Is exclusion of tenofovir from antiretroviral regimens safe in Africa: insights on hepatitis B from the switch to DTG/3TC (Sungura) study

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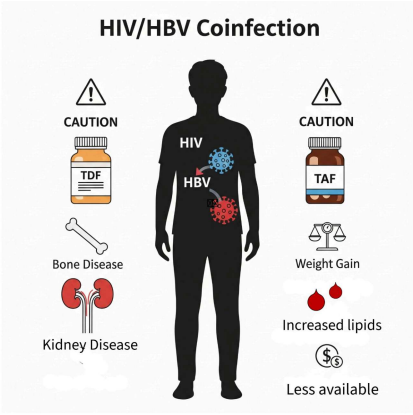
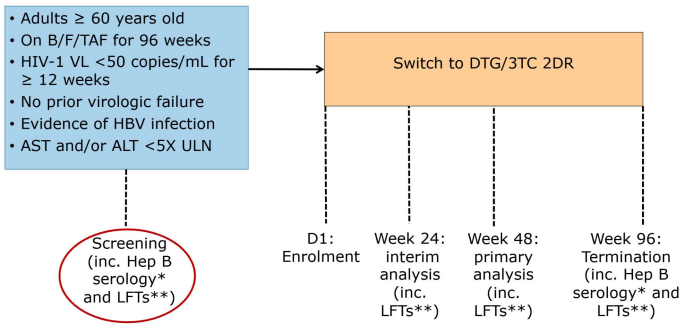
BACKGROUND

- Tenofovir, the WHO recommended nucleoside reverse transcriptase inhibitor in antiretroviral therapy, is useful for treatment of both HIV and HBV
- However, as comorbidities such as kidney and bone disease rise, particularly in older populations, dual drug therapies that exclude tenofovir are increasingly attractive
- It is unclear how best to deploy these regimens in contexts with high HBV prevalence and low uptake of HBV vaccination
- Reactivation of HBV remains a potential risk in those with previous exposure in whom tenofovir is withdrawn



METHODS

- The Sungura study (NCT06444620) is a phase 3 single arm clinical trial at multiple sites in Kenya enrolling participants
  - aged ≥60 years
  - VL <50 copies/mL
  - on bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF)

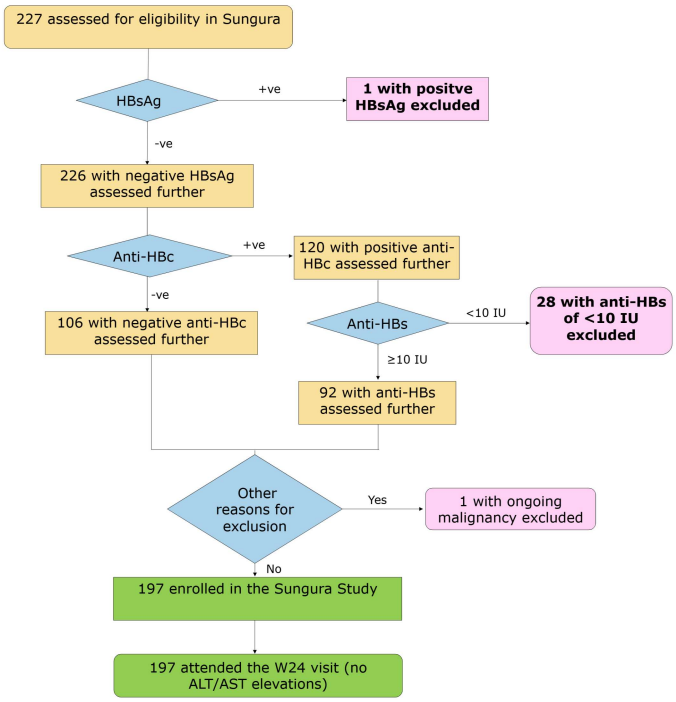


*Hep B serology: HBsAg, Anti-HBc, Anti-HBsAg
**LFTs: AST, ALT, GGT, ALP, Albumin, Total Protein, Total Bilirubin

- Participants with evidence of HBV infection during the screening visit were excluded; this was defined as:
  - Having a positive HBV surface antigen (HBsAg)
  - Having a negative HBV surface antigen (HBsAg) and:
    - ❖ a positive HBV core antibody (anti-HBc) and a negative HBV surface antibody (anti-HBs)
    - ❖ a positive HBV core antibody (anti-HBc) and HBV surface antibody (anti-HBs) of <10 IU
- All participants were switched to DTG/3TC at enrollment
- Liver chemistries were done at baseline and at week 24
- We evaluate the incidence of elevation of liver transaminases at 24 weeks post withdrawal of TAF
- The study is continuing to week 96

RESULTS

- Between July and September 2024, 227 participants on B/F/TAF were screened for enrolment into the study
- As shown in figure 3, 29 of the 30 participants who were excluded from the study lacked evidence of immunity to HBV:
  - 1 HBsAg positive
  - 28 with anti-HBs of <10 IU (18 with anti-HBs of <5 IU and 10 anti-HBs of between 5 and <10 IU)



- The median age was 66 years (range 62-81) and 49.2% were female.
- At week 24, no ALT or AST elevations were observed and there were no incident HBV infections
- Additionally, high rates of HIV-1 suppression were observed

CONCLUSION

- Prior hepatitis B exposure is common in older PWH, majority of whom have immunity and can be safely transitioned to a two-drug regimen that excludes tenofovir
- However, HBV serology panels to identify people at risk of HBV reactivation are not routinely available across much of sub-Saharan Africa, and further work is needed to evaluate the necessity of such screening

ACKNOWLEDGEMENT

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