



COVID-19 Vaccine Study Highlights Importance of Sex and Gender Inclusivity in Medical Research

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Abstract: We need to develop a human rights-based approach to the design and conduct of science. As part of this, it is vital to include a sex/gender perspective in clinical trials and scientific studies, including in the development of new vaccines

A small Spanish survey on possible effects of the COVID-19 vaccine on menstruation has spurred further research on the topic while emphasising the need to pay more attention to gender in medical research and clinical trials for new drugs.

[Midwife Laura Cámara](#) and her colleagues at University Hospital Virgen de las Nieves in Granada noticed that many women experienced changes in their menstrual cycles after receiving COVID-19 vaccines. She conducted an [online survey](#), which attracted more than 6,000 respondents (July 2021), on the impact (if any) of these vaccines on menstruation. Around 55 per cent of respondents, who had received Moderna, Pfizer or AstraZeneca vaccines, had noticed variations in the length of the menstrual cycle; duration, volume or absence of periods; and/or different levels of discomfort or pain than before. Most of these alterations seem to have been temporary and without

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serious consequences so far. However, some women were worried at the lack of explanation. Many of the survey respondents [reported](#) these menstrual changes to health professionals just after either the vaccination, or when they received their second dose. However, such side effects were not noted: [health authorities](#) do not consider them side effects of the vaccine. The aim of the survey was to gather women's testimonies and based on this preliminary assessment, the University of Granada in Spain is now undertaking a scientific study: the [EVA Project](#). Researchers are collecting and analysing data from vaccinated women aged 18-50 to categorise potential side effects of COVID-19 vaccines on the menstrual cycle. The intention is not to scare women: these side effects have appeared to be temporary and without any further consequences on women's fertility. However, researchers want to ensure that menstrual variations can be registered as side effects of the vaccines, similar to fever, sore arms, tiredness or headaches.

Concerns about potential impact of COVID-19 vaccination on menstrual cycles have been echoed in other countries such as [India](#) and the [United Kingdom](#). Yet this has been largely dismissed, neglecting women's right and need to be informed and reassured if possible.

Lack of sex/gender perspective in clinical trials

The issue has triggered a debate on the need to include a better sex/gender perspective in medical research. A recent [Nature](#) article concluded that there was a lack of consideration of sex and gender in COVID-19 clinical studies. The article found that of 4,420 SARS-CoV-2/COVID-19 studies collected between January 2020-January 2021, 935 (21.2 per cent) addressed sex/gender solely in the context of recruitment, while just 237 (5.4 per cent) planned sex-matched or representative samples or emphasised sex/gender reporting. A mere 178 (4 per cent) explicitly reported a plan to include sex/gender as an analytical variable. Moreover, only 8 (17.8 per cent) of the 45 COVID-19 related clinical trials published in scientific journals up until mid-December 2020 reported sex-disaggregated results or subgroup analyses.

[Different genders respond differently to disease and drugs](#) and this also relates to biological differences in [immune response to foreign and self-antigens](#) including the [coronavirus](#). Thus, the lack of representation of women in clinical research on COVID-19 is part of a bigger concern: women, and the diagnostics and treatments that affect them, not only those related to their sexual and reproductive health, have [been traditionally overlooked](#). [Human rights scholars](#) have stressed that drug transparency and inclusion of women in research is ethically imperative.

A human rights perspective

So, as regards administration of the current COVID-19 vaccines but also in preparation for future pandemics, including vaccines for new viruses, can a human rights-based approach to the design and implementation of clinical trials help resolve the lack of sex/gender perspective? I argue that International human rights law principles can usefully inform such an approach. I shall briefly analyse some precepts in light of the following three instruments:

- The right to the highest attainable standard of health ('right to health') as found in the [UN Covenant on Economic, Social and Cultural Rights](#) (ICESCR) (Article 12) and further explained in [General Comment 14](#)
- The [Convention on the Elimination of All Forms of Discrimination against Women](#), specifically Article 12 and the further explanation in [General Recommendation 24](#)
- The right to enjoy the benefits of scientific progress and its applications ('right to science') as found in the ICESCR (Article 15) and further explained in [General Comment 25](#)

General Comment 14 on the right to health sets a general recommendation to include the gender perspective in health policies. States are encouraged to:

integrate a gender perspective in their health-related policies, planning, programmes and research in order to promote better health for both women and men. [Further] ... disaggregation of health and socio-economic data according to sex is essential for identifying and remedying inequalities in health.

The Committee on the Elimination of Discrimination against Women, the body that monitors implementation of the Convention on the Elimination of All Forms of Discrimination against Women, is even more emphatic in its General Recommendation 24 on women and health:

States should place a gender perspective at the centre of all policies and programmes affecting women's health and should involve women in the planning, implementation and monitoring of such policies and programmes and in the provision of health services to women.

During the pandemic, the Committee issued [a guidance note](#) highlighting the need for an institutional response for the dissemination of information and data collection. According to the guidelines, states 'should strengthen and co-ordinate national mechanisms to respond effectively to COVID-19'.

They should widely disseminate updated, scientifically accurate and transparent information on the gendered risks of the virus and measures for available health and support services for women and girls. The Committee also anticipates human rights preparedness for the post-COVID-19 recovery path, calling on states to 'collect accurate and comprehensive age and sex-disaggregated data on the gendered impact of the health pandemic to facilitate informed and evidence-based policy-making regarding women and girls'. Another interesting though less-invoked obligation concerns the right to science. According to the Article 15 of the ICESCR, everyone has the right to enjoy the benefits of scientific progress and its applications. The recent General Comment 25 on science and economic and social rights states that 'accessibility means that scientific progress and its applications should be accessible for all persons, without discrimination'. This includes that information concerning the risks and benefits of science and technology should be accessible without discrimination.

Moreover, General Comment 25 acknowledges that it is 'very common that such research and new technologies are gender-biased and insensitive to the particular needs of women'. It states that:

[A] gender-sensitive approach ... [should] be incorporated from the first stage, such as the choice of the subject and the design of methodologies and must be present throughout all steps of scientific research and its applications, including during the evaluation of its impacts. Decisions concerning funding or general policies must also be gender-sensitive.

Preparedness for future health crises

Taking all these precepts into account, how might a human rights preparedness approach that includes a sex/gender perspective on clinical studies and trials be implemented to deal with future health crises? Five essential points emerge:

- The sex/gender perspective must be included in health policies, scientific research and clinical studies aimed at the creation of future vaccines.
- This perspective must be incorporated right from the first stage in design and throughout implementation of scientific studies.
- Collecting disaggregated data on the gendered impact of pandemics is a useful tool to assist with taking account of sex/gender differences.
- Women should be involved in the planning and implementation of health policies, particularly those that affect women's health.

- States must provide updated, scientifically accurate and transparent information on gendered risks: women must be informed of the potential impact of vaccinations on their sexual and reproductive systems.

* This article uses the term 'women' to refer to people that menstruate, noting that not every person that menstruates may identify as a woman and that not all people that identify as women menstruate.