SARS-CoV-2 vaccine-related adverse events in Zimbabwe: The need to strengthen pharmacovigilance in resource-limited settings

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The emergency use approvals (EUAs) of vaccines for the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by the World Health Organisation (WHO) starting in December 2020 was a welcome event.[1] Since their discovery, vaccines have become one of the best public health interventions to reduce the spread, morbidity and mortality associated with rapidly progressive infectious diseases. Unlike previous vaccines, SARS-CoV-2 vaccines were quickly developed and authorised when their safety and effectiveness data were not widely publicly available.[2] Understandably, given the unprecedented socio-economic burden, the COVID-19 pandemic presented,[3] expedited solutions for control, including vaccination, were warranted. Whilst part of the Janssen vaccine clinical trials were conducted in South Africa, safety and effectiveness studies for the majority of the vaccines were conducted outside the Sub-Saharan Africa region. Therefore, safety data specific for this population group were lacking.

Zimbabwe approved the Sinopharm and Sinovac vaccines in February 2021, and subsequently, the Covaxin, Sputnik V and the Janssen vaccines. The first four have been in use in the country. The Janssen vaccines are not yet available. The Sputnik V vaccines are still to be approved by the WHO. The Medicines Control Authority of Zimbabwe (MCAZ), in line with its mandate prescribed by the law, approved the first four before they had EUAs from the WHO and before there were any publicly available safety data. This resulted in scepticism and safety concerns in the general population, which may have contributed to vaccine hesitancy. As of 1 October 2021, Zimbabwe had administered ~6 million COVID-19 vaccines, the majority of which are Sinopharm and Sinovac vaccines. In this opinion piece, we highlight the need to maintain robust processes for pharmacovigilance by the MCAZ to identify and monitor potential SARS-CoV-2 vaccine-related adverse events (AEs).

Anecdotal evidence exists of AEs such as headaches, skin reactions and flu-like illnesses, with even deaths having been attributed to vaccination without adequate evidence-based. For example, early in the vaccination programme in Zimbabwe, there were widespread rumours and vaccine hesitancy after a healthcare worker had reportedly died after being vaccinated.[4]

Other widely circulated myths relate SARS-CoV-2 vaccines to reproductive and menstrual cycle disturbances, which have raised concerns and propagated hesitancy among women of reproductive age.[5] Reports of miscarriage, erectile dysfunction and other undesirable AEs following vaccination have emerged.[6] These are just some examples of unsubstantiated AEs that have been circulated widely for which neither evidence of causation or association is present or has been noted in any clinical settings. Though widely circulated on social media even beyond Zimbabwe, no convincing clinical evidence to substantiate the claims exists to date. If not addressed adequately, misinformation propagates widespread vaccine hesitancy, making it difficult for the country to reach its 60% vaccination target by December 2021, and the herd immunity threshold challenging to attain. The significant problems currently include lack of safety and effectiveness data of the currently available vaccines in Zimbabwe for the local population and lack thereof in comparable settings. This is compounded by a lack of clear and effective communication strategies by the relevant COVID-19 control pillars in the Ministry of Health and Child Care (MoHCC). The space is overtaken by social media, which now exists in several forms. It is easily accessible to the broader population, providing fertile ground for circulating unsubstantiated rumours, myths, falsehoods and misconceptions, blowing events out of proportion and propagating widespread vaccine hesitancy.

Zimbabwe has an established system of pharmacovigilance through the MCAZ. Unfortunately, because the pharmacovigilance system is unknown to many, the tendency to run to social media for quick answers is increasing. At this point, the critical public question is the strength of this system in its current form to monitor the safety of the SARS-CoV-2 vaccines precisely. Given that none of the clinical trials of the vaccines currently being used in Zimbabwe was conducted in this population or Sub-Saharan African countries, it is important that the relevant authorities set-up a prospective drug safety follow up programme in the country to reassure the population that their safety concerns are carefully monitored. Strengthening the system and implementing a solid evaluation system to provide strategic information regarding the effect of SARS-CoV-2 vaccines is as critical as availing the vaccines to the population. Taking advantage of existing platforms of the Zimbabwe Expanded Programme of Immunisation, which has been in existence since 1982, could provide an essential baseline for the country.[7]

As part of the solutions, more sophisticated reporting and capturing systems for AEs are urgently needed. Similar to reporting procedures for suspected SARS-CoV-2 infection, which included 24 h toll-free numbers and emergency call centres, and electronic data capturing and transmission systems for timely reporting, having specific ways of following up vaccines' AEs is essential. All service providers involved in vaccination and healthcare must be adequately made aware of these systems to work closely with the MCAZ and other relevant stakeholders to make such a system functional, effective, efficient, and informative. The public must be made aware of the existence of this system so that they can also fully utilise it, by making enquiries for any concerns for suspected vaccine-related AEs. The MoHCC and MCAZ need to implement precise mechanisms for reporting these suspected AEs and circulate them widely sufficiently to allow greater population reach. Additionally, the risk communication and community engagement (RCCE) pillar, which is responsible for disseminating health promotion and protection messages in Zimbabwe must becoming actively involved in engaging the community regarding AEs related to SARS-CoV-2 vaccination, allaying the population's anxiety, identifying key barriers of vaccine uptake and propagators of vaccine hesitancy. As the vaccination programme is extended to special populations such as children and pregnant and breastfeeding women, the MCAZ must up its pharmacovigialce game, whilst the RCCE pillar and other relevant stakeholders strengthen

their messages to increase vaccine uptake momentum and propel the country towards its herd immunity threshold.

It has become apparent that the COVID-19 pandemic is likely to become protracted, and several SARS-CoV-2 variants of concern continue to emerge. As Zimbabwe and many other countries prepare for further inevitable waves of the COVID-19 pandemic, it is essential to promote vaccination and prevention and control strategies. Fighting vaccine hesitancy is indispensable and providing prospective vaccine recipients with reassurance and meaningful safety data.[8] Therefore, there is an urgent need to strengthen pharmacovigilance systems in the country and operational research to provide the much needed answers regarding vaccine-related AEs. To this end, the MCAZ and other relevant stakeholders involved in public health and pharmacovigilance must converge urgently to improve, optimise and strengthen the existing systems. There is an urgent need for the strengthening of phamarcovigilance in Zimbabwe, a limited resource country, to use tailored, robust reporting or other pharmacoepidemiological methods that systematically collect and analyse AEs associated with the use of COVID-19 vaccines, identify signals or emerging problems, and communicate how to minimise or prevent harm.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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