## Human milk bank and donor milk in Japan

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## Abstract

With recent changes to the nutritional strategies for preterm infants, early initiation (within 24 hours of birth) of enteral nutrition is becoming a standard practice. Almost 30 years ago, there was a multicenter clinical trial revealing that the early initiation of enteral nutrition resulted in better growth during NICU stay, less chronic lung disease incidence, and less necrotizing enterocolitis. However, mother's own milk (MOM) was often not available, such that other women's milk (unpasteurized) was given to the infants. Some infants ended up being infected by cytomegalovirus (CMV) or multidrugresistant bacteria. No matter how the early initiation of enteral feeding is good for preterm infants, we were reluctant to use other women's milk due to the fear of infection. This is the major reason why we need human milk bank (HMB) in Japan. We can give DHM to the infants according to the standardized enteral feeding protocol.

Finally, in Japan, the first HMB is established in 2017 after 3 years of preparatory period and the amount of DHM delivered to NICUs has increased with time.

I am going to talk three topics regarding HMB and DHM in Japan; Firstly, I would like to share our experience about the first HMB in Japan.

Secondly, I would like to talk about lyophilization technique for fortification of mothers' milk.

Lastly, we currently found microwave procedure (500W for 40 sec) could inactivate human cytomegalovirus (HCMV), such that microwave technique could be a convenient method to prevent HCMV infection via breast milk.

1) The history of HMB in Japan Based on the results of our 3 years of preparatory period which was supervised by the Ministry of Health, Labor and Welfare, we established Japanese Human Milk Bank Association (JHMBA) in May 2017.

<u>Recipients:</u> At this moment, we offer DHM only to very low-birthweight infants. A total of 65 little? is given to 29 infants. Four babies were born less than 500g. All the babies received DHM survived and went home without serious problems. Needless to say, there have been never any claims reported to DHM.

Donors: Since May 2017, there were 22 donors who clarified the requirements of being a donor.

Of which, 13 were mothers of preterm infants who admitted to NICU (NICU mom) and 9 were mothers of healthy term infants and registered via website (Term mom). When we compared the bacterial tests of donated breast milk between NICU mom and Term mom, we found that the breast milk from NICU mom contains more diverse and more bacteria. From this experience, we thought we need to educate NICU mom repeatedly while they stay in the NICU with respect to clean expression methods?.

## 2) Fortification of MOM by lyophilized MOM

We asked if the lyophilized MOM could fortify MOM. Lyophilization is a well-established method for storing materials including food, medicine and vaccine. This method ensures no microbiological contamination and preserves properties of the material in the vial. The aim of this study was to determine whether lyophilization of human milk results in microbiological contamination and changes to the composition of human milk. In addition, we tested whether the addition of lyophilized human milk (powder form) to the original human milk (liquid form) could increase the concentration of major nutrients in human milk.

Lyophilization preserved the nutritional and anti-infective components of human milk without increas in microbiological contaminants observed. Additionally, as expected, the addition of lyophilized human milk to human milk (liquid form) increased its nutritional content.

3) Convenient pasteurization with microwave irradiation

The other research we have been working on is to pasteurize MOM by microwave, mostly due to HCMV prevention. HCMV Towne strain was added to formula, followed by heat processing using Holder pasteurization (HP) or MW irradiation at 500 W for 20, 30, 40, or 60 s. Addition of HCMV for a viral load of  $5.0 \times 10^3$  plaque-forming units (pfu)/mL achieved 772 pfu/mL at baseline, with a decrease to 257 pfu/mL after 20 s. The number of plaques reached 0 after 30 s of MW heat treatment. The number of HCMV DNA copies at baseline did not change with 40 s of MW heat treatment, remaining between 2,017 and 2,157 copies/mL.

We confirmed that the decline of breast milk components, such as SIgA, lactoferrin

were less by MW, compared to Holder pasteurization.