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HIV and COVID-19: juxtaposition of two pandemics

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For **COVID-19 prevalence and mortality** see https://www.worldometers.info/coronavirus/

The emergence of SARS-CoV-2 in 2019 has led to a juxtaposition of two pandemics: COVID-19 and HIV/AIDS. As of March 27, 2022, the world has reported more than 480 million confirmed cases of COVID-19 and more than 6 million deaths. HIV/AIDS continues to be a major global public health pandemic: more than 37 million people were living with HIV at the end of 2020, two-thirds of whom (an estimated 25 million) are in sub-Saharan Africa.[1] At the individual level, the COVID-19 pandemic has important implications for people living with HIV and has affected the delivery of HIV services.

In this issue of *The Lancet HIV*, two remarkable studies assess the effectiveness of COVID-19 vaccination in HIV-positive individuals. In one study, Lucas Netto and colleagues studied people living with HIV at the University of Sao Paulo, Brazil.[2] They compared CoronaVac immunogenicity responses in people living with HIV with CD4 counts less than 500 cells per µL with people living with HIV with CD4 counts of 500 cells per µL or more. Immunogenicity was reduced in those with CD4 counts less than 500 cells per µL, suggesting that these individuals could be at increased risk of an inadequate antibody response to vaccines. However, these results do not corroborate other findings from recent studies that found similar immunogenicity following other types of COVID-19 vaccines (eg, ChAdOx1 and BNT162b2) in people living with HIV compared to controls.[3] In a second study, Shabir Madhi and colleagues[4] studied NVX-CoV2373 vaccine immunogenicity in people with HIV compared with HIV-negative individuals and stratified by baseline SARS-CoV-2 serostatus. The safety of NVX-CoV2373 in people living with HIV was similar to that in those who were HIV-negative. However, people with HIV who were not previously exposed to SARS-CoV-2 had attenuated humoral immune responses to NVX-CoV2373 compared with their HIV-negative vaccine counterparts. It is unknown if the difference in the immunological responses observed in the study by Netto and colleagues and those by others using the ChAdOx1 and BNT162b2 vaccines were due to the type of the vaccines used. At any rate, both studies clearly suggest the need for strategies to improve vaccine immunogenicity in people living with HIV. The peculiarity in people living with HIV is the compromised immune system from chronic HIV infection and the use of antiretroviral therapy, which might increase the risk of SARS-CoV-2 infection and mortality from COVID-19. People with HIV with low CD4 counts and those not on antiretroviral therapy might have the greatest risk of developing severe symptoms of COVID-19 or not controlling SARS-CoV-2.

Vaccination of people living with HIV is essential as these individuals might not clear SARS-CoV-2 virus effectively, which could lead to the emergence of new variants.[5] In addition, unvaccinated people with HIV are four times more likely than HIV-negative people to experience symptoms of long COVID after acute COVID-19 illness. These symptoms are associated with higher levels of inflammatory markers.[6]

Two-thirds of people living with HIV are in Africa. However, only 15% of the 1·3 billion people living on the continent have been fully vaccinated. Vaccine inequity in low-income and middle-income countries (LMICs), especially where the burden of HIV/AIDS is high, will obviously lead to limited access to vaccines for people living with HIV. Because vaccines are steadily becoming available in LMICs, coordinated efforts and partnerships are needed to scale up vaccination and delivery in these countries. This is the only way that people living with HIV will be able to access COVID-19 vaccination.

The juxtaposition of the COVID-19 and HIV pandemics also has a tremendous impact on HIV service delivery. In South Africa, for instance, because of the COVID-19 pandemic and responses to it, there was a substantial decline in the number of people living with HIV starting treatment and an estimated 47% decrease in HIV testing in April, 2020.[7] Disruptions to HIV services could lead to worse outcomes for those with HIV and potentially increased HIV transmission. As such, addressing co-morbidities and ensuring a secure supply of antiretroviral therapy for people living with HIV during the COVID-19 pandemic is crucial. Delivery platforms for HIV services have been used to scale up COVID-19 vaccination in some African countries, such as Lesotho.[8] Such platforms could facilitate access to vaccination for people living with HIV. Longitudinal studies are also needed to gain further insights into responses to different COVID-19 vaccines in people living with HIV.

I declare no competing interests.

John Nkengasong
nkengasongj@africa-union.org

Africa Centres for Disease Control and Prevention, Addis Ababa W21K19, Ethiopia

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Moving forward with dolutegravir in children weighing less than 20 kg

See **Articles** pages e332 and e341

Dolutegravir was recommended as first line antiretroviral therapy (ART) across all ages by WHO in 2018. At that time, no dosing data was available for children living with HIV weighing less than 15 kg and appropriate formulations were not available in high burden settings.[1] There was also no evidence of superior outcomes in children living with HIV.[1] With approximately 800 000 children living with HIV not receiving ART and low viral suppression rates,[2] robust child friendly dolutegravir-based regimens will allow for once daily dosing, align with adult guidelines, and improve outcomes.[3]

We now use adult 50 mg film coated tablets in children weighing more than 20 kg.[1,4] For children weighing less than 20 kg, 5 mg and scored 10 mg dispersible tablets are approved by the United States Food and Drug Administration (FDA)[3] and European marketing approval was given to 5 mg dispersible tablets.[5] Licensing data comes from two studies, which used the same weight bands and doses, IMPAACT P1093 (P1093)[6] and the ODYSSEY trials.[7]

P1093, a phase 1–2 study, enrolled children from 4 weeks to 18 years in descending age and weight bands. In the *Lancet HIV*, Theodore D Ruel and colleagues report findings of the dosing, safety, and efficacy of 5 mg dispersible tablet dolutegravir in 73 children aged from 4 weeks to less than 6 years who received 5 mg dispersible tablet dolutegravir at the doses the study proposes.[6] During the study, the team pivoted from studying dolutegravir granules to 5 mg dispersible tablets in weight bands after stakeholders indicated that this was the preferred dosing strategy and formulation.[6] Remarkably, they recruited 25 children from 4 weeks to less than 6 months and 19 children from 6 months and older weighing from 3 kg to less than 10 kg, allowing for a robust assessment of exposures in a group of children in whom enzyme maturation might influence pharmacokinetics. The ODYSSEY study compared the efficacy and safety of dolutegravir with two nucleoside reverse transcriptase inhibitors to standard of care first and second line ART from 4 weeks to 18 years of age. The investigators nested pharmacokinetic studies of dolutegravir dosing in the larger study. Hylke Waalewijn and colleagues reported on 72 children weighing less than 20 kg, in *The Lancet HIV*.[7] They show data for children living with HIV from 3 kg to less than 20 kg exposed to dispersible tablets and for 24 children living with HIV weighing 14 kg to less than 20 kg who first received 25 mg film-coated tablets; the latter was abandoned after exposures were low. Pharmacokinetic profiles of 55 children including five children younger than 6 months were included.[7]

Proposed doses for children living with HIV who are older than 4 weeks but less than 6 months differs from the proposed doses for children living with HIV of similar weight but older than 6 months in P1093, however further analysis of pharmacokinetic profiles based on weight bands only showed acceptable