

# 1 **COVID-19 mRNA vaccine is not detected in human milk**

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## 15 **Abstract**

16 Several countries have recently approved the use of mRNA vaccines against COVID-19 under  
17 an emergency use authorization. However, no pregnant or lactating individuals were included in  
18 the Phase 3 clinical trials of these vaccines despite belonging to a group at high risk for severe  
19 complications of COVID-19 infection. We show here that the mRNA from anti-COVID  
20 BNT162b2 (Pfizer) and mRNA-1273 (Moderna) vaccines is not detected in human breast milk  
21 samples collected 4-48 hours post-vaccine. These results strengthen the recommendation of  
22 ABM and WHO that lactating individuals who receive the anti-COVID-19 mRNA-based vaccine  
23 should continue to breastfeed their infants uninterrupted.

## 24 **Introduction**

25 Several countries have recently approved the use of mRNA vaccines against COVID-19 under  
26 an emergency use authorization <sup>1</sup>. However, no pregnant or lactating individuals were included  
27 in the Phase 3 clinical trials of these vaccines despite belonging to a group at high risk for  
28 severe complications of COVID-19 infection <sup>2,3</sup>. As a result, there are no clinical data regarding  
29 the safety or efficacy of the vaccine in these populations. The World Health Organization (WHO)  
30 recommends breastfeeding people to obtain the vaccine if they are at a group recommended for  
31 vaccination (e.g. health workers), and does not advise cessation of breastfeeding following  
32 receipt of the vaccine <sup>4</sup>. The Academy of Breastfeeding Medicine (ABM) states that there is little  
33 plausible risk that vaccine lipid particles would enter the blood stream and be present in breast  
34 tissue, and that nanoparticles or mRNA would be transferred to milk <sup>5</sup>. However, regardless of  
35 the low predicted risk of harm to the baby, some mothers have declined vaccination, chosen to  
36 “pump and dump” breast milk for up to 72 hours after the vaccine, or decided to stop  
37 breastfeeding due to the lack of solid evidence about the effect of the mRNA vaccine on human  
38 milk.

39 We herein report that analysis of milk samples collected from six individuals within 24 hours  
40 after mRNA vaccination against COVID-19, and of six serial milk samples collected 4, 8, 22, 28,  
41 33, and 48 hours post vaccine showed no evidence of vaccine-related mRNA in breast milk.

42

## 43 **Methods:**

44 The University of California San Francisco (UCSF) institutional review board approved the study  
45 (20-32077). Informed consent was obtained from all study participants.

46 Human breast milk samples were collected fresh or frozen (immediately after milk was  
47 pumped). Total RNA was isolated from milk components (cells, milk supernatant and/or fat

48 layer) using the RNeasy Mini Kit (Qiagen) according to manufacturer's protocol. We performed  
49 RT-qPCR in triplicate using specific primers (supplementary materials) targeting the vaccines  
50 mRNA for SARS-CoV-2 spike protein. mRNA-1273 (Moderna) vaccine was spiked into pre-  
51 vaccine milk sample before RNA isolation and served as a positive control for this assay. Pre-  
52 vaccine samples served as negative controls.

### 53 **Results:**

54 Post-vaccine human milk samples were collected from six individuals 4-48 hours after  
55 administration, 5 vaccinated with BNT162b2 (Pfizer) and 1 individual with mRNA-1273  
56 (Moderna) vaccine (**Table 1**). We first optimized our RT-qPCR by isolating the residual vaccine  
57 mRNA from vials, showing that our assay is capable to detect up to 1.5 pico grams of the  
58 mRNA-1273 vaccine cDNA and up to 0.195 pico grams of the BNT162b2 vaccine (**Figure 1A**).  
59 We next used pre-vaccine milk samples and spiked-in the mRNA-1273 vaccine (12 and  
60 0.12ng/ul vaccine mRNA). RNA was extracted from the supernatant and fat layer of these  
61 spiked-in milk samples. We were able to detect the spiked-in vaccine mRNA in these samples  
62 (**Figure 1B**), with higher levels of vaccine mRNA in fat layer fraction (**Figure 1B**). We next  
63 analyzed 12 post-vaccine samples (4-48 hours post vaccine, **Table 1**) and found that none of  
64 the samples from vaccinated lactating mothers showed detectable levels of vaccine mRNA in  
65 milk fat layer or milk supernatant at any time point (7 samples from 24h post vaccine are shown  
66 in **Figure 1B**).

### 67 **Conclusion:**

68 We show here that the mRNA from anti-COVID vaccines is not detected in human breast milk  
69 samples collected 4-48 hours post-vaccine. These results strengthen the recommendation of  
70 ABM and WHO that lactating individuals who receive the anti-COVID-19 mRNA-based vaccine  
71 should continue to breastfeed their infants uninterrupted. Clinical data from larger populations

72 need to be collected and analyzed to better estimate the effect of these vaccines on lactation  
73 outcomes.

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75 **References:**

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96

97 **Conflict of interest:**

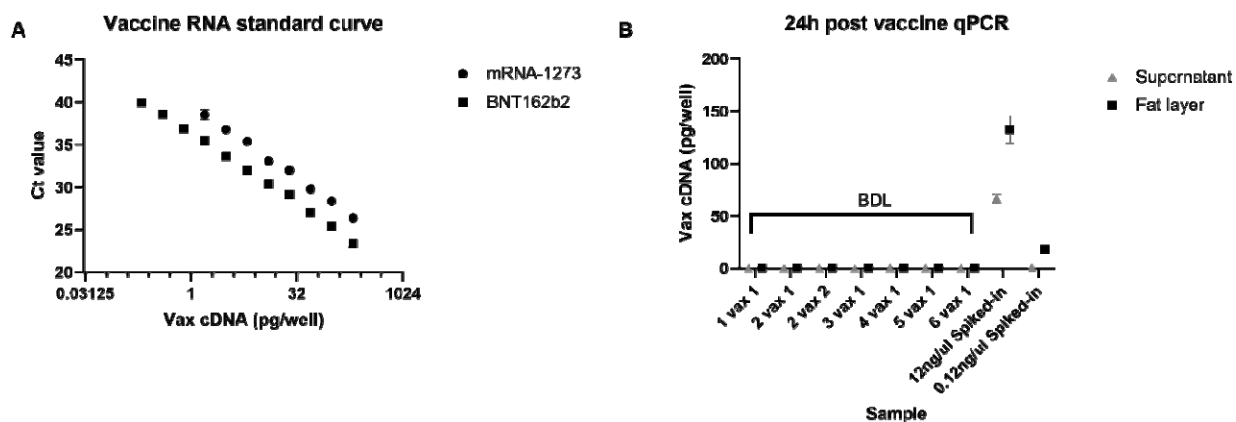
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Figure 1



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107 **Figure 1- qPCR analysis of post vaccine milk samples.** A) standard curves for mRNA-1273  
108 and BNT162b2 vaccines. B) mRNA concentrations of 24h post vaccine samples and spiked-in  
109 samples were calculated based on equations from standard curves. Samples names stands for  
110 participant number and if sample was collected after first (1) or second (2) vaccine (vax). Below  
111 detectable levels (BDL). Mean values  $\pm$  SD are shown.

**Table 1: Samples analyzed by qPCR analysis**

Participant number	Vaccine	Time point	Collection Method		Milk Fraction		
			Fresh	Frozen	Supernatant	Fat	Cells
1	BNT162b2	Pre-vaccine		X	X		
		24h postvaccine 1		X	X	X	
2	BNT162b2	Pre-vaccine		X	X	X	
		24h postvaccine 1		X	X	X	
		24h postvaccine 2		X		X	
3	BNT162b2	24h postvaccine 1		X		X	
4	mRNA-1273	8h postvaccine 1		X	X	X	
		<24h postvaccine 1		X	X	X	
		28h postvaccine 1		X	X	X	
		33h postvaccine 1		X	X	X	
		48h postvaccine 1		X	X	X	
		4h post vaccine 2		X	X	X	
5	BNT162b2	24h postvaccine 1	X		X	X	
6	BNT162b2	Pre-vaccine		X	X	X	X
		24h postvaccine 1	X		X	X	X

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