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# Retrospective review of serological testing of potential human milk donors

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## ABSTRACT

**Objective** To estimate the prevalence of positive serology among potential donors to a human milk bank.

**Design** Retrospective review of our experience with donor serological testing at our milk bank over a 6-year interval.

**Setting** Not-for-profit, regional human milk bank.

**Patients** Volunteer, unpaid potential donors of human milk.

**Interventions** Serological testing for syphilis, HIV, hepatitis B, hepatitis C, human T cell lymphotropic virus type 1 (HTLV-1) and human T cell lymphotropic virus type 2 (HTLV-2).

**Main outcome measures** Results of serological screening tests performed on potential donors.

**Results** Of 1091 potential donors, 3.3% were positive on screening serology, including 6 syphilis, 17 hepatitis B, 3 hepatitis C, 6 HTLV and 4 HIV.

**Conclusions** There is a significant incidence of positive serology among women interested in donating human milk. This implies that there may be significant risk associated with peer-to-peer distribution of human milk from untested donors.

## INTRODUCTION

Although the transmission of viral pathogens through human milk is well documented, the degree of risk associated with specific viruses is still debated.<sup>1,2</sup> Concern about possible viral transmission by human milk has resulted in recommendations against breast feeding by women either known or suspected to have certain viral diseases, such as HIV, human T cell lymphotropic virus type 1 (HTLV-1) and human T cell lymphotropic virus type 2 (HTLV-2).<sup>3</sup> Some have recommended that hepatitis B seropositive women should be advised not to breast feed.<sup>4</sup> Hepatitis C probably is not transmitted by human milk in the absence of maternal HIV infection, but this has been debated.<sup>3,5,6</sup> The risk of transmission of cytomegalovirus (CMV) has been deemed high enough that it has been recommended that a mother's milk be frozen prior to feeding to her own premature infant.<sup>7</sup> These concerns may have affected the acceptance of banked donor human milk, even though milk banks in North America only accept milk from donors who have passed serological screening, and then Holder pasteurise all milk. Despite these concerns among paediatricians, obstetricians, lactation consultants and milk banks, there have been ongoing reports of direct peer-to-peer sharing of non-pasteurised human milk from untested donors.<sup>8,9</sup> Women interested in donating to a milk bank are screened by their obstetricians, as well as by the bank with

## What is already known on this topic

- ▶ A significant number of potential blood and tissue donors have positive serological testing for potential pathogens.
- ▶ The prevalence of positive serology appears to be lower for potential blood and tissue donors than for the population at large.
- ▶ Peer-to-peer distribution of human milk from untested donors occurs at an uncertain frequency and with undetermined risk to the recipient infants.

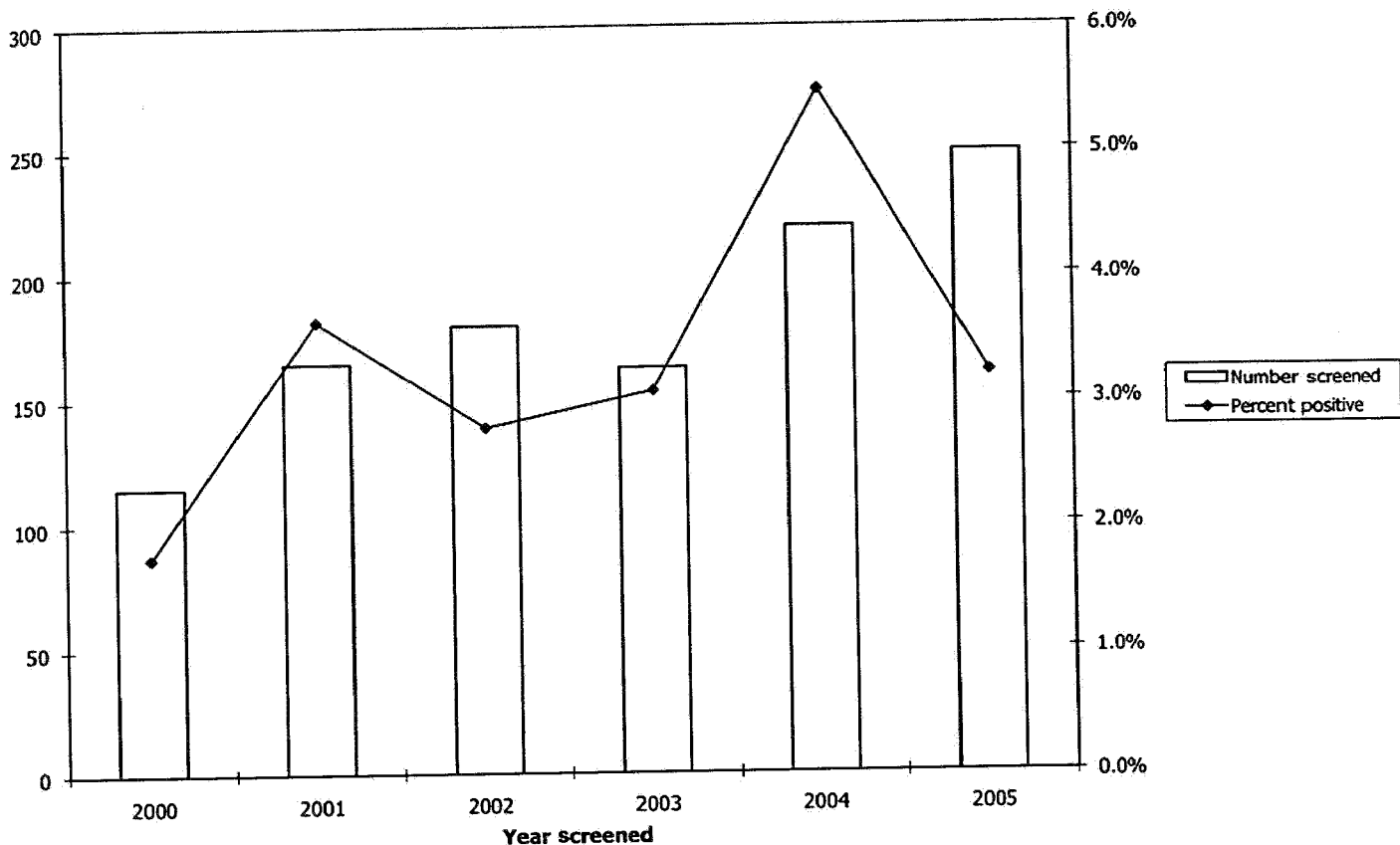
## What this study adds

- ▶ This study quantifies the prevalence of positive serology among women who seek to donate voluntarily to a milk bank, knowing they will be tested.

a questionnaire, before undergoing serological testing. Data from US blood banks indicate that potential donors have a lower prevalence of seropositivity for tested viruses than the population at large.<sup>10</sup> We would therefore expect potential donors to milk banks to have a lower incidence of positive serological testing than untested women. We assessed this risk by reviewing retrospectively the results of serological testing performed on potential donors to our milk bank over a 6-year period.

## METHODS

Records from the Mothers' Milk Bank (MMB) of San José, California, USA, a not-for-profit member of the Human Milk Banking Association of North America (HMBANA), were reviewed retrospectively. These records are required for quality assurance purposes. Potential milk donors consent to a multi-level screening process according to HMBANA guidelines<sup>11</sup> and do not receive any payment for donating. In brief, this process begins with screening by their obstetricians for history or signs of significant illness, including hepatitis, syphilis and HIV. After being screened again with a questionnaire similar to that used by blood banks, remaining potential donors have blood samples drawn for serological testing for syphilis, HIV, HTLV-1 and 2, hepatitis B and hepatitis C.



**Figure 1** Number of potential donors screened versus percentage with positive serology.

Testing was performed by local independent laboratories using standard screening methods. De-identified results were collected, and the results for the 6 years 2000 through 2005 are presented here. The institutional review board of Stanford University approved this study.

## RESULTS

Over the 6-year study period, 1091 potential donors were cleared by their physician, passed the questionnaire and then went on to have serological testing. The majority of the patients (57%) had their blood drawn by the MMB, and samples tested by either the American Red Cross of Santa Clara County or the Blood Bank of Central California in Fresno. The rest were distant donors in either California (34%) or 11 other states. For these donors, testing was performed by blood banks or private licensed laboratories in their communities.

The annual rate of positive serological screening varied from 1.7% to 5.5%, with an average of 3.3% (figure 1). A total of 36 out of the 1091 potential donors were rejected due to abnormal serological screening results; nearly half of these (17/36 or 47%) were due to positive hepatitis B screens. Although the sample is too small to have significant power, the number of positive hepatitis B serology tests appears to have increased over the study period (table 1).

## DISCUSSION

We found that 3.3% of the women who voluntarily sought to donate milk to our milk bank had positive serological screening tests for syphilis, HIV, HTLV-1 and 2, hepatitis B or hepatitis C. There is a clear need to ensure the safety of all body fluids and tissues, including donor human milk, which may be

**Table 1** Positive serological screening tests of potential human milk donors

| Year | N    | RPR | HIV | HTLV | Hep B | Hep C | Total (%) |
|------|------|-----|-----|------|-------|-------|-----------|
| 2000 | 115  | 1   | 0   | 1    | 0     | 0     | 2 (1.7)   |
| 2001 | 165  | 1   | 2   | 0    | 0     | 1     | 4 (2.4)   |
| 2002 | 180  | 1   | 0   | 3    | 0     | 1     | 5 (2.8)   |
| 2003 | 163  | 1   | 0   | 0    | 3     | 1     | 5 (3.1)   |
| 2004 | 219  | 2   | 2   | 1    | 7     | 0     | 12 (5.5)  |
| 2005 | 249  | 0   | 0   | 1    | 7     | 0     | 8 (3.2)   |
| All  | 1091 | 6   | 4   | 6    | 17    | 3     | 36 (3.3)  |

Hep B, hepatitis B; Hep C, hepatitis C; HTLV, human T cell lymphotropic virus; N, number tested; RPR, rapid plasma reagin test for syphilis.

donated from one person to another. In California, where our bank is located, milk banks are considered tissue banks, and therefore are licensed and regulated as such.<sup>12</sup>

We do not screen potential donors for CMV, as the prevalence of CMV in adult American women ranges from 50% to over 80%.<sup>13 14</sup> In Norway, 62% of human milk donors were positive for CMV IgG.<sup>15</sup> It has been shown that Holder pasteurisation according to standard HMBANA processing eliminates CMV infectivity.<sup>16 17</sup> Therefore, CMV screening by milk banks would add expense, markedly decrease the available number of donors and add nothing to the safety of properly processed donor human milk. However, simple storage in a home freezer would not eliminate the risk of CMV transmission completely.<sup>18</sup> For normal term newborns, the morbidity of CMV acquired from human milk is probably quite low.<sup>19</sup> However, the risk to preterm infants is not clear but more worrisome.<sup>20</sup>

Syphilis does not appear to be transmitted via human milk except in the presence of breast lesions.<sup>2</sup> Transmission of the HTLV viruses by human milk is well documented, with breast-fed offspring having an infection rate of 43% for HTLV-1<sup>21</sup> and about 15% for HTLV-2.<sup>22</sup> The risk of acquisition of HIV via human milk has also been well documented; a large randomised controlled trial estimated the transmission rate for HIV through breast milk to be about 16%.<sup>23</sup>

Potential donors to tissue banks in the USA were found to have a 3.16% prevalence of positive screening for the same viral agents, with 1.48% confirmed positive.<sup>24</sup> This screening result is similar to what we report here. Although we do not have results of confirmatory testing, we would expect a similar rate of false positives for our screening. Nevertheless, based upon data from blood banks in the USA<sup>10</sup> and Germany,<sup>25</sup> we would expect the prevalence of true seropositivity to be higher in the population at large than in our potential donors.

The number of women screened increased over the study period, commensurate with the increasing demand for donor human milk experienced by the MMB. The apparent increase in positive hepatitis B serology over the 6-year study period most likely reflects normal variation over time. However, it might be due to changes in the sensitivity of the screening test,<sup>26</sup> or increased false positives due to greater rates of maternal hepatitis B vaccination.<sup>27</sup> Although we do not have the details of the testing methods used for these women over 6 years and a broad geographical area, most of the testing was performed by licensed blood banks, with a minority carried out by licensed clinical laboratories. Thus, the sensitivity and specificity of the tests may have varied over the course of the study.

In conclusion, at least 3% of potential donors to a human milk bank, a relatively low-risk population, were found to test positive for the rapid plasma reagin (RPR) test for syphilis, HIV, hepatitis B, hepatitis C, HTLV-1 or HTLV-2, on screening serology. Although screening tests overestimate the number of true positives, the prevalence of these viruses in the unscreened adult population at large would likely be higher than in our donors. The use of unpasteurised donor human milk from untested women may pose a significant health risk to exposed infants.

**Ethics approval** The institutional review board of Stanford University approved this study.

**Patient consent** All subjects signed consent for anonymous research approved by the Human Milk Banking Association of North America. Additional informed consent for this study was waived by the institutional review board at Stanford University.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Contributors** The initial idea for this study came from RSC. Data collection was by SCX and PS, with analysis by RSC. Initial writing was done by RSC, with input and review by all three authors. Guarantorship is shared by RSC and PS.

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