



Statement from the GP Infant Feeding Network, the Hospital Infant Feeding Network and Breastfeeding for Doctors

There is an urgent need to amend UK guidance on administration of the mRNA-based Covid-19 vaccines to lactating people - in line with American guidance - and to commit to immediate collection of safety data in this population.

As groups representing front line healthcare professionals who are lactating or have an interest in supporting lactation, we are extremely concerned at the impact of the "very precautionary approach"[1] that the Medicines & Healthcare products Regulatory Agency (MHRA) have taken in actively advising that the Pfizer-BioNtech Covid-19 vaccination "should not be used during breast-feeding"[2] and the resulting Public Health England (PHE) position that people should wait until they have finished breastfeeding to have the vaccine.[3]

In contrast, the US Advisory Committee on Immunization Practices (ACIP) has already confirmed that they intend to take a pragmatic general principle "that breastfeeding would not be a contraindication to receive a COVID-19 vaccine"[4] due to the lack of theoretical basis for concern, and the FDA has simply stated that as no lactation data are available that women should discuss their risk/benefit profile with their healthcare provider[5]. Following on from this position the American College of Obstetricians and Gynecologists (ACOG) recommends that "COVID-19 vaccines should be offered to lactating individuals similar to non-lactating individuals when they meet criteria for receipt of the vaccine based on prioritization groups"[6]. The Academy of Breastfeeding Medicine (ABM) "does not recommend cessation of breastfeeding for individuals who are vaccinated against COVID-19. Individuals who are lactating should discuss the risks and benefits of vaccination with their health care provider, within the context of their risk of contracting COVID-19 and of developing severe disease."[7]

If the UK were to follow the FDA's example, lactating front line workers would be able to make an informed decision about their level of risk and benefit in deciding whether or not to take up the mRNA based vaccines, as advised by ACOG and ABM. Instead they face either being refused the vaccine, being forced to give up breastfeeding, or having to lie about their breastfeeding status in order to enact their informed decision.

There is minimal theoretical basis to suspect a risk to a breastfeeding child from mRNA Covid-19 vaccines - mRNA is unstable and would degrade at the body temperature maintained during lactogenesis, let alone the acidic stomach environment of the breastfeeding child. The only vaccines not considered safe in lactation are smallpox and yellow fever, both live and completely different in nature to the Covid-19 vaccinations. On the other side of the equation, breastfeeding is a powerful public health tool and a lever for reducing health inequalities[8]. Sadly breastfeeding is historically undervalued in the UK, leading to some of the lowest breastfeeding rates in the world by one year of age[8].

There has been an outpouring of anxiety from our members on this issue and many feel that they have been put in an impossible and discriminatory position because of the UK regulator's decision. All the examples of consent forms used by NHS trusts that they have shared with us asked explicitly if the person is pregnant or breastfeeding and would deny the vaccine if this was disclosed. The MHRA and PHE should urgently follow the example of the FDA and allow women to make their own choices about the risks and benefits of Covid-19 vaccines to themselves and their children. At the very least the JCVI should clarify that, similarly to their explicit advice on pregnancy,[1] (which our members tell us is not being followed in practice) lactating women should be able to consider the available evidence and then confirm their understanding of this information during vaccine consent rather than being asked formally whether they are lactating and denied the vaccination if lactation is disclosed.

It is also urgent to put in place the channels for further safety data in lactation and pregnancy immediately - this is a critical priority for policymakers so that a firm recommendation can be made as soon as evidence allows. Currently studies in pregnancy have been appropriately prioritised but no plans made for lactation, despite over 500 lactating front line workers standing ready to take part in breastmilk monitoring as soon as a collaborative partner can be obtained. We seek full collaboration from PHE on this matter. We applaud Janssen for including lactating participants in their phase three vaccine trials[4] and would encourage all vaccine manufacturers to prioritise the same approach in any future work.

We would like to explicitly note that combining pregnancy and lactation into one category does not have a physiological basis and that these two categories must be discussed separately in further MHRA, PHE and

JCVI advice. Potential oral intake of vaccine byproducts by babies and children is clearly a risk profile entirely different from potential blood borne exposure of a developing foetus. Thus, should studies in pregnancy conclude that pregnancy is a contraindication to vaccination, lactation should not be automatically considered to fall into the same category; and equally there is no logic to waiting for studies of pregnant women in order to make decisions on use in lactation.

We applaud the incredible achievement of vaccine scientists, manufacturers, regulators and government funding streams in getting to this point of mass vaccination in such a short time from the start of the Covid-19 pandemic. Now we need to ensure that the vaccines can be provided in an equitable way, actively seeking to reduce the discrimination and inequalities faced by women in the structure of the pharmacological and regulatory systems. We look forward to swift engagement from vaccine manufacturers, MHRA, PHE and the JCVI.

Hospital Infant Feeding Network

GP Infant Feeding Network

Breastfeeding for Doctors

References

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