



Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.

The approvals of the first COVID-19 vaccines in the EU are a key milestone in the response to COVID-19. The first EU marketing authorisations for COVID-19 vaccines not only offer hope to control the pandemic but also provide proof of concept for a new approach to vaccine development in response to future emerging health threats.

MC is the Chair of the EMA's COVID-19 Task Force. HE is the Chair of the EMA's Committee for Medicinal Products for Human Use. SS is the Chair of the EMA's Pharmacovigilance Risk Assessment Committee. EC is Executive Director of the EMA. We declare no other competing interests. The views expressed in this Comment are the personal views of the authors and may not be understood or quoted as being made on behalf of or reflecting the position of the EMA or one of its committees or working parties.

*Marco Cavaleri, Harald Enzmann, Sabine Straus, Emer Cooke

marco.cavaleri@ema.europa.eu

European Medicines Agency, 1083 HS Amsterdam, Netherlands (MC, HE, SS, EM); Federal Institute for Drugs and Medical Devices, European Union and International Affairs, Bonn, Germany (HE); Medicines Evaluation Board, Utrecht, Netherlands (SS)

- 1 European Medicines Agency. Comirnaty assessment report. Dec 21, 2020. https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf (accessed Jan 8, 2021).
- 2 European Medicines Agency. Comirnaty EU product information. 2020. https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf (accessed Jan 8, 2021).
- 3 International Coalition of Medicines Regulatory Authorities. ICMRA statement on clinical trials. June 24, 2020. http://icmra.info/drupal/news/statement_on_clinical_trials (accessed Jan 8, 2021).
- 4 Polack FP, Thomas SJ, Kitchin N, et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. *N Engl J Med* 2020; **383**: 2603–15.
- 5 European Medicines Agency. Comirnaty risk management plan. Dec 21, 2020. https://www.ema.europa.eu/en/documents/rmp/comirnaty-epar-risk-management-plan_en.pdf (accessed Jan 8, 2021).
- 6 European Medicines Agency. EMA recommends COVID-19 vaccine Moderna for authorisation in the EU. Jan 6, 2021. <https://www.ema.europa.eu/en/news/ema-recommends-covid-19-vaccine-moderna-authorisation-eu> (accessed Jan 8, 2021).
- 7 European Medicines Agency. COVID-19 Moderna vaccine EU product Information 2021. https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-moderna-product-information_en.pdf (accessed Jan 8, 2021).
- 8 European Medicines Agency. Pharmacovigilance plan for COVID-19 vaccines. 2020. https://www.ema.europa.eu/en/documents/other/pharmacovigilance-plan-eu-regulatory-network-covid-19-vaccines_en.pdf (accessed Jan 8, 2021).
- 9 European Centre for Disease Prevention and Control. Threat assessment brief on SARS-CoV-2 variant in United Kingdom. Dec 20, 2020. <https://www.ecdc.europa.eu/en/publications-data/threat-assessment-brief-rapid-increase-sars-cov-2-variant-united-kingdom> (accessed Jan 8, 2021).
- 10 European Centre for Disease Prevention and Control. Risk related to spread of new SARS-CoV-2 variants of concern in the EU/EEA. Dec 29, 2020. <https://www.ecdc.europa.eu/sites/default/files/documents/COVID-19-risk-related-to-spread-of-new-SARS-CoV-2-variants-EU-EEA.pdf> (accessed Jan 8, 2021).
- 11 European Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council. https://ec.europa.eu/health/sites/health/files/eudralex/vol-1/reg_2006_507/reg_2006_507_en.pdf (accessed Jan 8, 2021).

COVID-19 vaccines and women's security

Pandemics such as COVID-19 are gendered with regard to who is infected, who dies, who provides care, who is secured against violence and economic change, and who leads and makes decisions.¹ Vaccines are no different and there is a need to address male bias in vaccine development to make women safe from deadly diseases.² For example, clinical trials that are not done in both men and women can raise adverse outcomes during implementation due to sex-based differences in immunological response.³ The excitement and awe at the speed of COVID-19 vaccine development and delivery needs to be attentive to the social and political dynamics in which the vaccine is delivered—women's work and their security are at the heart of this.

The delivery and facilitation of COVID-19 vaccines will disproportionately depend on the unpaid labour of women. Vaccine uptake partly depends on the free labour of women within the household, impacting women's economic and personal security. Unpaid labour will generally fall to women as parents or family carers; women will typically have the responsibility for arranging

when and how children and wider family members, such as older relatives, get immunised. This process is likely to be more onerous with vaccines requiring two doses, such as the Pfizer-BioNTech, Moderna, and Oxford–AstraZeneca options.^{4–6} This effort to practically access



Published Online
December 22, 2020
[https://doi.org/10.1016/S0140-6736\(20\)32727-6](https://doi.org/10.1016/S0140-6736(20)32727-6)



COVID-19 vaccines will add to the already exploitive care burden placed on women during the COVID-19 pandemic.⁷ Women in care roles may have to give up time otherwise spent on paid work or education, and incur out-of-pocket expenses related to travel and other costs of accessing vaccines for those they care for and themselves, which could require multiple different trips depending on national vaccination strategies.⁸ This is likely to be particularly true for women in precarious work and those who live in poverty or in rural areas.

The delivery and administration of COVID-19 vaccines also depends on the paid labour of women as the majority of health-care workers. Administering the doses and vaccine delivery could increase exposure to other harms and increased workloads.

Attacks on health-care workers and immunisation teams are a real concern in global health settings and have occurred during polio campaigns and Ebola vaccination efforts.⁹ Such violence is distinct in that it can take place in conflict and non-conflict settings and is linked to both suspicion of the motives and legitimacy of the vaccinators and the vaccine itself.¹⁰ Given that most health-care workers are women, such attacks could be seen as a form of violence against women. As has been seen during COVID-19 thus far, violence against health-care workers exists¹¹ and might be amplified over access to the finite resource of COVID-19 vaccines. Access to, and delivery of, COVID-19 vaccines is thus not only a security concern with regard to vaccine nationalism, cyber security, and as a protected commodity, but is also a concern for women, peace, and security agendas, given the feminised nature of the health-care workforce and vaccination teams responsible for vaccine delivery.

The feminised nature of violence surrounding vaccines extends to sexual violence and exploitation of women who access vaccines. During the Ebola vaccination programme that began in 2018 in Kivu, Democratic Republic of the Congo (DRC), some male health-care workers offered the Ebola-related services, including vaccination, in exchange for sexual favours from women and girls.¹² This contributed to a wider picture of sexual exploitation and violence within the DRC that mired the response to the outbreak of Ebola virus disease in 2018–20, including reports of alleged sexual abuse by aid workers¹³ and wider mistrust towards the global health and vaccine community.¹⁴ Although the DRC may be an extreme example as a state with a history of

sexual violence and protracted conflict,¹⁵ it showcases how gender-based violence is an important factor in responding to pandemics and in access to vaccines.

Debate over COVID-19 vaccines has rightfully focused on discovery and development, vaccine hesitancy, and equitable access. Vaccine delivery depends on the paid and unpaid labour of women around the world in ways that can threaten their economic and physical security. Vaccines are thus both an important component of the gendered nature of pandemics such as COVID-19 and of the relation between gender and global health security.

We declare no competing interests.

*Sophie Harman, Asha Herten-Crabb, Rosemary Morgan, Julia Smith, Clare Wenham
s.harman@qmul.ac.uk

School of Politics and International Relations, Queen Mary University of London, London E1 4NS, UK (SH); Department of International Relations (AH-C) and Department of Health Policy (CW), London School of Economics and Political Science, London, UK; Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA (RM); Faculty of Health Sciences, Simon Fraser University, Burnaby, BC, Canada (JS)

- 1 Azcona G, Bhatt A, Davies SE, Harman S, Smith J, Wenham C. Spotlight on gender, COVID-19 and the SDGs: will the pandemic derail hard-won progress on gender equality? New York: UN Women, 2020.
- 2 Criado Perez C. Invisible women: exposing data bias in a world designed for men. London: Random House, 2019.
- 3 Gibney E. The researcher fighting to embed analysis of sex and gender into science. *Nature* 2020; **588**: 209.
- 4 Polack FP, Thomas SJ, Kitchin N, et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. *N Engl J Med* 2020; published online Dec 10. <https://doi.org/10.1056/NEJMoa2034577>.
- 5 Jackson LA, Anderson EJ, Roupheal NG, et al. An mRNA vaccine against SARS-CoV-2—preliminary report. *N Engl J Med* 2020; **383**: 1920–31.
- 6 Knoll MD, Wonodi C. Oxford–AstraZeneca COVID-19 vaccine efficacy. *Lancet* 2020; published online Dec 8. [https://doi.org/10.1016/S0140-6736\(20\)32623-4](https://doi.org/10.1016/S0140-6736(20)32623-4).
- 7 Power K. The COVID-19 pandemic has increased the care burden of women and families. *Sustain Sci Pract Policy* 2020; **16**: 67–73.
- 8 Hilber AM, Bosch-Capblanch X, Schindler C, et al. Gender and immunisation: summary report for SAGE. Geneva: Gavi, the Vaccine Alliance, 2010. https://www.gavi.org/sites/default/files/document/2019/immunization_gender_report_without_graphics.pdf (accessed Dec 18, 2020).
- 9 Abimbola S, Malik AU, Mansoor GF. The final push for polio eradication: addressing the challenge of violence in Afghanistan, Pakistan, and Nigeria. *PLoS Med* 2013; **10**: e1001529.
- 10 Larson HJ. Stuck: How vaccine rumors start—and why they don't go away. New York, NY: Oxford University Press, 2020.
- 11 George AS, McConville FE, Vries S de, Nigenda G, Sarfraz S, Mclsaac M. Violence against female health workers is tip of iceberg of gender power imbalances. *BMJ* 2020; **371**: m3546.
- 12 Holt K, Ratcliffe R. Ebola vaccine offered in exchange for sex, Congo taskforce meeting told. *The Guardian*, Feb 12, 2019. <http://www.theguardian.com/global-development/2019/feb/12/ebola-vaccine-offered-in-exchange-for-sex-say-women-in-congo-drc> (accessed Dec 18, 2020).
- 13 The Guardian. More than 50 women in DRC allege abuse by Ebola aid workers. *The Guardian*, Sept 29, 2020. <http://www.theguardian.com/world/2020/sep/29/women-in-drc-say-aid-workers-sexually-abused-them-during-ebola-crisis> (accessed Dec 18, 2020).
- 14 Vinck P, Pham PN, Bindu KK, Bedford J, Nilles EJ. Institutional trust and misinformation in the response to the 2018–19 Ebola outbreak in North Kivu, DR Congo: a population-based survey. *Lancet Infect Dis* 2019; **19**: 529–36.
- 15 Autesserre S. The trouble with the Congo: local violence and the failure of international peacebuilding. Cambridge: Cambridge University Press, 2010.