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vaccine would contribute to safe prescribing, transnational distribution, enhanced pharmacovigilance, and, ultimately, the safety of vaccine recipients, as it does for therapeutic medicinal substances.

For the safety of vaccine recipients and the global recognition of vaccine ingredients, the WHO International Nonproprietary Names Programme encourages vaccine developers to submit INN requests for well defined vaccine ingredients and urges regulatory authorities to facilitate INN implementation.

We declare no competing interests.

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- 1 WHO. International nonproprietary names (INN) for biological and biotechnological substances (a review). 2019. <https://www.who.int/medicines/services/inn/BioReview2019.pdf> (accessed Jan 19, 2021).
- 2 WHO. International nonproprietary names for pharmaceutical substances (INN). Proposed INN: list 113. *WHO Drug Inf* 2015; **29**: 195–301.
- 3 WHO. International nonproprietary names for pharmaceutical substances (INN). Recommended INN: list 75. *WHO Drug Inf* 2016; **30**: 93–170.
- 4 WHO. International nonproprietary names for pharmaceutical substances (INN). Proposed INN: list 124—COVID-19 (special edition). *WHO Drug Inf* 2020; **34**: 641–85.

trialled in breastfeeding women.¹ Pfizer's current recommendation states that breastfeeding women should "ask your doctor or pharmacist for advice before you receive this vaccine".²

We fear that, like Public Health England's initial recommendation not to vaccinate lactating women,³ many clinicians will recommend against taking the vaccine when breastfeeding, as is the default in the absence of data, as though breastfeeding is a neutral health decision. Those individuals immediately impacted by the advice, of course, are breastfeeding women working as front-line health-care providers and caregivers, who might be required to choose between their own health, their infant's health, and potentially, their job because not being vaccinated might be disadvantageous in the workplace.

Although the UK has reversed its stand and now advises offering the vaccine to breastfeeding women,³ concerns remain because the vaccine has not been tested in lactating women, not because of empirical evidence or biological plausibility for harm.

However, we want to highlight that human milk is not a vector for severe acute respiratory syndrome coronavirus 2.⁴ Moreover, the milk contains antibodies that could potentially protect the breastfed baby from COVID-19.⁵ We need research to determine whether coronavirus vaccines in general, and mRNA vaccines in particular, enter the milk and transfer to the infant. Even if they do, there seems no plausible reason to recommend against vaccination for breastfeeding women. Antibodies generated in response to the vaccine should protect the breastfeeding women and the breastfed infants. Perhaps with this protection in mind, the American College of Obstetricians and Gynecologists stated upfront that "COVID-19 vaccines be offered to lactating individuals similar to

non-lactating individuals when they meet criteria for receipt of the vaccine".

To improve maternal-infant health and maintain public confidence in vaccines in handling this pandemic and preparing for the next, vaccine manufacturers and regulators must work closely with lactation scientists, infectious disease specialists, and public health experts to assess vaccine safety in breastfeeding women at early stages of product development. It is encouraging that many nations, including England, are now adopting a more positive tone around vaccine recommendations for breastfeeding women, but in many cases the finer points of the recommendation will still lie with individual providers or institutions.

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- 1 Doshi P. Will covid-19 vaccines save lives? Current trials aren't designed to tell us. *BMJ* 2020; **371**: m4037.
- 2 Pfizer. Package leaflet: information for the recipient. COVID-19 mRNA Vaccine BNT162b2 concentrate for solution for injection. December, 2020. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948518/Information_for_UK_recipients_on_PfizerBioNTech.pdf (accessed Jan 18, 2021).
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- 4 Chambers C, Krogstad P, Bertrand K, et al. Evaluation for SARS-CoV-2 in breast milk from 18 infected women. *JAMA* 2020; **324**: 1347–48.
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For more on the advice from the American College of Obstetricians and Gynecologists see <https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19>



Breastfeed or be vaccinated—an unreasonable default recommendation

Breastfeeding promotes the good health of mothers and infants and is a crucial international public health issue. None of the COVID-19 vaccines currently in phase 3 trials have been

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