


## COMMENTARY

# The COVID-19 vaccine in women: Decisions, data and gender gap

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## 1 | BACKGROUND

The year 2020 will be recorded in memory and world history as the year of the COVID-19 pandemic. On December 31, 2019, the Wuhan Municipal Health and Sanitation Commission (Hubei, China) alerted about some cases of pneumonia of unknown etiology in a wholesale market (World Health Organization, 2020a). On January 7, 2020, Chinese authorities identified a new virus of the Coronaviridae family as the causing agent: SARS-CoV-2. The disease caused was named COVID-19 (World Health Organization, 2020b). Pregnant women experience immunological and physiological changes that may make them more susceptible to COVID-19 and to develop obstetric complications with adverse perinatal outcomes (Kotlar et al., 2021).

The first case of the COVID-19 disease presented with fever, dry cough, dyspnea, and bilateral pulmonary infiltrates (World Health Organization, 2020a) with no apparent differences in clinical picture and evolution of the disease between pregnant women and the rest of the population (Kotlar et al., 2021). On the other hand, since the beginning of the pandemic, the initiation and maintenance of breastfeeding has been recommended by various organizations such as the World Health Organization (World Health Organization, 2020a) and the strong immunological response of the female body to COVID-19 has been subsequently demonstrated with the passing of antibodies against SARS-CoV-2 into breast milk (Fox et al., 2020).

SARS-CoV-2 has highlighted already existing gender inequalities, particularly in the field of care (Escuriet et al., 2020; O'Sullivan et al., 2009). Moreover, women represent 70% of health care workers worldwide and 80% of nurses in most regions (Boniol et al., 2019),

with this profession engaging in particularly close contact with sick patients. Considering these data, not contemplating data collection and research in pregnant and breastfeeding women appears to be a fundamental mistake. The World Health Organization has already warned that this important gender data gap in research in previous epidemics would be crucial in subsequent pandemics (World Health Organization & Regional Office for the Western Pacific, 2011). It is important to reflect that the systematic exclusion of pregnant and lactating women from research is probably derived from the abuses in research in the middle of the last century (Modi et al., 2021). But this approach must be adapted to the real emergencies of epidemic outbreaks where an imminent response is needed, that must be driven by innovative and updated approaches, as was the case with the Zika and Ebola virus (Krubiner et al., 2021). These new approaches should also contemplate the separation of research on pregnant or lactating women, and it should be noted that, if studies on pregnancy conclude that this circumstance is a contraindication for vaccination, lactation should not automatically be considered in the same category. Likewise, it is not logical to depend on studies of pregnant women to make decisions on its use in breastfeeding mothers (Hospital Infant Feeding Network, 2021).

On the other hand, in Spain we have two digital tools that seem to be key in supporting lactation among women: LactApp and e-lactancia. Since their creation, both digital tools have received thousands of visits and often medical and nursing professionals alike also make use of these tools (Padró-Arocas et al., 2021; Paricio-Talayero et al., 2020). The teams of lactation professionals at LactApp and e-lactancia have developed information on COVID-19, its vaccination, and its possible compatibility with

breastfeeding in their respective websites and apps, that aim to empower women through scientific evidence in their decision-making process regarding breastfeeding by offering them reliable and updated information.

## 2 | THE IMPORTANCE OF DATA: SUMMARY OF RESULTS

On the website e-lactancia.org, the section entitled “Maternal Coronavirus 2019-nCoV infection (COVID-19)” rated as “very low risk for breastfeeding” was first published on March 4, 2020, and since then, this information alone has received 165,255 visits. On the other hand, on December 20, 2020, the information titled “COVID-19 vaccine” rated as “low risk for breastfeeding” was published and has received a total of 125,791 visits as of January 22, 2021, being the most visited item in the last month out of 30,228 search items available on e-lactancia. Looking at all visits over the last year, among the most accessed articles are “Maternal Coronavirus 2019-nCoV infection (COVID-19)” in seventh place and “COVID-19 vaccine” in fourteenth place.

On the other hand, LactApp has published on December 20, 2020, a blog post entitled “Covid-19 vaccine and breastfeeding.” Since the date of publication and as of January 22, 2020, this post has received a total of 12,886 visits, which is 20% (12,886/64,423) of the total visits to the LactApp blog. LactApp also created a special in-app decision tree on the topic of coronavirus and published a “COVID-19 Vaccine” section as of December 20, receiving 11,772 visits out of a total of 560,255 queries, so 2.1% of LactApp traffic has been directed to this section. Finally, the LactApp in-app chat has received a total of 401 queries related to the COVID-19 vaccine in the same period, accounting for 1.22% of total queries handled through the LactApp chat (401/31,781).

## 3 | THE NEED FOR INFORMATION AND EMPOWERMENT TO MAKE DECISIONS: CONCLUSIONS

It appears that the constant visits and the exponential increase in visits to both e-lactancia and LactApp speak by themselves for a need of reliable and validated information on the compatibility of lactation and the COVID-19 vaccine.

The evolution of the pandemic, the monitoring of cases in almost real time worldwide, and the development of a vaccine against a microbiological agent that has damaged our lives in just a few months have been a true revolution. To carry out the development of this vaccine, enormous efforts have been made to ensure its approval and distribution. The vaccination strategy has been organized on an individual level for each country, starting with the most important general criteria for the most vulnerable population or most exposed to COVID-19, such as health care workers (Modi et al., 2021). Among these health care workers, the majority are female

nurses of reproductive age (World Health Organization & Regional Office for the Western Pacific, 2011).

Despite multiple petitions calling for changes, reformation of legal frameworks and action on the inclusion of pregnant and lactating women in COVID-19 trials and vaccine development (Heath et al., 2020; Whitehead & Walker, 2020), these requests seem to have been overlooked. Women, once again, are in second place of attention in terms of policy and research. Thus, the overprotection of women and the seemingly prevailing paternalism, especially for pregnant and lactating women, potentially undermine their sexual and reproductive health, by acting in a harmful way to such important health areas as lactation (Kuehn, 2021). This position has resulted in the decision-making process about the COVID-19 vaccination in lactating women falling solely on women themselves or on their health care providers, with a total lack of information to help them shape an informed decision or, on the contrary, the imposition of a paternalistic decision without the participation of women themselves, in which they have to choose between protection against COVID-19 or the maintenance of their breastfeeding journey. This decision goes beyond just health consequences, because economic and family implications are also present, given that in some cases there is no paid parental leave to reconcile work and family life, so mothers are not able to protect themselves against a disease (Modi et al., 2021). Furthermore, the exclusion of pregnant and lactating women from COVID-19 vaccination programs in high-income countries is likely to have a much greater effect in low-income and lower- to middle-income countries, because it is very unlikely that governmental organizations will take on a different view there (Modi et al., 2021). On the other hand, it needs to be highlighted that pregnant and lactating women also seem to be interested in participating in clinical studies that require non-invasive collection of biological samples, such as breast milk, especially with the aim of maintaining breastfeeding, as this is seen as a scientific contribution to obtain valid information and ultimately provides help to other women (Lemas et al., 2021).

In view of the above, we strongly agree with other (female) authors that, from now on, pregnant and breastfeeding women should be considered in phase III trials (Modi et al., 2021; Stuebe, 2021). Changes are often brought about at the request of independent bodies, but it must be the institutions themselves and those responsible within them, who implement important changes in legislation and regulation so that those changes and the implementation of new responsibilities can become a reality (Escuret et al., 2020).

As of the time of writing, there are no published data on excretion into breast milk or the effects on lactation or breastfeeding infants of the COVID-19 vaccine. Although the biology is reassuring, we will have to wait for definitive scientific information in form of data and results once the vaccine is used in lactating women. In the 21st century and with the exponential scientific progress that COVID-19 has brought, it is unthinkable that independent researchers, private companies, and interested individuals must fill or attempt to fill the gaps that politics, bureaucracy, legislation, and big pharma companies leave by not completing this research. It is necessary to highlight again that women also have the right to be

protected (from a non-obvious practice) "through research," as opposed to being protected from (the risks) "of research" (Modi et al., 2021; Stuebe, 2021).

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## CONFLICT OF INTEREST

None.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author, DMT, upon reasonable request.

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