Impact of HIV Pre-Exposure Prophylaxis (PrEP) on HIV incidence and hepatitis B outcomes among female sex workers living with hepatitis B: a modeling analysis in Côte d'Ivoire

595

Amir M. Mohareb,[1] Arthur Y. Kim,[1] Menan Gérard Kouamé,[2] Marcellin Nouaman,[2] Patrick Coffie,[2] Maya Hajny Fernandez,[1] Virginia Talbot,[1] Ruitian Hu,[1] Anne Neilan,[1] Anders Boyd,[3] Kenneth Freedberg,[1] Joseph Larmarange,[4] Emily Hyle [1]
[1]Massachusetts General Hospital, Boston, MA, USA [2]Programme PAC-CI, Abidjan, Côte d'Ivoire [3]University of Bern, Bern, Switzerland [4]Ceped, Université Paris Cité, Université Sorbonne Paris Nord, IRD, Inserm, Paris, France

Funding: NIAID (K01AI166126 to AMM; R37AI058736 to KAF), Harvard University Center for AIDS Research (P30AI060354), NICHD (R01HD111355 to AMN), Jerome and Celia Reich Scholar in HIV/AIDS Research at MGH (EPH). The PRINCESSE project was funded by the ANRS|MIE (12381).

BACKGROUND

- Between 5-10% of the 2.5 million sex workers in sub-Saharan Africa live with chronic hepatitis B virus (HBV).
- There are potential tradeoffs to using HIV pre-exposure prophylaxis with tenofovir/emtricitabine (TDF/FTC) in people with chronic HBV because cessation of TDF/FTC increases the risk of hepatitis flares (ALT > 2 x ULN) but can also produce HBV cure (HBsAg loss).
- TDF/FTC as PrEP has not been systematically studied in sex workers with HBV.

OBJECTIVES

- To simulate HIV and HBV outcomes of TDF/FTC as PrEP in female sex workers with chronic HBV in Côte d'Ivoire.

METHODS

- We used CEPAC, a validated computer simulation model of HIV and HBV disease to compare PrEP strategies:

(1) No TDF/FTC

(2) TDF/FTC as PrEP, with routine disengagement from care

(3) TDF/FTC as PrEP, with 100% engagement in care (i.e., no loss to follow-up from PrEP care)

Population

- Female sex workers with chronic HBV in Côte d'Ivoire eligible for TDF/FTC as PrEP, the population enrolled in the PRINCESSE (ANRS 12381) open-label trial.

Key Inputs

- HIV incidence: 0.8 – 3.0 per 100 person-years[1]
- PrEP adherence: 55%[2]; PrEP efficacy: 95%
- Disengagement from PrEP care: 4% per month (within 12mo), 13% per month (>12mo).[3]
- Return to PrEP care: 1% (within 6mo), 3% (6-12mo), 6% (>12mo).[4]
- Hepatitis flare incidence: 2.0-4.0 per 100 person-years, increasing following TDF/ FTC cessation[5]
- HBsAg loss incidence rate: 1.0 per 100 person-years, increasing following TDF/FTC cessation[5]

References for Input Parameters

1. Nouaman, et al., PLoS One 2022; Jones, et al., Lancet Glob Health 2024.
2. O Murchu, et al., BMJ Open 2022
3. Mpirirwe , et al., BMJ Open 2022
4. Derived from PRINCESSE and Shipp, et al., PLoS One, 2024.
5. Hall, et al., Gut 2022; Mohareb, et al., Lancet HIV 2022

TDF/FTC as PrEP would reduce HIV incidence and improve survival in female sex workers with hepatitis B, despite the short-term risk of hepatitis flares after PrEP cessation.

METHODS (continued)

Model Outcomes

- Cumulative HIV incidence
- Hepatitis flares per person
- Cumulative HBsAg loss ("functional cure")
- Survival

Sensitivity Analyses

- Incidence rates of HIV, hepatitis flares, mortality
- PrEP adherence, disengagement from care
- Probability of HBsAg loss after hepatitis flare
- Impact of TDF/FTC on HBV-related liver disease

RESULTS

Strategy/ Scenario	HIV Incidence (%)		Hepatitis Flares (per person)		HBsAg Loss (%)		Survival (%)		
	2-year	5-year	2-year	5-year	2-year	5-year	2-year	5-year	10-year
No TDF/FTC	5.7	12.7	0.08	0.19	2.3	5.7	96.2	89.4	72.6
TDF/FTC	4.1	10.1	0.28	0.76	2.9	8.4	96.2	89.4	73.8
TDF/FTC with 100% engagement in care	2.9	6.7	0.06	0.15	2.3	5.5	96.2	89.8	79.9

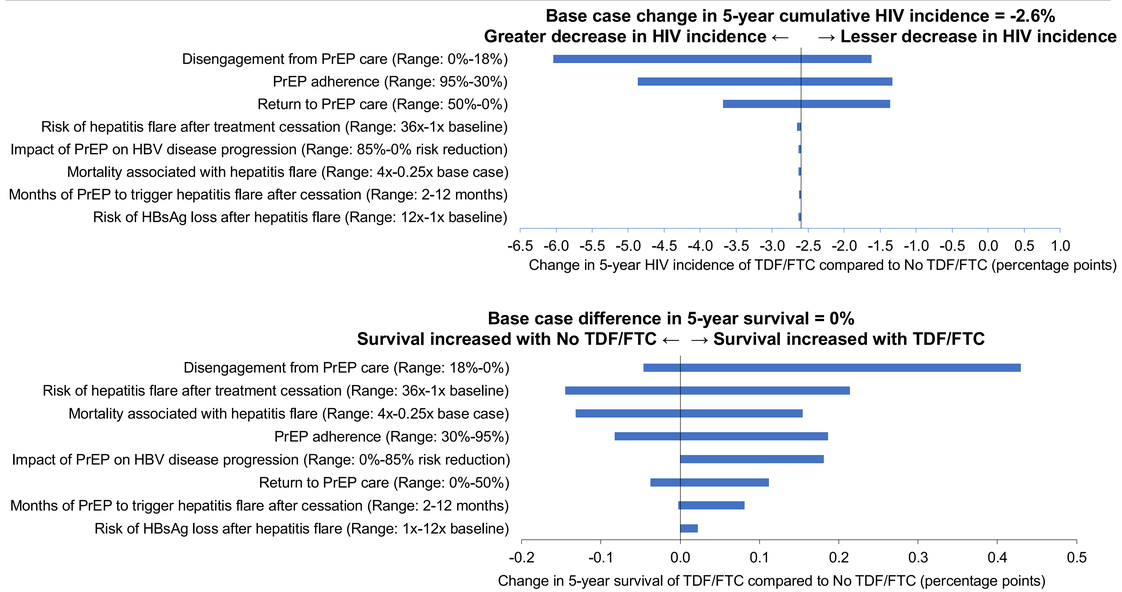


Figure 1. One-way sensitivity analyses of cumulative 5-year HIV incidence (top) and survival (bottom)

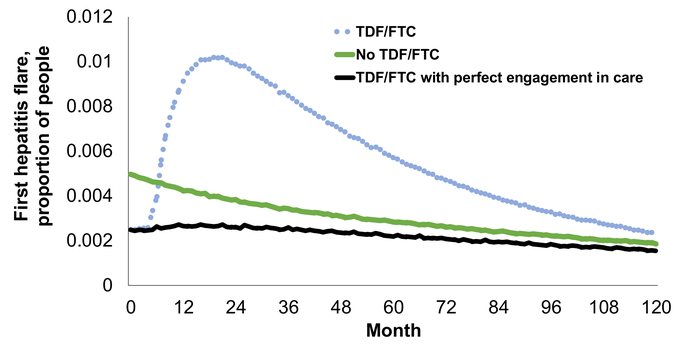


Figure 2: Simulated proportion with first hepatitis flare relative to PrEP start

	5-year Cirrhosis (%)	5-year HCC (%)
No TDF/FTC	0.28	0.04
TDF/FTC	0.23	0.04
TDF/FTC, 100% engagement	0.12	0.03

LIMITATIONS

- Uncertainty in model parameters related to HBV outcomes.
- Did not model benefits of preventing onward HIV transmission.

CONCLUSIONS

- TDF/FTC as PrEP would be effective in preventing HIV and improving survival in sex workers with chronic HBV.
- The risk of hepatitis flares after TDF/FTC cessation would be outweighed by the prevention benefits of PrEP.
- HBV-related benefits of TDF/FTC would be less apparent with short duration of PrEP use and low adherence.

Amir Mohareb, MD
Massachusetts General Hospital
amohareb@mgh.harvard.edu

PLAIN LANGUAGE SUMMARY

When PrEP is taken by mouth, it can prevent HIV and treat hepatitis B, a chronic infection of the liver. However, there is a risk of short-term liver disease after PrEP is stopped in people with hepatitis B. We used simulation modeling to show that this risk is small relative to the benefits of HIV prevention in sex workers in Côte d'Ivoire. Hepatitis B should not be a reason to avoid using PrEP.