal wards under medical supervision and in the community. In the 1980s, the emergence of HIV supressed all developments in milk banks in Australia, unlike other countries where milk banks continued after adopting pasteurization and donor testing.

Benefits and risks of donor milk – what needs regulation?

'In evaluating infant feeding methods, all relevant risks should be considered contextually and comparatively' (Gribble and Hausman 2012)

Benefits of PDHM for supplementation (displaces formula)

- Improved health and survival of premature infants in NICUs
  - Reduced Necrotising Enterocolitis (NEC), bronchopulmonary dysplasia (BPD), improved feeding tolerance.
  - Non-significant effects on sepsis, retinopathy of prematurity (ROP) (PATH 2019)
- Health system savings:
  - 50% reduction in NEC (Quigley, 2019 – Cochrane review of 12 trials) –estimated to save $13 million in 2010 (Commonwealth of Australian 2014)
  - Shorter NICU stay (~18 days for medical NEC and 50 days for surgical NEC (Buckle and Taylor 2017)
  - PDHM costs $250-330/L, infants need 2-10 L per NICU stay
- Fortification for infants for VLBW – human-derived or bovine fortifier?
  - Human-derived: insufficient evidence of benefit (Premkumar, 2019 - Cochrane review, 1 study)
  - Bovine fortifier: increased risk of NEC - relative risk (RR) 4.2; NEC surgery or death RR 5.1; head circumference gain (Lucas et al 2020, multicentre trial)
  - Cost-effective for infants <750g, not <1500g (van Katwyk et al 2020) –Canada …. long term, societal effects uncosted

Risks

- Infection, contamination, adulteration of donor milk (Hartmann 2019)
  - Managed by milk bank donor screening and testing, pasteurization and milk testing (HIV, Hepatitis B, C, HTLV, CMV, syphilis, bacteria)
- Donor infant and mother wellbeing – individuals or groups (colonialism, racism)
  - Donor infant or care suboptimal? Exploitation, obligation -unremunerated - time, labour and skill, pump, power, storage, transport
- Wastage of milk
- Displacement of breastfeeding?
  - Varies: any breastfeeding on discharge from NICU: 10% decrease to 20% increase …to 6X -increase (Smith, Cattaneo et al 2018)
  - Delay initiation of breastfeeding
  - Competition for lactation support resources
  - Improved awareness of breastfeeding

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So what are the drivers for milk banks, the benefits, risks and costs?

Benefits are mainly to use human milk products to supplement very low birthweight and premature infants in NICUs, and displace formula.

The 2 key human milk products for NICUs are:

1. Pasteurized donor human milk (PDHM)
2. Fortifiers, that consist of added protein and calories added to mother's own milk (MOM) or PDHM, for VLBW (<1500g) and premature infants (<32 weeks gestational age).

However these products are costly.

The main value of these is to reduce the incidence of Necrotising Enterocolitis (NEC), and reduce hospital costs in doing so.

Benefit costs analyses for use of human milk products show cost savings to hospitals, but do not include the considerable long term social costs of reducing NEC and other improved health outcomes for these very vulnerable infants.

There are also potential harms from using donor milk, the most serious being the risk of displacing breastfeeding.

Consequently, PDHM and fortifiers need to be integrated into breastfeeding policy and used only with very strong lactation support for mothers.

Others harms of milk banks are the potential diversion of scarce funds to milk banks

and away from lactation support, i.e. a focus on these expensive ***products***, and not the ***process*** of breastfeeding.

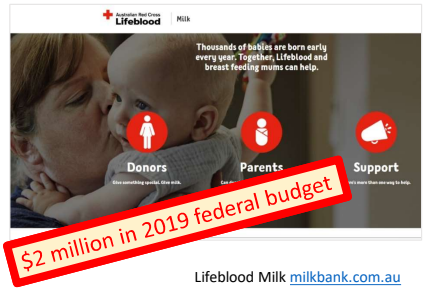
"Formal" milk banks in Australia – current

Supply NICUs -pasteurized donor human milk (PDHM):

1. (2005 Royal Prince Alfred Hospital milk bank -closed 2019)
2. 2006 Perron Rotary Express Milk Bank (PREM Milk Bank) -Perth
3. 2012 Queensland Milk Bank – Brisbane → Qld, Tasmania
4. 2012 Mercy Health Breastmilk Bank – Melbourne, expanding
5. 2018 Lifeblood Milk (Australian Red Cross Blood Service) – Sydney → NSW, SA

Supply public:

6. 2007 Mothers' Milk Bank Charity – Gold Coast, Qld → ACT (**NICU**)
   - PDHM, cost recovery via charitable donation $110/L
   - (2019 ACT Health – Feasibility of a milk bank in the ACT – rejected)
7. 2020 Australian Breast Milk Bank -Sydney – to public
   - High pressure, shelf-stable liquid or powdered freeze-dried donor milk
   - For-profit
   - Affiliation with Mothers' Milk Bank Charity
     - Australian Breast Milk Reserve
     - Donor milk for Indigenous mothers with diabetes



Lifeblood Milk milkbank.com.au

Powdered breastmilk
(Australian Breast Milk Bank "Bridging Milk")
Jacques, O. ABC News 24 March 2020

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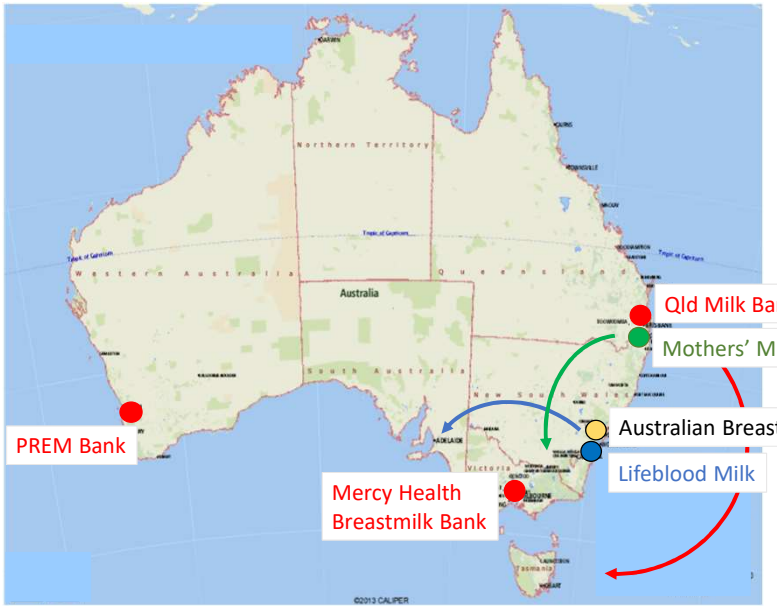
So what is the current situation with milk banks in Australia?
Australia now has 6 milk banks, operating under a mix of governance arrangements.
Milk banks were located in 4 hospitals in NSW, WA, Qld, and VIC and supply PDHM to some NICUs, according to strict medical criteria for vulnerable infants typically VLBW (<1500g) or <32 weeks gestation.
Outside the hospital system, the Mothers' Milk Bank Charity on the Gold Coast in Queensland, supplies PDHM to less vulnerable infants in ACT NICUs (from 2017) and the public. (In 2019 the ACT government investigated the feasibility of a milk bank in the ACT and rejected the proposal as too costly).
All these milk banks are not-for-profit.

In 2018 the Red Cross Blood Service opened an independent milk bank, Lifeblood Milk, to supply all eligible NICUs in NSW and SA. Consequently, the Royal Prince Alfred (RPA) hospital milk bank in Sydney closed.

This year an independent for-profit milk bank was launched, the Australian Breast Milk Bank to supply direct to the public, and is currently waiting for approval for its 2 unique shelf-stable products that are treated by high pressure rather than Holder pasteurization, in a shelf-stable form, as a liquid or freeze-dried powder.

So we are started to see the emergence of market forces in this sector in Australia, with semi-commercial and commercial, for-profit milk banks, along with *competition*, *market segmentation* and *consolidation*.
Is this a good thing for Australian mothers and babies?

Access, funding and governance



Formal milk banks:
State/Territory Acts
- Human Tissue
- Food
Hospitals

Informal milk sharing?
- Gaps in access

Hospital-based Milk Banks

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So there are issues to do with different sectors in milk sharing and laws between jurisdictions and access, funding and governance
In 2014 Commonwealth Dept Health *Donor Human Milk In Australia, Issues and Background Paper*
raised questions about whether existing regulations could handle:

1. buying and selling of breast milk
2. guidance to minimise the potential health risks of informal peer to peer milk sharing
3. unscrupulous trade or profiteering in human milk or therapeutic claims

Despite legal inconsistencies and costs, paper concluded that

"Decisions about establishing, managing and resourcing milk banks are a matter for consideration by local hospital networks, subject to local priorities".

In Australia, there is no national association of milk banks, or operational guidelines, [although the PREM Bank has published its "best practice guidelines", drawn from overseas milk banks and food production systems (HACCP)].
Currently have a mix of governance through hospitals and variable application of state/territory legislation for Human Tissue or Food.

These laws affect consent, payment of donors, sale of product and advertising and other requirements (There is no food standard for human milk in the FSANZ Food Standards Code).
Consequently, no Australian milk banks pay donors.
But costs must be covered: PDHM used in NICUs is covered by public health system. Milk banks that supply the public directly must charge.

- Mothers' Milk Bank requires a "charitable donation" of about $110/L. (ABMB costs are not available).

Funding sources are a mix of philanthropy and public funds from the state-or local health system.
In the 2019 federal budget the Lifeblood Milk Bank received funding of $2 million, reflecting its long-established capacity to lobby government, as the monopoly supplier and distributor of blood in Australia. Its important to note that Red Cross supplies a commercial company that produces plasma and plasma products, CSL, once an Australian government-owned entity, now privatized and "*one of the top 3 most valuable biotech companies in the world*" and ranked 15th globally among biotech and Pharma firms after companies like Johnson & Johnson, Roche and Pfizer (1).

Reference

1. CSL enters ranks of world's biggest biotechs Australian Financial Review 17 Jan 2020 Yolanda Redrup
https://www.afr.com/companies/healthcare-and-fitness/csl-enters-ranks-of-world-s-biggest-biotechs-20200114-p53rbv
"*When the rankings are extended to include pharmaceutical companies such as $US387 billion healthcare giant Johnson & Johnson, Roche and Pfizer, CSL ranks within the top 15 biotech and pharma firms*."

Global context for milk banking in Australia

"Markets work by holding costs down, and selling at a profit to those willing and able to pay, not to the children who most need it."
(Smith 2017)

Internationally, over 700 milk banks in 60 countries

Global trade in milk

- 2017 Exports from Cambodia to USA (Ambrosia)
  - Cambodian government stops export

Imports into Australia:

- 2017 - from India (NeoLacta)
  - No milk imported, permit lapsed
- 2020 - from USA? (Prolacta Bioscience)
  - human origin fortifier, not PDHM

Introducing Humavant™ Neonatal Nutritional Products From Prolacta Bioscience®

Ethical Issues

- Role of markets in milk (Smith 2015, 2017)
  - Exploitation or income to enable breastfeeding? –
    - Both supply and demand countries without maternity leave, lactation breaks, WHO Code
  - Shows where governments fail to protect breastfeeding, and regulate to develop formula markets
- "Value" – local or international? Whose standards? (Hartmann 2019)

Cambodia stops export of breast milk to US
southeastasiaglobe.com
Ambrosia Labs paid Cambodian women 64 cents for 30ml, sold in the US for $4.

Breast milk mothers mourn trade
Phnom Penh Post 22 March 2017

However, Australian milk is linked to **global markets in milk**.

In 2017 the press reported the export of human milk from Cambodia to USA.
Raised concerns about exploitation of donors, who were poor, and trade was stopped by Cambodian government.
However payment for milk enabled women in Cambodia (and USA) to continue breastfeeding under regimes that prevented them from breastfeeding through weak gender equity, and a lack of paid maternity leave and WHO Code implementation.
Around the same time Neolacta, an Indian company, was granted a permit by the Australian Government to import breastmilk from unpaid donors.

- However no milk was imported, and the permit was not reissued.
- In 2020 Prolacta Bioscience, a US company, is likely to be granted a permit to import into Australia human-derived fortifiers for use in NICUs. No PDHM will be imported at this stage.
- Julie Smith's 2017 article in *The Conversation* highlighted the complexity of trade in milk, where women who had no government support to breastfeed were forced to accept payment for milk through market mechanisms. However "*Markets work by holding costs down, and selling at a profit to those willing and able to pay, not to the children who most need it.*"
- Markets in milk have not provided long-term policy solutions and government

action to address the problem of weak regulation and lack of resources to protect and support breastfeeding.

Overarching ethical governance for donor milk

- *Oxford-PATH Human Milk Working Group* (Israel-Ballard et al 2020)

"Governments should …protect women, their own infants, and recipients of milk informally shared or sold for corporate profit" (PATH 2019)

  - **Ethical principles to address:**
    - Vulnerability - medical, social, economic of donor and recipient
    - Equity and fairness –supply, access and allocation – benefits, exploitation
    - Autonomy –personal and community, religion, kinship
    - Human Rights – equitable access, UN Conventions
  - **4 Actions on donor milk guidance**
    1. Ethical principles shape milk bank guidance and legislation
    2. Global governance –model operational standards, regulatory framework
    3. Regional and national –policies, legislation and standards
    4. Address biomedical and social science research gaps to inform global and national strategies
       - Motivations, barriers, and trade-offs for women donating, selling and sharing their milk and for their infants receiving donor human milk
       - Effects on breastfeeding
       - Operational research on scaling up

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These ethical have been raised at a global level. In 2020 the-*Oxford-PATH Human Milk Working Group* developed some ethical principles to guide international trade in milk and milk banks (Israel-Ballard et al 2020).

Ethics

Vulnerability - medical, social, economic of donor and recipient
Equity and fairness –supply, access and allocation – benefits, exploitation
Autonomy –personal and community, religion, kinship
Human Rights – equitable access, UN Conventions

4 Actions on donor milk guidance

1. Ethical principles shape milk bank guidance and legislation
2. Global governance –model operational standards, regulatory framework
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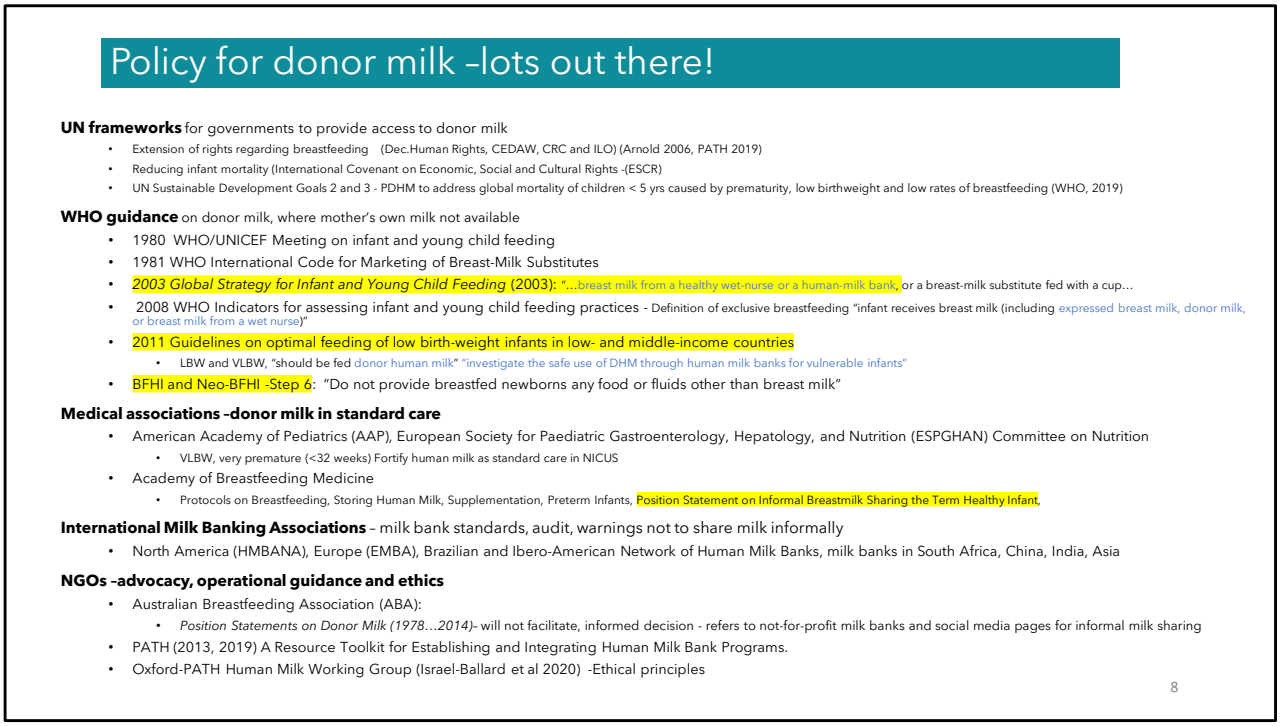
Motivations, barriers, and trade-offs for women donating, selling and sharing their milk and for their infants receiving donor human milk
Effects on breastfeeding

Operational research on scaling up

Governance complexity: Not-For-Profit and unpaid donation vs Trade.
Some considerations include:

1. Scope of the WHO Code: does marketing of donor milk need to be covered by an expanded WHO Code?
    - What are the implications of this? – will we see a greater regulatory burden on human milk, than on formula, that reduces the competitiveness of donor milk over formula, which is already far cheaper and more pervasive than donor milk?
2. Milk Banking Associations – North America (HMBANA), Europe (EMBA), Brazilian and Ibero-American Network of Human Milk Banks, milk banks in South Africa, China, India, Asia
3. Donor payment
4. Wastage of milk



There is a range of international guidance on milk banks, and less about informally shared milk.

UN, WHO, medical associations, milk banking associations and NGOs

UN Human Rights basis for governments to provide access to donor milk is an extension of human rights to breastfeed, (Arnold 2006, PATH 2019)

United Nations Human Rights frameworks –Declaration of Human Rights , gender equality (CEDAW) maternity protection (ILO), and rights of women and children to adequate food, nutrition, health and informed choice. All children (CRC) Convention on the Rights of the Child (CRC)

"Right of the child to "highest attainable standard of health and to the facilities for the treatment of illness and rehabilitation of health."CRC Article

24 Governments must "educate all mothers and parents so that they can make informed choices"

Donor milk fits under: steps to reduce infant mortality (International Covenant on Economic, Social and Cultural Rights -(ESCR) Everyone includes sick and premature, mothers and children entitled to special care and assistance

UN Sustainable Development Goals 2 and 3 - PDHM to address global mortality of children < 5 yrs caused by prematurity, low birthweight and low rates of breastfeeding (WHO, 2019)

Guidance on donor milk from WHO and other agencies

- *WHO Global Strategy for Infant and Young Child Feeding* (2003):
    - where mother's own milk not available::
        - "…breast milk from a healthy wet-nurse or a human-milk bank, or a breast-milk substitute fed with a cup…" Definition of exclusive breastfeeding "infant receives breast milk (including expressed breast milk, donor milk, or breast milk from a wet nurse)" WHO 2008. Indicators for assessing infant and young child feeding practices - Part 1, Definitions. Conclusions of a consensus meeting held 6–8 November 2007 in Washington, DC, USA. 2008. Geneva, Switzerland: World Health Organization.
        - LBW and VLBW, "should be fed donor human milk" *Guidelines on optimal feeding of low birth-weight infants in low- and middle-income countries* (2011)
- BFHI and Neo-BFHI -Step 6: "Do not provide breastfed newborns any food or fluids other than breast milk"
- PATH (2013, 2019) "*A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs*."

Milk banking associations

- EMBA, HMBANA, Brazil-South America-Spain and some African countries and South Africa

Medical associations include groups that are highly influential on policy in IYCF:

- American Academy of Pediatrics (AAP), European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) Committee on Nutrition
- AAP and ESPHAGN: VLBW, very premature (<32 weeks) Fortify human milk as standard care in NICUS
- Academy of Breastfeeding Medicine Protocols –on Breastfeeding, Position Statement on Informal Breastmilk Sharing the Term Healthy Infant, Storing Human Milk, Supplementation.
    - In particular, we need to note the Academy of Breastfeeding Medicine 2017 *Position Statement - Informal Breast Milk Sharing for the Term Healthy Infant Position statements on informal milk sharing*

Other Non-Government Organizations (NGOs) also have important contributions:

Ethical issues -*Oxford-PATH Human Milk Working Group* (Israel-Ballard et al 2020)

Two key Australian policies come from

1. Australian Breastfeeding Association (ABA) *Position Statements on Donor Milk (1978…2014)*
    - ABA will not facilitate, informed decision - refers to not-for-profit milk banks and social media pages for informal milk sharing

2. Australian College of Midwives "*Position Statement on the use of Donor Human Milk*." (2014)

Further background:

Key international developments in milk sharing policy since 2007 include:

- expansion of milk bank associations (EMBA, 2016; HMBANA, 2015c; Ortiz, 2012) and guidelines (HMBANA, 2015a; NICE, 2010; Weaver et al., 2019),
- resources for the establishment of milk banks (PATH, 2013, 2019) and the adoption of PDHM as standard care in NICUs (AAP, 2017; EMBA, 2019; G. E. Moro et al., 2015; Guido E. Moro et al., 2019; PATH, 2017; WHO, 2011).
- fortification of PDHM for VLBW infants
- support from international coalitions of governments, NGOs and commercial interests in infant nutrition, including formula companies (Every Preemie-SCALE, 2019; Kumar et al., 2017).
- Sustainable Development Goals 2, 3 and 4 have motivated policy to supply PDHM as a means to address global mortality of children under 5 years caused by prematurity, low birthweight and low rates of breastfeeding (WHO, 2019).

- At the same time, milk banking associations and health authorities have issued **warnings about informal milk sharing** as a risk to infant health, maternal breastfeeding and the viability of milk banks (AFSSAPS, 2011; American Academy of Nursing, 2016; EMBA, 2019; EMBA/HMBANA, 2015; FDA, 2010; Health Canada, 2010; HMBANA, 2015b).
- Detailed guidance for health professionals on the safe use of milk shared through informal arrangements was issued by medical experts in breastfeeding, the Academy of Breastfeeding Medicine (ABM) (Sriraman et al., 2018).

Detail on Human Rights frameworks for milk banks

Rights to access donor milk are derived from international human rights frameworks. These frameworks aim to protect breastfeeding through children's and women's rights to health, food and medical care in the United Nations 1948 *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* (Arnold, 2006; Galtry, 2015). Australia has ratified these conventions, and is obligated under international law to implement them nationally.

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. Cl 24 (e)).

(Law Council of Australia 2016 Australia's International Human Rights Obligations http://www.lawcouncil.asn.au/lawcouncil/index.php/divisions/legal-practice-division?id=113 Accessed 5 November 2016]

Australian policy for donor milk -fragmentation

Milk Banks

- Calls for publicly-funded network of not-for-profit milk banks
  - Australian Breastfeeding Association (1978 -), Best Start Report (2007)
- No national milk bank association or standards
- Integration of PDHM into breastfeeding policy – NSW Health (2018), SA Health
- Jurisdictional structures, governance, operations and legal and financial barriers
  - Donor Human Milk Banking in Australia- Issues and Background Paper (Commonwealth of Australia (2014)
    - Local governance …Innovation?
    - "Warnings from overseas health authorities about milk sharing via social media and concerns about health risks, selling milk, therapeutic claims and potential capture by milk bank standards of "*mothers' own milk in hospital or child care settings, wet nursing, and informal milk sharing in the community*"

Informal milk sharing – altruistic

- In health services
  - Few protocols for directed donation (unpasteurized milk from known, screened, tested donor)
  - Covert use by mothers, health professionals
  - Risks, legal waivers, threats of child removal
- In the community –gaps in breastfeeding support
  - (Prevalence?? USA data on milk sharing -mothers: 94% aware; donors (12%), recipients (6%) - O'Sullivan et al 2018)
  - Demand and workload:
    - Reasons for prevalence of pumping? -donors don't want to waste milk
    - Recipients want to avoid formula, highly motivated to breastfeed but lack support e.g. latching problems
  - Awareness and pathways:
    - Social media e.g. Eats On Feets, Human Milk For Human Babies, parenting advice
    - Cultural; Long (2003), Thorley (2008, 2009, 2012), Gribble (2012, 2013, 2014, 2018)

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Australian policy about milk: ***Fragmented*

In contrast, Australian policy for milk banks has lagged, with little application of these international developments. As a result Australian policy on donor milk is fragmented. In 2014, in response to the demand for milk banks in Australia, the Australian Government released a *background and issues* paper that examined the legal and jurisdictional barriers to milk banks that I mentioned earlier. The paper concluded that governance of Australian milk banks should be self-regulated and under local hospitals, which also allowed for technical innovation. There was no recommendation for public funding or a coordinated network of milk banks operating under national standards and fully integrated into breastfeeding policy.

The paper focussed on milk banks and largely ignored milk sharing outside NICUs in the health services and through informal arrangements in the community and cultural groups. This is largely altruistic in Australia.

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Where is the voice of mothers in this process?

Australian policy for donor milk - conflicting messages
- rights vs nutrition vs infection risk vs occupational safety

- Tightening definitions:
  - Breastfeeding as *maternal* breastfeeding
  - Donor milk as "PDHM from an approved milk bank"
- Number of infectious agents transmitted via milk: 3 (Vic) - 21 (NSW)
- Varying approaches to informal milk sharing:
  - Victorian Breastfeeding Guidelines for Health Professionals (State of Victoria, 2014):
    - "Informal breastmilk sharing networks exist in Victoria and it is important that health professionals are aware if they are being used. …"
  - SA Health policy (2018):
    - Staff "*must not proceed to store or administer EBM if there is doubt the EBM derives from the infant's birth mother*"
    - *"Unused EBM (i.e. greater than 10mls), should be discarded via the sewage system"* (brochure for parents, 2018)
    - HTLV and Central Australian Indigenous communities– HTLV infected mothers avoid breastfeeding
- Milk Donation After Infant Death vs Informal milk sharing
  - Respectful vs punitive

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Australian policy about milk: *Conflicting*

As a result of policy inaction, state/territory and hospital-level policies on PDHM and informal sharing and human milk are ad hoc, and contain very conflicting messages about milk: about rights to milk, nutritional value, infectious disease risks and worker (occupational) safety.

Four examples of conflicting messages are:

1. The emergence of milk banks as standard care in tertiary-level NICUs has tightened infant feeding definitions of breastfeeding as *maternal* and exclude donor milk in other areas of infant feeding policy.
2. There is no consistency between state/territory policies of the risk of disease transmission via milk: number of infections 3 (Vic) - 21 (NSW)
   - One Victorian guideline lists 3 viral infections of concern (HIV, Hepatitis C and CMV) (Safer Care Victoria & Victorian Agency for Health Information, 2018a), while another lists 5 (State of Victoria, 2014). A South Australian policy lists 9 diseases, including tuberculosis and HTLV (SA Health, 2018b) and a NSW policy lists 21 (NSW Health, 2010). 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) (SA Health, 2018b).

3. Some state/territory policies recognize informal milk sharing (e.g. Guidance for doctors in VIC), while South Australian policy tells staff to not handle milk if milk sharing is suspected and for parents and staff to discard milk in the *sewerage* system (toilet), rather than down the *sink (*in the kitchen*)*. This highlights the framing of milk as a noxious bodily fluid rather than a food, and is contrary to normal practice in homes and breastfeeding-friendly programs and policies that aim to improve acceptance of milk expression in workplaces for women returning to work after a baby.

4. In contrast to the fear and loathing of milk in the previous two points, some policies are emerging to enable donation of milk to milk banks by mothers whose infant has died ("Lactation After Loss" or Bereavement). The wording and framing of policy and brochures for mothers in this situation is extremely gentle and respectful of her desire to donate milk as an expression of grief. However no such respect is afforded mothers in the community who want to share milk. Attitudes toward these mothers, in particular recipients, are extremely punitive in Australia, and in some cases involve threats of child removal by government Child Protection Services.

Donor milk in the ANBS
2.4 Milk banks

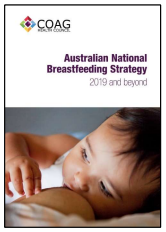
Establish a Human Milk Working Group

to advise AHMAC on the regulation and importation of human milk (Aust and NZ) on:

- A needs assessment - supply and demand for human milk and human milk products
- Regulation and importation of human milk and human milk products
  - in the context of Human Tissue Acts (State/Territory).
- Benefits of national standards for milk banks
- Complexity -ethical and social implications, safety and quality standards, regulation and legislation, research and therapeutic use.

Evaluation

☐ National ethics and regulatory framework for human milk and human milk banking
☑ Expansion of milk banks



3.2 Support families in exceptionally difficult circumstances:

- Full-time lactation support in NICUs and special care nurseries
- Lactation support in emergencies
- Policy on IYCF-E

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Australia is well-behind in developing coordinated milk bank policy
As we have seen, developments have been "market" driven by local demand, and not integrated into IYCF policy.

ANBS Action Area 2.4: milk banks

ANBS policy in this area was focused on milk banks, in an attempt to overcome the barriers described in the 2014 issues paper, and respond to the 2007 parliamentary inquiry that recommended that milk banks are expanded and funded.
However in 2019, around the time the ANBS was being finalized, a high level Working Group on Human Milk was set up to advise the Australian Health Ministers Advisory Council on developments in milk banking in Australia, including the issues about importation, mentioned earlier. Realizing the complexity of this topic, the focus of the working group was expanded.
The ANBS evaluation criteria for his action area are:

- A national ethics framework, (which aligns with calls by the PATH-Oxford group, mentioned earlier, and
- Expansion of milk banks, which has already occurred under the clunky "free market" governance arrangements for milk banks in Australia.

So the ANBS is waiting for this advice and guidance on milk banks.

- Another are where donor milk emerges in the ANBS is in policy for **infant feeding in emergencies**.

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2.4 Milk banks

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Evaluation

- ☐ National ethics and regulatory framework for human milk and human milk banking
- ☑ Expansion of milk banks

High level policy attention !
Precedes National Breastfeeding Committee ??
Transparency??

Trade focus
- Biosecurity Act (Cth)
- (Therapeutic Goods Act (Cth)
- FSANZ, Food Standards (Cth)
- Human Tissue Acts
- Food Acts

3.2 Support families in exceptionally difficult circumstances:

- Full-time lactation support in NICUs and special care nurseries
- Lactation support in emergencies
- Policy on IYCF-E

Integrates donor milk into IYCF policy

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The AHMAC Human Milk Working Group (WG) is an important development in governance because it signals high level government attention to issues surrounding donor milk and infant feeding in Australia and internationally.

However there are some problems with the policy development process.

- Firstly, it is occurring outside the ANBS framework, and precedes the establishment of the National Breastfeeding Committee, the core of ANBS policy coordination and governance.
- Secondly, although the principles for the Human Milk Working Group are meant to be aligned with ANBS policy, the process is being driven by a narrow focus on questions about trade and milk banks, with little focus on the broader issues about informal milk sharing, breastfeeding and women, the producers of milk. Where is the consultation with mothers and **gender equity** in this?
- Thirdly, there is no transparency in the WG process because AHMAC committees do not make publicly available their constituent members or agendas or minutes of meetings or processes. We can see how there are now powerful commercial interests involved in donor milk, and the history of formula industry influence on infant feeding policy making makes me extremely nervous about what this all means for Australian mothers an babies.

WG Principles:

- Protect infant health and optimise **maternal** breastfeeding
- Align with ANBS principles
- Consult stakeholders

IYCF food security and shared milk

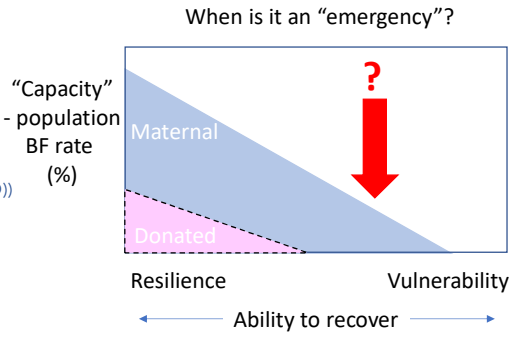
Food security
- Appropriate, available, accessible, (affordable), stable, efficient, sustainable (FAO))

Everyday precariousness of breastfeeding – motivation to share milk
- Applies to donors and recipients -pumping and storing milk,
- Health system: maternity care - BFHI, supplementation options - clinical guidelines
- Community: BF support, in public, employment
- Origins of milk supply gaps
  - Fostering, adoption, surrogacy, no female parent
  - Gestational diabetes, smoking, obesity, caesarean, PCOS, IVF, breast surgery, cancer…
  - Difficulties with infant "latch" ("Tongue Tie")

Emergencies– resilience: food safety, supply chains + immunological capacity
- Feeding at the breast (FAB), not EBM, cold chains, bottles and teats
- Informal milk sharing – community capacity in a disaster?
  - Safe enough to breastfeed own child, safe enough to share??
  - Local cultures and resources - social networks, social media
  - Cross-feeding and cup feeding donor EBM -Ethics: informed consent, allocation within IYCF-E guidelines
- Milk banks - vulnerabilities
  - Power cuts, donor access, storage and distribution
  - "Australian Breast Milk Reserve" (Australian Breast Milk Bank with Mothers' Milk Bank Charity) - Freeze dried, sterile water to reconstitute??
- WHO Code
  - Displacement of BF -prioritize mum before donor; FAB before EBM
  - Displacement of BMS by relactation and cross-feeding
  - Avoiding bottles and teats

Salmon (2015)

When is it an "emergency"?




Breast milk bank issues call-out to build reserve for emergencies such as bushfires, pandemic

ABC Gold Coast
By Solua Middleton

Australia's first community-based breast milk bank is hoping four mothers in every 100 can donate breast milk to help build a reserve for emergency events like fire, drought, floods, and now a global pandemic. 13

https://www.mothersmilkbank.com.au/blog

Outside the ANBS, there is a broader role for donor milk in **infant food security**
Infant food security is based on the FAO definition of food security (Salmon, 2015).
In Australia, breastfeeding itself is precarious, with low rates of exclusive and continued breastfeeding, and inadequate government protection and support.
However women value breastfeeding and milk, and want to bridge gaps in milk supply that arise from a host of individual clinical issues and system-level failures.
Neglect of these conditions indicates deep **gender inequities** in maternal and child health.

Milk sharing also has a role in **infant feeding in emergencies** (IFYCF-E), the focus of this webinar series, in the aftermath of floods, bushfires and COVID-19.
Supporting maternal breastfeeding as a secure source of infant food in emergencies is the goal.
However, cross-feeding (wet-nursing) also has a role because it avoids the use of bottles and teats which are very dangerous in disaster situations.
Of concern is the proposal that expressed donor milk in liquid or powdered form is safe in emergencies. Concerns arise about issues of supply chains for liquid EBM and the safety of water for reconstituting powdered EBM.
In these forms, EBM also has the potential to displace feeding at the breast.

Advocacy for milk sharing policy

Set objectives!

- Donor milk integrated within ethical and breastfeeding policy frameworks (not trade!)
- Ensure shared milk displaces formula
- Transparency and disclosure - mothers, health professionals and milk banks, Milk Working Group
- Milk Working Group -jurisdictional issues -legal classification for human milk or Food Standard or unique?

Develop national ethical framework -communicate with AHMAC Human Milk Working Group

- Principles, governance and funding (public, not-for-profit and for profit – current law)
- Trade
- Establish the Australian Milk Bank Association – mandatory membership
  - Develop milk bank operational guidelines that include PDHM, unpasteurized, other treatments (Hartmann 2007, NICE, etc)
    - e.g. NSW Policy Directive for PDHM with LifeBlood Milk, Hospital Directed Donation protocols, 'Eats On Feets' Resource
- Competition with infant formula:
  - **Strengthen WHO Code** - coverage of manufacturers/importers/retailers and scope of products: 0 - 36 months, legislate
  - Access and Affordability = Medicare for Milk: provider numbers for IBCLCs, items for donor testing and screening by an IBCLC-GP
  - commercialized breast milk in WHO Code? (Smith 2017) -regulation of human milk exceeds BMS?

Legitimize safe use of donor milk - for infants, parents and health professionals

- NHMRC Infant Feeding Guidelines – types of evidence
  - Donor milk for feeding or supplementation for different categories of infant vulnerability, clinical indications (NICUS, SCN, full term)
    - Academy of Breastfeeding Medicine protocols e.g. 2017 Position Statement - Informal Breast Milk Sharing for the Term Healthy Infant
    - Indigenous health e.g. cross feeding as a cultural practice and HTLV policy
  - Emergencies
    - Revise for cross-feeding, policy for powdered products -human milk and BMS
  - Resources for parents and carers, social media - FRAMING: New Zealand (not SA!)
  - BFHI - Step 6

Reduce demand for donor milk:

- Progress health professional education in breastfeeding, BF support for mothers
- Antenatal education – donor milk options- informed decision making

Monitor

- Include shared milk in IYCF, perinatal, NICU statistics – is donor milk displacing breastfeeding?
- Emerging disease risks – for all types of milk sharing
- Regional breastfeeding exclusivity and duration = food security, emergency preparedness

Gender budgeting?

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So, back to progressing policy for milk banking and sharing policy under the ANBS. Here is list of advocacy activities: …It's a long list, I've tried to prioritize it…

1. Set objectives
2. Develop an National Ethical Framework for milk sharing
3. Legitimize the use of safe donor milk
4. Reduce demand for donor milk
5. Monitor milk sharing to inform policy

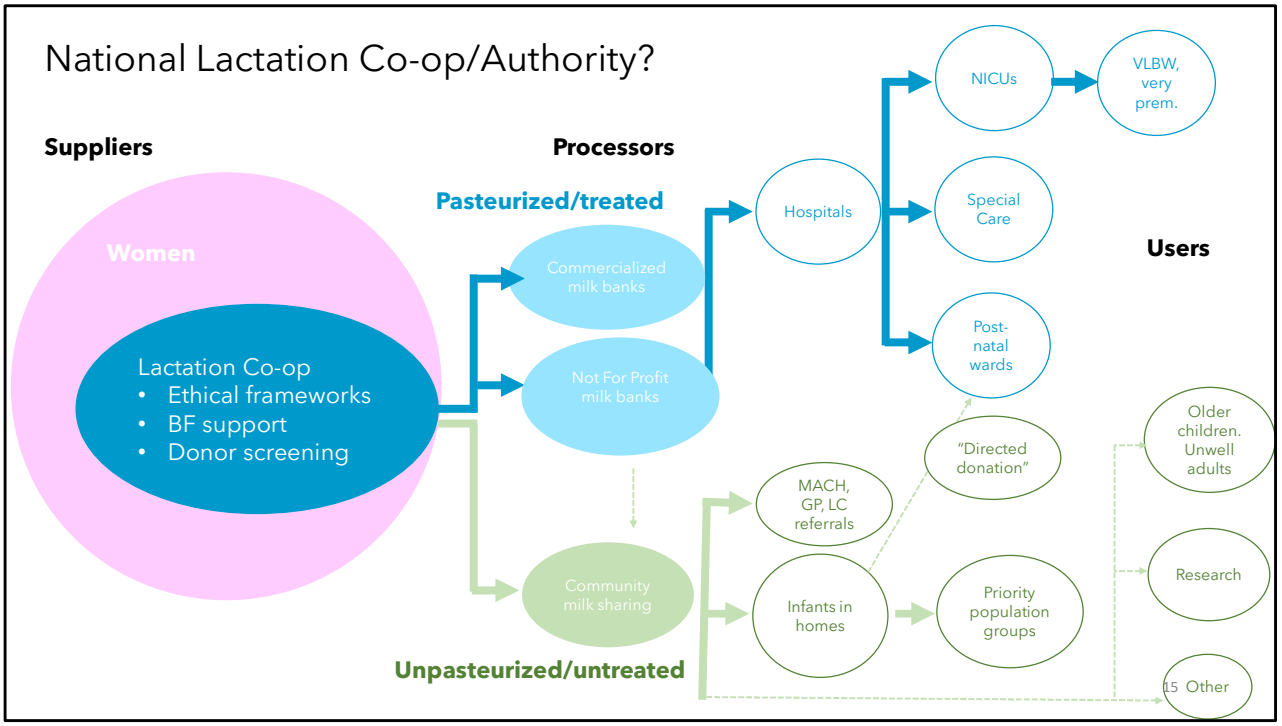
The main point to note is that an integrated approach to milk banking and sharing, that ensures that these practices enable and support breastfeeding, requires work on *ALL other areas in ANBS policy*.
But if you don't think you'll live long enough to see the National Breastfeeding Committee funded and established, one regulatory strategy is to shift the forum, and disrupt entrenched power that prevents action.
…But there's another way to think about all this.

An important policy action is to improve framing of messages about informal milk sharing, e.g. consider NZ approaches?
Policy and pamphlets for parents in NZ make an effort to acknowledge the generosity of mothers who donate milk, and reinforce the message that human milk is good stuff

and superior in every way to formula, as well as addressing safety issues in a practical way.

[Complexities with shared policy positions by Aust-NZ on donor milk (milk banks and informal sharing) include:

- Shared food regulatory framework (FSANZ)
- But rejects donor payment under NZ Human Tissue Act
- Implications for imported human milk products
- Different implementation of WHO Code
- Also a dairy/formula exporter
- Unified Trans-Tasman formula industry representation (Infant Nutrition Council)]

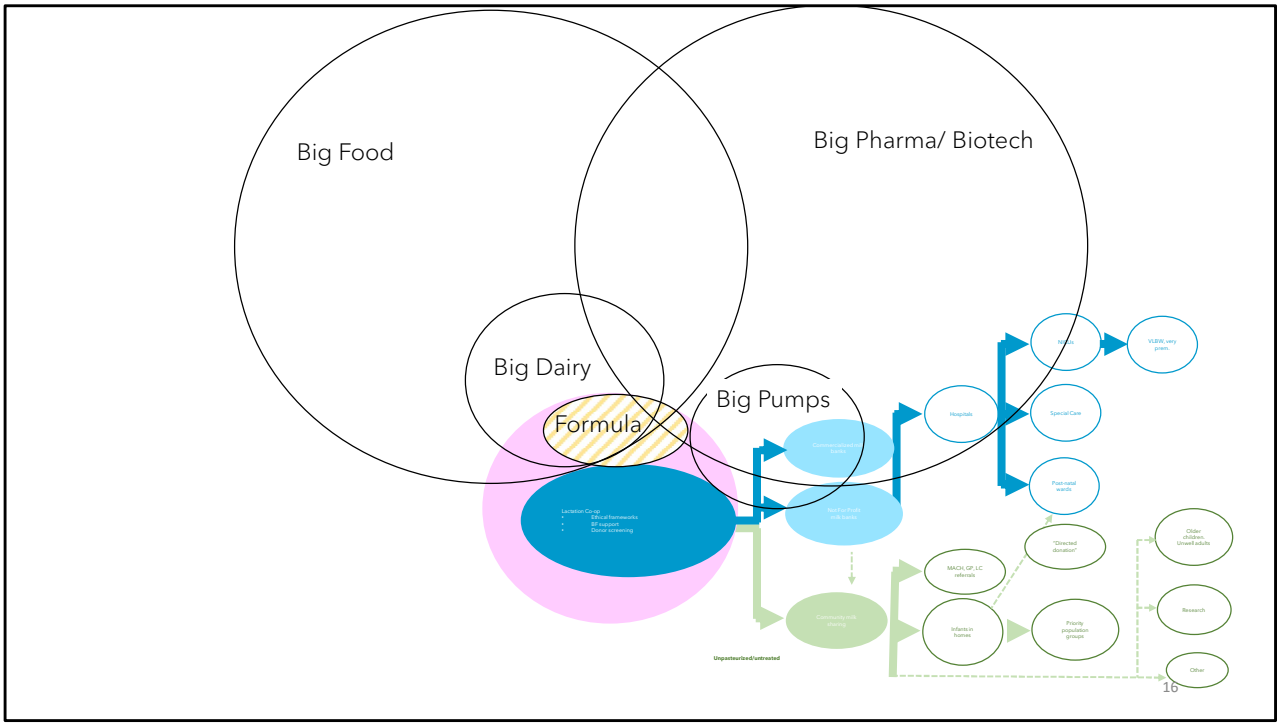


But is the ANBS addressing the whole milk sharing system and its role in breastfeeding.?
So we've talked about the formal milk banking sector supplying NICUs shown as the top blue pathway.
But milk banking is not the only type of milk sharing in Australia.
Women also share milk to feed infants outside the milk banking system, in the community through informal private arrangements with people they know and strangers, using social media, sometimes facilitated by health professionals.

Some of this milk is used in hospitals by women who do not want to use formula but do not have access to PDHM, which as we have seen is very restricted.
So the question is what governance arrangements are needed, for milk banks and the informal system, and a changing set of players with the emergnec of commercial milk banks and international trade?

What we need is an authority for women, the producers of milk, to control governance of milk at scale: a National Authority or Co-op
Julie has mentioned a Co-op in her 2017 article.
This organization might not handle donor milk directly, but provide the following services:

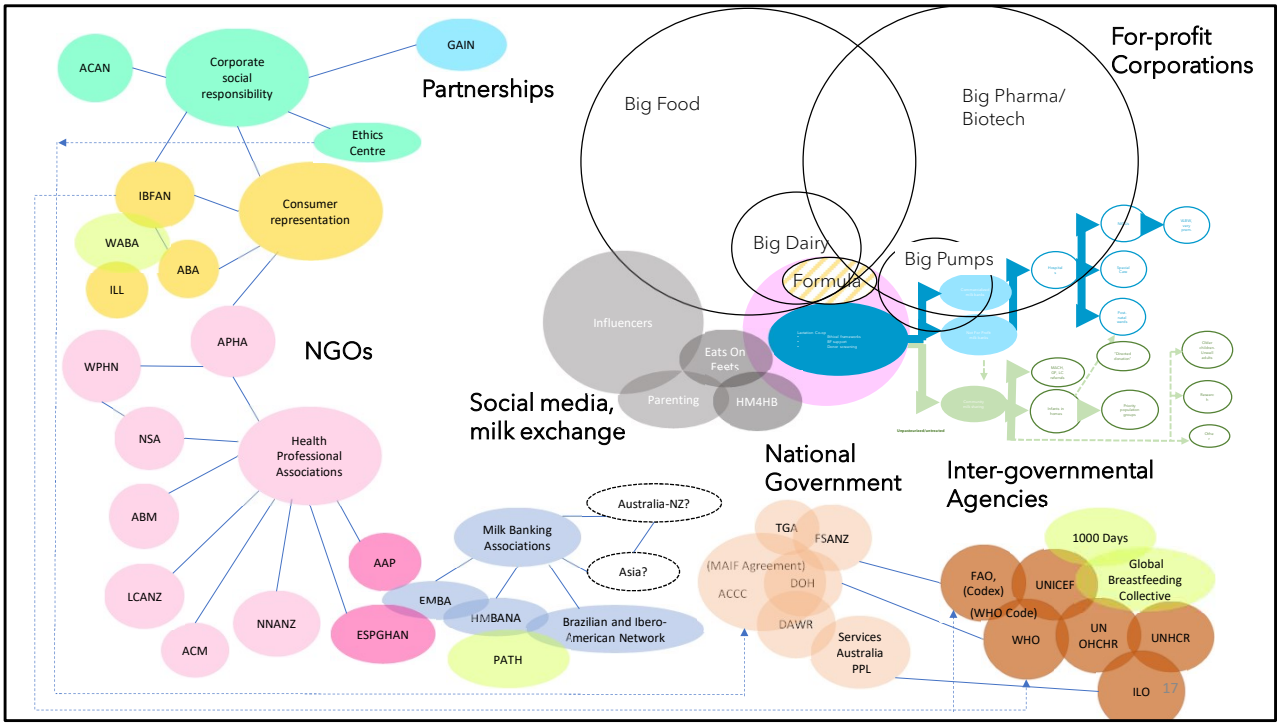
- Breastfeeding support - Lactation support and referral - IBCLCs
- Donor screening and categorization –multisector
- Recipient eligibility
- Allocation – multi-sector system
    - pasteurized/treated or unpasteurized – vulnerability of infant, settings (NICU, post-natal wards, community)
- Users pay co-op for milk/L
- Data collection, records and tracing
- Policy agenda – National Guidelines, import and export control
- WHO Code and MAIF oversight
- Emergency and siaster policy and response
- Research agenda



So we need to talk about **power**.
The power of Big Food, Big Biotech/Pharma, Big Pumps, not just about formula as a separate entity.

- All these groups have an interest in human milk.
- At the intersection of this nest of circles are organizations like the International Society for Human Milk Research (ISRHML), funded by the dairy industry to conduct research on human milk, for example into human milk oligosaccharides that are now in Australian toddler formulas.
- All these groups focus on milk, the product, not women or breastfeeding other than as walking glandular tissue.
- Existing regulatory authorities for example, at the international level Codex, WHO and at the national level, FSANZ and the TGA, struggle to deal with this power as well.

But some thing is missing in this representation…



Governance of milk by civil society
This looks like acronym city (apologies)!

- This map shows that there are also a host of other organizations with interests and "governance" in milk, including civil society.
    - From intergovernmental agencies like WHO, national government agencies, like Dept Health, NGOs to represent health professionals, for example ACM and LCANZ, and consumers, for example ABA and IBFAN.
    - Floating around as a grey area is social media, that is essential for informal milk sharing, but diffuses information about infant feeding, good and bad, and is a tool for formula marketing, and influencers, and deletes images of breastfeeding breasts.
- The lines, the linkages and coalitions between these groups, are important at national and international scales.
    - So you can see the overlaps between milk baking associations and powerful health professional associations, like the American Academy of Pediatrics (AAP) and the European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN). Not all the links are shown. For example, health professionals and research are linked to corporations through funding and education.

    - You can also see how the WHO Code and the Australia's MAIF Agreement, and its oversight by the ACCC and the Ethics Centre, and internationally by IBFAN are linked, with the dotted blue lines.
- This **map of interests** or rough **network analysis** in human milk is not complete or accurate, or to scale, and apologies for any misrepresentations.
- The point is, it demonstrates the **"the strength of weak ties"**, which enable small, local actors, to gain power through strategic links and associations.
- However these alliances can change. We've seen how rapidly the milk scene is developing in Australia.
- The key governance issue to focus on is to ask **what structures will ensure women retain power over the conditions for the production and use of their milk?**
- Let's engage in some open thinking here.
    - Going back to our original pink circle that represents women who feed infants. Women do have real power- they have the breasts and their milk - and all they need is a structure with legal authority that they control, for example, a co-op. Julie has mentioned a Co-op in her 2017 piece in the Conversation about the ethics of milk from Cambodia.
    - The co-op, acting on behalf of its members, **is** in fact the *repository of the social licence to supply milk*.
    - As for other public goods, like water, it provides *oversight of the supply chain for milk*, "from nipple to need", according to ethical and sustainable principles that meet the aspirations of women who are investing in the future of their children and the planet.
    - If women want to sell milk, then the Co-op discusses this with them and becomes the political force, the lobby group and organized labour union that demands 12 months paid parental leave.
    - If the Co-op is so successful that the need for donor milk falls to a trickle, then no problem, it continues to invest its energy in breastfeeding and *gender budgeting* to fight misogyny. The Co-op is the quintessential expression of **feminized power**, building on the decades of work to protect breastfeeding and realize the women's and children's rights.

Windows of opportunity

- At the moment, this political, corporate, local, global, regulatory moment, we have a **window**, an opportunity to establish this kind of structure. Most of it could be done via Zoom, (and WBTi has learned about Incorporation).
    - The Co-op could hold discussions with the stakeholders in CSL behind Lifeblood Milk about their corporate reputation and we get some social media influencers on board and we shift the conversation, the "Mommy Wars" and Lactavist backlash.

But back to the ANBS… The work for the ANBS is essential. ANBS guidelines, tools and instruments can be **leveraged**, if we develop **smart regulation** for milk that harnesses the powerful to support the interests of breastfeeding women and infants.

Thank you

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