

Potential Risk which could be associated with Consumption of some Human Breast Milk

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Potential Risk which could be associated with some Human Breast Milk

- Categories where donated human milk may pose a risk
 - Infectious Diseases
 - Non-Infectious Contaminants
 - Nutrition
- Contamination may be
 - Infectious or chemical (e.g., pharmaceutical, environmental)
 - intrinsic (in expressed milk) or extrinsic (introduced after milk expressed)

Potential Risk which could be associated with some Human Breast Milk

- Intrinsic Infectious Risks
- Extrinsic Infectious Risks
- Noninfectious Risks

Intrinsic Risks which are Donor related

➤ Microbial

- Viral

- Bacterial and Mycobacterial

- Fungal

➤ Parasitic



Potential Risk which could be associated with some Human Breast Milk

- Human milk can transmit
 - bacteria, viruses, fungi or parasites
 - Agents present because of
 - Maternal infection or contamination after collection
- Unaware of any reports of direct infectious disease transmissions, including viral transmissions, from banked human donor milk within the US
- Occasional literature reports of bacterial transmissions in neonates through ingestion of donor milk, where sources of bacterial contamination were identified in the hospital environment

Reported Rates of Transmission

➤ Viral

➤ Microbial

- Bacteria

- Mycobacterial

- Fungal

➤ Parasitic

Transmission Rates of Viral Contaminants

Viral Contaminant	Transmission Rate to Breast-fed Infant	Screening Capability
Cytomegalovirus (CMV)	38-76% ^(1,2,3)	yes
Human immunodeficiency virus (HIV)	14-42% ^(7,9)	yes
Human T-lymphotropic virus type-I (HTLV-I)	10.6-25% ⁽¹⁰⁾	yes
Human T-lymphotropic virus type-II (HTLV-II)	Claims of transmission, but data are inadequate regarding rate ^(See slide # 20)	yes
Hepatitis B (HBV)	negligible to <4% ^{a (8,13)}	yes
Hepatitis C (HCV)	negligible to 1% ^{b (13,14,15)}	yes
Bovine spongiform encephalopathy (BSE)	Infinitesimal ^(16,18)	no
West Nile virus (WNV)	rare ⁽¹⁹⁾	yes

a = HBV present in 71 % of breast milk samples but the transmissibility is negligible to <4 %.

b = 20-29 % of viremic mothers have detectable virus in their breast milk but vertical transmission is negligible to 1 % .

Isolated contaminants from expressed human milk that caused infection (cont.)

- *Acinetobacter* sp. ___two
- *Enterobacter cloacae* ___two
- *Escherichia coli* ___several
-
- *Klebsiella oxytoca* ___two
- *Klebsiella pneumoniae* ****six** (three from a single donor)
- *Klebsiella* sp ___six
- *Pseudomonas aeruginosa* ___one death, several infections

- **** can multiply at room temperature. *K. pneumoniae* and *P. aeruginosa* has cross-contaminated pasteurized milk.**

Bibliography for this table is available at <http://www.latrobe.edu.au/microbiology/table5.html>

Isolated contaminants from expressed human milk that caused infection

- *Serratia marcescens* **several
- *Staphylococcus epidermidis*
(coagulase-negative) *several; two deaths
(mother's milk transported to twins)
- *Staphylococcus aureus*
(methicillin-resistant) —several; one death
(transported from mother)
- *Salmonella kottbus* *seven

*from a single donor

** can multiply at room temperature. *K. pneumoniae* and *P. aeruginosa* has cross-contaminated pasteurized milk

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Methods for Ensuring Safety

- Available means of screening donors
- Potential shortcomings of the system



Current Industry Practices that Mitigate Infectious Disease Risks

- Donor screening and testing
- Self-exclusion
- Instructions to minimize contamination by the donor
- Milk bank storage and handling procedures
- Heat Processing
 - Holder or Flash Pasteurization
 - Kills or inactivates many infectious agents

Methods for Ensuring Safety

➤ Pasteurization

- Types Holder, Flash
- Effect on bacteria, viruses, parasites
- toxins?

Issues to consider with the sterilization process:

- Holder pasteurization (62.5C for 30 minutes) destroys HIV, CMV and skin bacteria and also eliminates or significantly decreases titers of most other viruses.
- Flash pasteurization (72C for 15 seconds) destroys CMV and 99% of skin bacteria are eliminated.
- At 56C, HTLV-1 is destroyed within 30 minutes and HIV-1 is reduced ten-fold after 121 seconds.

Issues to consider with the sterilization process:

- 60C for 10 hours kills hepatitis B and almost eliminates hepatitis C in serum.
- Heating at 100C destroys staphylococcus and diphtheroids
- Pasteurization should kill all parasites which are rarely found in breast milk
- After pasteurization, milk has been contaminated with *Pseudomonas aeruginosa* when bottles (even with tight lids) were cooled in cold water containing the organism. Also, 14 infants had symptomatic infection with four dying of *Pseudomonas aeruginosa* that contaminated milk from a pasteurizer and bottle warmer during thawing of milk.
- After pasteurization, milk may be cross-contaminated with *Klebsiella pneumoniae*.

There is a report of *B. cereus* producing a toxin that survived sterilization and contaminated the milk at one bank even after the bacterium had been eliminated

Issues to consider with the sterilization process:

- Holder pasteurization has no effect on vitamin A, oligosaccharides or IL-8 but it completely destroys IgM, complement, milk cells and lipases. In addition, there is some decrease in bacteriostatic activity and a 30% decrease in secretory IgA and Ig G activity.

Potential Risk which could be associated with some Human Breast Milk

- Extrinsic or post milking contaminants:
Experience



Potential Non Infectious Risks which could be associated with some Human Breast Milk

➤ Pharmacological contaminants

- Prescription/OTC drugs
- Drugs of abuse
- Tobacco Products

➤ Environmental contaminants

- Perchlorate
- Methyl mercury
- Heavy metals

Non-Infectious Contaminants— Mitigation and Gaps

- Current industry practices to mitigate risks
 - Donor exclusion criteria for intake of drugs of abuse, medication, ETOH, tobacco
 - Donor instructions for self-deferral
- Gaps in risk mitigation
 - Donated milk not tested for contaminants
 - No information re: compliance with donor exclusions



Uncertainties Related to Infectious Disease Transmission Risk

- No data to demonstrate direct infectious disease transmissions from banked donor milk
- Compliance with HMBANA or Prolacta protocols would mitigate infectious disease risks posed by banked donated human milk, but residual risk is unknown
- Risk level in human milk donor population is unknown
- Lack of data for evidence-based determination regarding the most important criteria to assure recipient safety

Additional Reference for Transmission Rates of Viral Contaminants

- Ruff, Andrea J. Breast Milk, Breastfeeding and Transmission of Viruses to the Neonate. Seminars in Perinatology 1994; 18(6):510-516