

COVID-19 Vaccines in Persons with HIV

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General considerations for this patient population

- Several studies have shown that HIV increases the risk for death and/or poorer outcomes from COVID-19.
- Other studies do not support this but conclude that persons with HIV face similar structural factors that increase risk in racial/ethnic minorities.
- The NIH has recommended that people with HIV should be considered a high-risk group when making decisions about COVID-19 vaccine priority.
 - <https://clinicalinfo.hiv.gov/en/guidelines/covid-19-and-persons-hiv-interim-guidance/interim-guidance-covid-19-and-persons-hiv>
- Persons with HIV should be offered COVID vaccination regardless of CD4 count or HIV viral load (**AIII** level recommendation).



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Potential Reasons Why PWH May Have Worse COVID-19 Outcomes

- **Immunodeficiency or immune dysregulation**

- Patients with immunodeficiency, such as organ transplant recipients, are at increased risk for severe COVID-19
- Prolonged SARS CoV-2 replication reported in immunocompromised hosts
- Suggests PWH with low CD4 cell counts may be at increased risk for severe COVID (as they are for influenza)
- Residual inflammation in PWH on ART
 - Most pronounced in PWH with low CD4 cell count nadirs, incomplete CD4 cell reconstitution, low CD4/CD8 ratio
 - Immune dysregulation “legacy effect”: impact on COVID-19 not certain

- **Comorbidities**

- PWH have high rates of comorbidities that are also risk factors for severe COVID-19

- **Social determinants of health**

- PWH more likely to be racial/ethnic minorities, poor – risk factors for worse COVID-19 outcomes



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Persons with HIV in COVID-19 vaccine phase 3 studies

- Pfizer enrolled 196 people with HIV, but they were not included in the published analysis or the data which has led to approval by regulators in the US and UK.
- Moderna enrolled 176 people with HIV. One person who received the placebo and none who received the vaccine developed COVID-19. No unusual safety concerns were reported in people with HIV.
- Oxford/AstraZeneca studies have recruited 160 people with HIV in the UK and South Africa, but they were not included in the main data set published in *The Lancet*.
- The Janssen (Johnson & Johnson) vaccine study recruited 1218 people with HIV or 2.8% of all participants. There were two cases of COVID-19 in people with HIV receiving the vaccine and four in people with HIV receiving the placebo.



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Reasons for PWH vaccine prioritization

- Low nadir CD4, detectable VL – compromised immune system
- Higher numbers of comorbidities compared to HIV-neg aged matched controls
- Aging and HIV
- Social determinants/inequalities – worse for PWH
- Housing instability – less able to quarantine



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What do the experts say?

- The British HIV Association (BHIVA) has concluded there is no reason to think the COVID vaccines will be less safe in persons with HIV and recommends they are given.
 - <https://www.bhiva.org/SARS-CoV-2-vaccine-advice-for-adults-living-with-HIV-plain-english-version>
- The CDC concluded that there is limited safety data but that persons with HIV may receive the vaccine
 - <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/underlying-conditions.html>



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CDC: Interim Clinical Considerations for COVID-19 Vaccines

“People with HIV or other immunocompromising conditions or people who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19 ... Currently authorized ... vaccines are not live vaccines and therefore can be safely administered to immunocompromised people.”

- PWH might be at increased risk for severe COVID-19
 - Persons with stable HIV included in vaccine trials, but data are limited
- Contraindications:** Severe allergic reaction (e.g., anaphylaxis) after previous dose or to component of COVID-19 vaccine; immediate allergic reaction of any severity to previous dose or known allergy to component of vaccine



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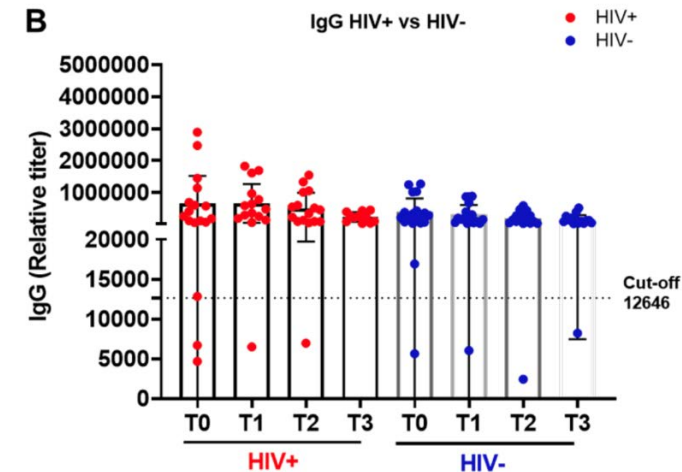
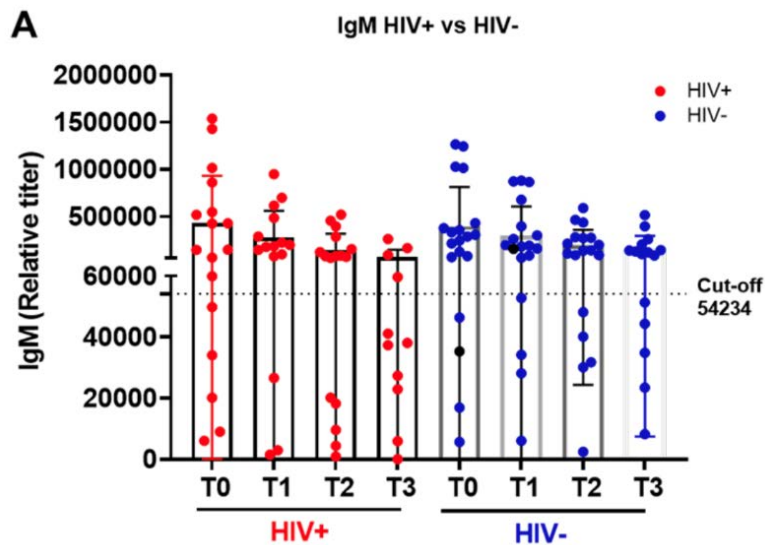


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Antibody Responses after COVID-19 in PWH

- Outpatients with mild to moderate COVID: 17 with HIV, 19 without HIV
 - PWH: median age 55, 24% females; people without HIV: median age 38, 58% females
 - All PWH were on ART, mean CD4 cell count 859
- No difference in IgM or IgG antibodies to spike RBD by HIV status over at least 3-4 mo.



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Special situations to consider with this population

- However it is possible that the level of protection after vaccination may not be the same in people with HIV as in people without HIV.
- We don't know if the response is different in people with low CD4 and/or uncontrolled HIV vs those with stable HIV (on ART and virally suppressed).
- We also don't know how long the protection will last.



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Addressing common patient questions



COVID-19 Vaccines and People with HIV
Frequently Asked Questions
Version: 3/16/21



Vacunas contra la COVID-19 y VIH
Preguntas frecuentes
Versión: 3/16/21

<https://www.hivma.org/globalassets/idsa/public-health/covid-19/covid-19-vaccines-hiv-faq.pdf>



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