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ORIGINAL ARTICLE

Safety of donor milk: a brief report

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OBJECTIVE: To review the standard processing and testing of human donors and donor milk and to report the frequency of detected markers of potential harm.
STUDY DESIGN: This was a retrospective analysis of the data gathered by a donor and human milk screening and monitoring process over a period of 3 years.
RESULTS: Screening results from 2011 to the end of 2015 demonstrated that careful history taking resulted in rejection or hold of 29.7% of willing donor candidates. Individual infection screening tests rejected an additional 0.3–2.9 per 1000 donations. DNA fingerprinting of donations eliminated 2 out of 13 491. Drug testing rejected 42 out of 12 408 and dilution or adulteration eliminated 73 out of 4935 donations. Only the dilution rejection rate was significantly higher in the remunerated donors. The details of these results are presented.
CONCLUSIONS: There are significant risks involved in the collection, processing and distribution of donor milk-based products. The behaviors of the donors, biochemical and genetic screening and milk processing are critical to mitigation of these recognized risks. Testing at this level of rigor appears to be justified.

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INTRODUCTION

The American Academy of Pediatrics recommends human milk for all infants, primarily mother's own milk based on documented short and long-term health benefits. In addition, pasteurized donor milk is recommended for preterm infants when mother's milk is unavailable.[1–3] When compared with a diet of formula, premature infants fed their mother's milk have improved feeding tolerance and a lower incidence of late-onset sepsis and necrotizing enterocolitis.[2–4]

Three challenges appear as providers focus on an exclusive human milk diet. First is the desire and capability of the mothers, second the nutritional content of raw human milk (requiring fortification) and the last is the safety and availability of donor milk and human milk-based fortifiers. Increasing efforts to support the provision of mother's own milk and the issues of fortification are critical, but have been dealt with by others.[3,5]

The sharing of human milk from high-volume producers (wet nurses) to infants of women whose production does not meet the needs of their infants has a long history. The risks for the baby include exposure to diluted human milk, animal milk proteins, infectious diseases, chemical contaminants, such as some illegal drugs, and to a limited number of prescription drugs that might be in the human milk (http://www.fda.gov/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/ucm235203.htm). In our more modern and safety oriented society, donor screening and milk processing has taken on the characteristics of blood donation for screening and bovine milk processing for the preparation and distribution.

Our objective is to understand how the donor screening and testing of human milk reduces risks associated with using donor human milk.

METHODS

In a special request to Prolacta Bioscience (Prolacta, City of Industry, CA, USA), the author gained access to the detailed steps in the process and subsequently the de-identified retrospective data from the donor screening and human milk testing process for the time period 2011–2015. Some of the assay methods changed during this time period, so we requested data from the date of the change to October 2015.

The screening process starts with questions about lifestyle, medical history and medication usage. Responses to the questionnaire are evaluated by a trained milk bank coordinator. Non-standard responses to the questionnaire are evaluated by a Medical Director. Four types of responses are possible: pass—response acceptable to move applicant to next qualification step; pending—response requires additional information to make assessment of applicant qualification; temporary deferral—response makes applicant ineligible for a period of time; and permanent deferral—response makes applicant permanently ineligible. If the donor's responses to the questionnaire are acceptable, the donor provides Prolacta written clearance from her physician as well as her child's physician. (Prolacta Staff, Personal Communication 2015).

Donor blood screening is performed for hepatitis C virus and antibody, hepatitis B virus and surface antigen, HIV-1/2 antibody, human T-lymphotropic virus I/II, antibody to human T-lymphotropic virus I & II, syphilis serologic tests, nucleic acid test for hepatitis B virus, HIV type I and COBAS tag screen multiplex assay nucleic acid test for HIV, hepatitis C virus and hepatitis B virus (NMPX). Also, all donor milk undergoes screening for nicotine, amphetamine, benzodiazepine, cocaine, marijuana (THC), methamphetamine, opiates and their principle metabolites. To ensure milk received is from the qualified donor, donor identity matching is performed using DNA fingerprinting. Adulteration and dilution testing is performed on the incoming milk before use in production. Donors undergo re-qualification (questionnaire and blood tests only) every 4 months to continue donating (Prolacta Staff, Personal Communication 2015).

Additional processing steps are taken to reduce bioburden, formulate specific products, pasteurize following the standards of the Pasteurized Milk Ordinance set by the FDA, aseptically filled in ISO certified clean rooms and then package for distribution.

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Table 1. Reason and frequency of human milk donor and donation rejections

	Non-remunerated N *(%)*	*Remunerated* N *(%)*
Screening survey	15 870	1987
Pended or rejected	4761 (30)	536 (27)
Infection screening	7969	2473
Hepatitis B surface antigen	11 (0.14)	3 (0.12)
Hepatitis C antibody	15 (0.19)	3 (0.12)
HIV antibody	3 (0.04)	1 (0.04)
HTLV Ab	23 (0.29)	3 (0.12)
NMPX	6 (0.08)	2 (0.08)
Syphilis serology	2 (0.03)	3 (0.12)
DNA matching	10471	3020
	2 (0.02)	0 (0)
Drug screening	9439	2969
Cotinine	32 (0.34)	8 (0.27)
Amphetamine	0 (0)	0 (0)
Oxycodone/oxymorphone	2 (0.02)	0 (0)
Benzodiazepine group	0 (0)	0 (0)
Cocaine/BZE	0 (0)	0 (0)
THC	0 (0)	0 (0)
Opiate group	0 (0)	0 (0)
Adulteration	2060	2875
Other protein source	1 (0.05)	1 (0.03)
Dilution	14 (0.68)	57 (1.98)

Abbreviation: BZE, benzoylecgonine.

RESULTS AND ANALYSIS

Screening questionnaires from 1987 remunerated and 15 870 non-remunerated applicants did not reveal significant differences, with 14 and 18% pended, and 13% and 12% permanently or temporarily deferred, respectively. The blood testing (serological and nucleic acid test) results from October 2011 to October 2015. Both revealed very low-frequency rejection events with no significant differences.

The DNA matching assay was changed in February of 2013. Two non-matched donations were received (2/10471) from non-remunerated donors and none were received (0/3020) from remunerated donors. Both of the non-matched donations were determined to be a mix-up of milk stored in hospital NICUs.

Drug screening assay by ELISA and confirmed by a quantitative analysis using chromatographic methods and adulteration screening assay failure and dilution are noted in Table 1. The dilution testing noted a significant difference of 0.68% for non-remunerated versus 1.98% for remunerated donors ($P < 0.001$).

DISCUSSION

In the absence of regulation, there are significant risks involved in the collection, processing and distribution of donor milk-based products. The behaviors of the donors, biochemical and genetic screening and milk processing are critical to mitigation of these recognized risks. Although most risk elements are eliminated with the screening questionnaire, the described extensive lab testing of donors and donated milk is important to ensure the safety of the donor milk supply.

CONFLICT OF INTEREST

The author declares no conflict of interest.

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REFERENCES

1 American Academy of Pediatrics, Section on Breastfeeding. Breastfeeding and the use of human milk. *Pediatrics* 2005; **115**: 496–506.
2 Narayanan I, Prakash K, Murthy NS, Gujral VV. Randomized controlled trial of the effect of raw and holder pasteurized human milk and of formula supplements on the incidence of neonatal sepsis. *Lancet* 1984; **2**: 1111–1113.
3 American Academy of Pediatrics, Section on Breastfeeding. Breastfeeding and the use of human milk. *Pediatrics* 2012; **129**: e827.
4 Schanler RJ, Shulman RJ, Lau C. Feeding strategies for premature infants: Beneficial outcomes of feeding fortified human milk vs preterm formula. *Pediatrics* 1999; **103**: 1150–1157.
5 Schanler RJ, Lau C, Hurst NM, Smith EO. Randomized trial of donor human milk versus preterm formula as substitutes for mothers' own milk in the feeding of extremely premature infants. *Pediatrics* 2005; **116**: 400–406.

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