

# The changing policies on COVID-19 vaccines and the need for local pharmacovigilance

## Políticas cambiantes sobre las vacunas contra el COVID-19 y la necesidad de vigilancia farmacológica local

Céleo Ramírez, Sandra Gómez-Ventura y Reyna M. Durón

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In recent months, vaccination policies against COVID-19 have evolved worldwide as pharmacovigilance provides new evidence on efficacy, and adverse events of all vaccines available. The first alerts that prompted changes in vaccination policies in several countries were related to rare severe thrombosis occurring mainly in women under 55 years old, happening several days after the first dose of the ChAdOx1 nCoV-19 (AZD1222, AstraZeneca) vaccine (1), and the single dose of Ad.26.COV2.S (Johnson & Johnson, J&J/Janssen) vaccine (2).

The European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) recommended to continue the use of these vaccines, considering that benefits outweighed the risks. However, some high-income countries mandated that the AZD1222 vaccine be given only to people over 60 years old, while other countries paused its use indefinitely. On the other hand, many governments of low-middle income countries continue using the AZD1222 vaccine in people under 60 years of age, as they vaccinate their population with the options they have available.

In the case of the BNT162b2 (BNT, Pfizer) and mRNA-1273 (Moderna) vaccines, there are some reports of rare cases of non-severe acute myocarditis and pericarditis in young people older than 16 years, especially men, and typically a few days after the second dose (3). The mechanism for this adverse event of these two mRNA vaccines is still under study, and it is unknown whether a second booster of these vaccines could lead to more cases of acute myocarditis in the susceptible population. The recommendation to actively monitor and study the aforementioned adverse events to determine a cause-effect relation, seems to be under looked in many low-middle income countries where pharmacovigilance or post marketing studies are not being conducted.

Another issue forcing policy changes is the vaccine delay in production and delivery. Recently, there was a warning about the insufficient production of the Gam-COVID-Vac (Sputnik v) second dose, leaving several million people awaiting indefinitely to complete the immunization schedule. A few preliminary studies about mixing and matching vaccines in case of shortage, are being used to justify the administration of a different vaccine for second dose. This has raised debates about which vaccines could be used to complete immunization in these cases. However, despite the race against time to end the pandemic, it is imperative to carry out more clinical trials and pharmacological surveillance to evaluate the effectiveness of those combinations before they become part of emergency public health policies.

Post-vaccination pharmacovigilance should be systematic worldwide, and should run parallel to genomic surveillance of SARS-CoV-2 and its variants. This will allow to revisit the effectiveness and the safety profile of COVID-19 vaccines, and to provide evidence-based vaccination policies ♦

CR: MD. Ophthalmologist. Hospital del Valle. San Pedro Sula, Honduras. Consorcio de Investigadores COVID-19. Honduras, Honduras. [celeoramirez@yahoo.com](mailto:celeoramirez@yahoo.com)  
SG: DDS. M. Sc. Public Health. Ph. D. Public Health. Consorcio de Investigadores COVID-19. Honduras, Honduras. [drsgomezv@hotmail.com](mailto:drsgomezv@hotmail.com)  
RD: MD. Neurologist. Facultad de Ciencias de la Salud, Universidad Tecnológica Centroamericana. UNITEC, Tegucigalpa, Honduras. Consorcio de Investigadores COVID-19. Honduras, Honduras. [reyna.duron@unitec.edu.hn](mailto:reyna.duron@unitec.edu.hn)

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