Letter to the Editor

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Universal Screening for SARS-CoV-2 of all Human Milk Bank Samples

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A decrease in donations of human milk has been observed during the novel coronavirus disease 2019 (COVID-19) pandemic (Moro & Bertino, 2020), but high-risk infants still need human milk in our Neonatal Intensive Care Units (NICUs). The pandemic has not, at any point, led us to suspend the collection and processing of donor human milk at our human milk bank (HMB) at Bambino Gesù Children's Hospital in Rome, Italy. We have recommended that donor mothers interrupt milk donation and be tested promptly if any related symptoms occur. Nevertheless, considering that asymptomatic carriers could acquire and transmit the virus (Li et al., 2020), and that they could contaminate the outside of milk containers (De Rose et al., 2020), we aimed to assess if a universal screening of milk containers and human milk samples could be useful, despite the rigorous controls in place regarding donor mothers.

From May 1 to July 31, 2020, we tested all received containers' external surfaces before sanitizing them, as well as a random percentage of human milk before pasteurization. Nucleic acid was extracted using the automatic platform QIAsymphony DSP Virus/Pathogen Midi kit. As recommended by the manufacturer, 400 µl per sample was extracted and then eluted in 115 µl of elution buffer. Prior to RNA extraction, milk sample specimens were incubated for 12 hr at 4°C to separate and remove the fat. Severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2) reverse-transcriptase polymerase chain reaction (RT-PCR) was performed on CFX96 (Bio Rad Laboratories) with Allplex™ 2019-nCoV Assay. Strictly in accordance with the Italian National Institute of Health and World Health Organization (WHO) protocols, assay targets were the E gene (encoding the envelope protein of Sarbecovirus), RdRp (RNA-dependent RNA polymerase), and N (nucleocapside) genes specific for SARS-CoV-2. A positive control was included in each sample to control both extraction efficiency and RT-PCR inhibition; a negative control was included in every run to assess carry-over contamination in both workflows. For each reaction, 8 µl of the extracted RNA, in a final volume of 25 µl, was used. The results were analyzed automatically using the Seegene software (2019 nCoV viewer; Concato et al., 2020). Donor mothers provided written informed consent for their milk to also be used for microbiological control and research purposes.

During the study period, we collected approximately 304 L of human milk (from 34 donor mothers). We processed 34 samples of human milk and 34 swabs from containers' external surfaces for testing for SARS-CoV-2 molecular detection. None of the human milk samples or the container swabs tested positive for SARS-CoV-2.

Mothers with suspected or confirmed COVID-19 can directly breastfeed using appropriate precautions (Salvatori et al., 2020). To date, there is no sure evidence that novel severe acute respiratory Coronavirus Virus 2 (SARS-CoV-2) can be transferred through human milk (Auriti et al., 2020), although an intermittent excretion of the virus has been reported (Costa et al., 2020). Furthermore, detection of viral RNA by RT-PCR in human milk does not equate with infectivity (Chambers et al., 2020). Cold storage of SARS-COV-2 in human milk did not significantly change viral load over a 48 hr period according to a study in which the virus was experimentally inoculated into human milk samples (Walker et al., 2020). Nevertheless, SARS-CoV-2 is effectively inactivated by Holder pasteurization (62.5°C, 30 min) of human milk, if present (Pitino et al., 2020; Unger et al., 2020). These observations suggest that current human milk bank (HMB) processes would effectively reduce an eventual risk of transmission of respiratory viruses such as SARS-CoV-2 to most fragile neonates. Nevertheless, strict screening of donor mothers should be always performed.

The main limitation of our study was the single center site in a medium-risk region, whereas 70% of positive COVID-19 cases were registered in northern Italy. Not all received containers and human milk samples were analyzed, in order to avoid wasting precious human milk, but we analyzed at least one container and one milk sample for each donor mother.

However, our observations, combined with the negativity of human milk samples after Holder pasteurization confirmed by different authors (Pitino et al., 2020; Unger et al., 2020; Walker et al., 2020), support that

donor human milk is a safe product, after carrying out an appropriate evaluation of donor mothers to obtain eligibility for the donation. To the best of our knowledge, our study is the first one to analyze human milk containers and milk samples from all donor mothers. Our data are reassuring regarding the safety of human milk provided through milk banks during this viral outbreak, when careful selection of donor mothers and Holder pasteurization are performed. According to our data, the universal screening of all milk samples did not appear to be necessary.

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Ethical Disclosures

The authors declare that they have followed the protocols of their work center and the Helsinki Declaration on the publication of patients' data.

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