LETTER TO THE EDITOR

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A Call to Enhance Active and Transparent Pharmacovigilance for COVID-19 Vaccines

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Dear Editor,

We read with interest the paper by Chirico and Teixeira da Silva calling for transparent data sharing between scientists, governments, and policymakers.[1] The authors also indicated the importance of strengthening vaccine safety monitoring systems with effective evidence-based communication to reduce the risk of vaccine hesitancy. We wish to reiterate this with a call to enhance active and transparent pharmacovigilance for COVID-19 vaccines.

As of 7 October 2022, 47 COVID-19 vaccine candidates had been approved globally for emergency use and 89 were in phase three clinical trials.[1] Eswatini approved the Oxford/AstraZeneca, Johnson and Johnson, Pfizer/BioNTech, and Moderna vaccines and received its first COVID vaccines in March 2021 with additional doses in July 2021. Vaccine coverage quickly climbed to over 20% of the eligible population within a month of receiving sufficient consignments of the vaccine. However, medical mistrust and anecdotal reports of deaths following COVID-19 vaccination became a major contributor to the stalling of what started off as one of the most successful COVID-19 vaccination rollouts in Africa. Lack of transparency and perceptions that healthcare professionals and policymakers were withholding COVID-19 vaccine safety information eroded public trust, perpetuated misconceptions around the vaccine, and exacerbated vaccine hesitancy.[2]

Medical mistrust is the mistrust of healthcare providers, the healthcare system, medical treatments, and the government as a steward of public health. The COVID-19 vaccine mistrust in Eswatini stemmed from the perception that healthcare professionals concealed adverse events following immunization and the population was used to test poor-quality vaccines.[3] Active pharmacovigilance is a prerequisite to a robust vaccination program, as timely, accurate, and verifiable COVID-19 vaccine safety data can improve vaccine confidence and serve as a source of data for evidence-based decision-making for healthcare professionals and policymakers. Active pharmacovigilance refers to intentional and systematic monitoring, and detection, assessment, and mitigation of adverse effects related to pharmaceutical products.[4] However, COVID-19 vaccine pharmacovigilance was complicated by the existence of multiple approved vaccine candidates, emerging guidance on the interchangeability of vaccine candidates, dose interval adjustments and flexibilities, and existing comorbidities and their interaction with SARS-CoV-2.[4] These factors added a layer of complexity to causality assessment and risk-benefit assessment of COVID-19 safety signals.

The large-scale rollout of vaccines with emergency authorization increased the burden on healthcare professionals to place patient safety monitoring as a top management priority with a need for active rather than passive pharmacovigilance for COVID-19 vaccine safety signal detection. Vaccination and risk-mitigation measures remains as medical cornerstones to reduce COVID-19-related deaths, stem community transmission, and end the COVID-19 pandemic.[5] The medical principle of 'first do no harm' means that healthcare professionals have a responsibility to monitor, manage, and report adverse events following immunization. Pharmacovigilance data should be shared responsibly with the public as consumers of health services and with policymakers,

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so that evidence-based patient safety data is used to inform public health policy.

REFERENCES

1. Chirico F, Teixeira da Silva JA. COVID-19 health policies: the need for transparent data sharing between scientists, governments and policymakers. Oman Med J 2022 Sep;37(5):e418.
2. VIPER Group COVID-19 Vaccine Tracker Team. COVID-19 Vaccine Tracker. Vaccines candidates in clinical trials. [cited 2022 October 10]. Available from: https://covid19.trackvaccines.org/vaccines/.
3. Ginindza S, Nabukera S. Community engagement as key to COVID-19 vaccine uptake: lessons from Eswatini. May 2022 [cited 2022 October 10]. Available from: https://www.pactworld.org/blog/community-engagement-key-covid-19-vaccine-uptake-lessons-eswatini.
4. Teo SP. COVID-19 vaccine safety surveillance and emerging concerns of vaccine-induced immune thrombotic thrombocytopenia. J Geriatr Cardiol 2021 Nov;18(11):952-956.
5. Naniche D, Hotez P, Bottazzi ME, Ergonul O, Figueroa JP, Gilbert S, et al. Beyond the jab: a need for global coordination of pharmacovigilance for COVID-19 vaccine deployment. EClinicalMedicine 2021 Jun;36:100925.