REACTOGENICITY AMONG PEOPLE LIVING WITH HIV AFTER mRNA-1273 VACCINE IN UBUNTU STUDY

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BACKGROUND

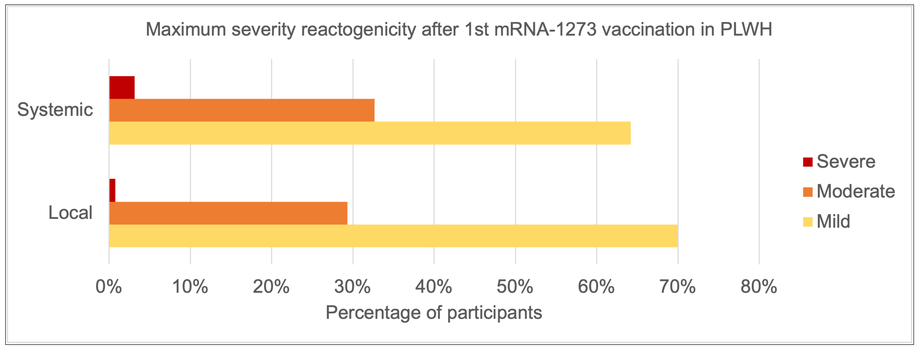
- The tolerability of mRNA COVID-19 vaccines among people living with HIV (PLWH) has been understudied in vaccine trials.
- CoVPN 3008 (Ubuntu), the largest multicenter Phase 3 efficacy trial of mRNA vaccines in sub-Saharan Africa, provided a unique opportunity for assessing reactogenicity in PLWH.

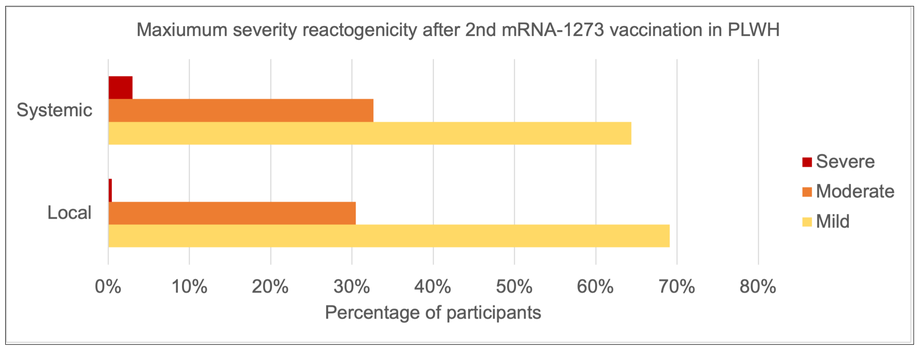
METHODS

- We enrolled adults age ≥18 years living with HIV or another comorbidity associated with severe COVID-19. Previously vaccinated individuals were excluded.
- Baseline testing: HIV, CD4 count and HIV viral load (VL) (if HIV+), anti-SARS-CoV-2 antibodies, and nasal swab SARS-CoV-2 nucleic acid amplification test (NAAT).
- All participants receive vaccinations at months 0 and 6, and SARS-CoV-2 seronegative individuals also received vaccination at month 1. This analysis includes mRNA-1273 vaccinations at months 0 and 1.
- Reactogenicity (solicited adverse events [AEs]) was assessed among a representative subset of participants (Safety Subset, SS) for 7 days post-vaccination.
- Baseline characteristics associated with moderate/severe reactogenicity events were assessed by univariate and multivariate logistic regression.

BASELINE CHARACTERISTICS	FULL STUDY POPULATION	SAFETY SUBSET POPULATION
	N = 14 002	N = 1 510
Female	10 114 (72%)	1 065 (71%)
Age (years)	median 38 (IQR 31 - 46)	median 38 (range 32 - 46)
BMI	median 24.6 (IQR 20.8 - 30.2)	median 25 (IQR 20.8 - 31.3)
History of tuberculosis	1 753 (16%)	197 (16%)
SARS-CoV-2 seropositive	11 026 (79%)	1 108 (73%)
Nasal swab SARS-CoV-2 PCR positive	742 (5.3%)	131 (8.7%)
HIV positive	11 681 (83%)	1 267 (84%)
CD4 T-cell count (cells/mL)	median 635 (IQR 424 - 866)	median 614 (IQR 414 - 861)
CD4 T-cell < 200	766 (6.9%)	91 (7.8%)
Detectable HIV VL (≥ 50 copies/mL)	2 164 (20%)	238 (21%)
HIV viral level (if detectable)	median 1 050 (IQR 120 - 15 815)	median 1 660 (IQR 182 - 23 932)

mRNA-1273 was well tolerated by people living with HIV. By far most reactions were mild. More moderate/severe reactogenicity was seen in females and those with CD4 counts >500 cell/μL. Severe reactions were rare, and there were no life-threatening or fatal reactions.





RESULTS

- 14 002 participants were enrolled in the trial (1 510 into SS) at 46 sites from 2 Dec 2021 to 9 Sep 2022.

- Overall, after 1st vaccination, 43% (540/1262) of PLWH had local and/or systemic reactions, the most severe of which were 62% (333/540) mild, 36% (192/540) moderate, and 3% (15/540) severe.
- Overall, after 2nd vaccination, 51% (278/542) of PLWH had local and/or systemic reactions, the most severe of which were 59% (165/278) mild, 38% (106/278) moderate, and 3% (7/278) severe.
- There were no life-threatening or fatal reactions.

- Female PLWH and CD4 count >500 cell/μL had 35% (p=0.03) and 44% (p=0.04) increased odds of moderate/severe reactogenicity, respectively.
- Other baseline characteristics were not associated with the odds of reporting moderate/severe reactogenicity among PLWH after 1st vaccination. Similar trends seen after 2nd vaccination, none statistically significant.

CONCLUSIONS

- Similar to observations in HIV-negative populations, mRNA-1273 was well tolerated by PLWH with more reactogenicity in females.

- Impaired T cell-mediated immune responses among participants with CD4 counts <500 cell/μL may explain less moderate/severe reactions.

ADDITIONAL INFORMATION

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Acknowledgements: The authors thank the participants and study staff of the Ubuntu trial team for their ongoing dedication and contributions to this study.