

# A Phase IV Open-Label Evaluation of Safety and Tolerability of Coformulated Bictegravir/Emtricitabine/Tenofovir Alafenamide for Post-exposure Prophylaxis Following Potential Exposure to HIV-1

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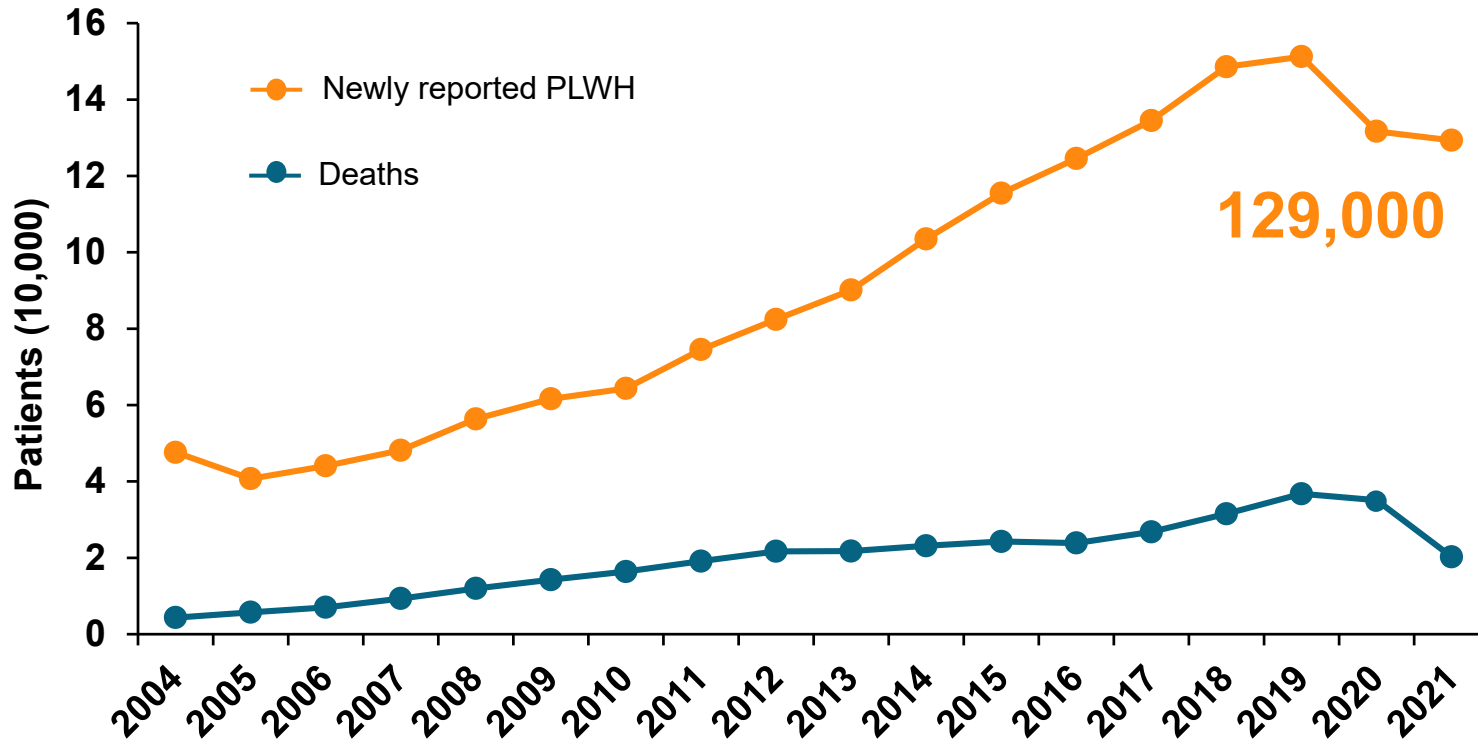
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# Background Prevalence of HIV in China

Annual report of people living with HIV and death in China



2021



**Homosexual transmission** is the main way in young students, accounting for 83.8%



**Heterosexual transmission** made up 94.3% in people older than 60 years

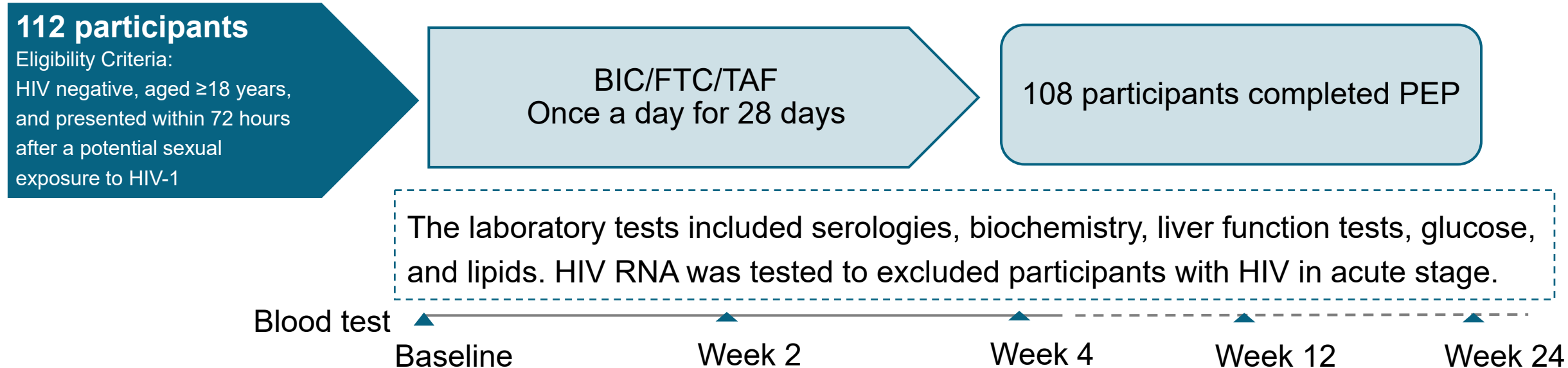
- In studies with people living with HIV (PLWH), BIC/FTC/TAF was effective, well-tolerated, and convenient, while there is only limited data on BIC/FTC/TAF for PEP, especially in China
- The latest Chinese Guideline for Diagnosis and Treatment of HIV/AIDS ( 2021 Edition) updated recommendation for PEP regimens, which include BIC/FTC/TAF
- Older PEP regimen may cause various side effects which may impact the completion of 28-day course, including cutaneous allergy, gastrointestinal disorders, and hepatorenal toxicity. Although these adverse effects are generally not severe, a meta-analysis demonstrates that only 56.6% of PEP users completed the full standard 28-day course of therapy

# Objective

- To evaluate the safety, tolerability, and adherence of BIC/FTC/TAF when used as a 28-day PEP regimen in China

# Study Design

A prospective, open-label, single-arm trial conducted in the STD/AIDS clinic of Beijing Youan Hospital, from May 2021 to February 2022



# Baseline Characteristics

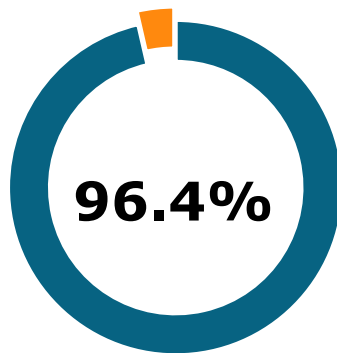
Demographic and Behavioral Risk Profile of Participants Who Used BIC/FTC/TAF for Postexposure Prophylaxis (N = 112)

<b>N=112</b>	<b>Mean ± SD</b>
<b>Age (years)</b>	30 (8)
<b>Male, n (%)</b>	109 (97.3)
<b>Type of exposure, n (%)</b>	
<b>Anal sex</b>	58 (51.8)
<b>Vaginal intercourse</b>	43 (38.4)
<b>Oral sex</b>	29 (25.9)
<b>Time from exposure (h)</b>	27.5 ± 18.8
<b>≤24 h, n (%)</b>	54 (48.2)
<b>24-48 h</b>	45 (40.2)
<b>48-72 h</b>	13 (11.6)

- No participant was found to acquire HIV through week 24

## PEP completion

(108/112)



- Two participants stopped PEP because the source partner was found to be HIV negative;
- One participant was excluded due to HBV positive;
- One discontinued due to participant's decision;

## Self-reported adherence to all expected doses

(n=108)

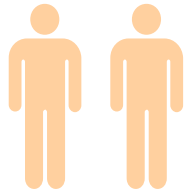
**98.9%**

## Pill count data adherence to all expected doses

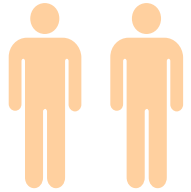
(n=95)

**98.5%**





**Mild headache**



**Mild diarrhea**



**Mild nausea**

Resolved spontaneously without stopping PEP



One serious adverse event not related to study drug: the participant died as a result of a traffic accident

# Conclusion

- Compared with previous reported data, the once-daily, single-tablet regimen of BIC/FTC/TAF used as PEP for 28 days was safe and well tolerated, with high levels of adherence and completion rates
- BIC/FTC/TAF may be a good option for PEP



**Thank You**

