# Safety and Tolerability of Once Daily BIC/FTC/TAF for Post-Exposure Prophylaxis

Kenneth H. Mayer[1,2], Jonathan Holmes[1], Marcy Gelman[1], Jessica Kraft[1], Kathy Melbourne[3], Matthew Mimiaga[1,4]

1. The Fenway Institute, Fenway Health, Boston, MA; 2. Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA; 3. Gilead Sciences, Foster City, CA; 4. Brown University School of Public Health, Providence, RI

Poster
P-S04,1996

## Background

- The use of antiretrovirals for post-exposure prophylaxis (PEP) is well-established, though completion rates with most regimens have been suboptimal because of pill burden or side effects.
- The purpose of the current study has been to evaluate the single tablet combination of Bictegravir (BIC), Emtricitabine (FTC), and Tenofovir Alafenamide (TAF) for PEP, administered orally as a single daily pill for 28 days after a high risk exposure.

## Methods

- The analyses assessed the clinical experience of participants enrolled in a prospective clinical trial of open label BIC/FTC/TAF who were recruited through referrals in a Boston community health center specializing in HIV care, as well as via self-referral after a community education campaign.
- Eligible participants needed to present for PEP within 72 hours of a high risk exposure (per CDC Guidelines) and be willing to consent to prospective monitoring over the subsequent 3 month period.
- SAS® 9.4 was used to analyze data, with statistical significance determined at the alpha 0.05 level. Chi square tests were conducted to assess if BIC/FTC/TAF differed with respect to side effects and completion rates compared to historical PEP regimens.

**Sociodemographic Profile of BIC/FTC/TAF Users (N=48)**

| | | |
|---|---|---|
| **Age** | Median 32 (range 22-71) | |
| **Race;/Ethnicity** | White | 79.2% |
| | Black/African American | 4.2% |
| | Mixed | 12.4% |
| | Asian/Pacific Islander | 4.2% |
| | LatinX | 8.3% |
| **Sexual Orientation/Gender Identity** | Gay/Cisgender (CG) Male | 75.0% |
| | Bisexual/CG Male | 12.5% |
| | Heterosexual/CG Male | 4.2% |
| | Heterosexual/CGFemale | 4.2% |
| | Queer/Transgender Male | 2.1% |
| | Don't Know/CG Male | 2.1% |
| **Educational Status** | Graduate School | 35.4% |
| | College Graduate | 35.4% |
| | Some College | 22.9% |
| | High School or Equivalent | 6.3% |

## Results

- Of 48 enrollees, the median age was 32 years (range: 22-71), with 79.2% being white, and 8.3% Latinx
- Most (87.5%) were cisgender gay or bisexual men.
- Most (70.8%) completed college +/- advanced degrees.
- Behaviors that led to PEP initiation included: receptive anal (49.7%), insertive anal (43.6%), receptive oral (15.4%), and insertive or receptive vaginal sex (7.7% for each).
- The most commonly reported adverse events by PEP patients using BIC/FTC/TAF were nausea +/- vomiting (15.0%), fatigue (6.0%), and diarrhea (6.0%).
- One participant noted mild gastrointestinal discomfort and another reported flatulence. All but one of the symptoms were grade 1, and only one symptom (grade 2 fatigue) was associated with product discontinuation.
- The only lab abnormalities were noted in 2 participants with elevated transaminases and 1 with decreased creatinine clearance. These changes did not lead to product discontinuation, reverting to normal after the regimen was completed.
- Of the fully evaluable participants, 85.4% completed the regimen as prescribed, and 10.4% stopped or modified the regimen; 2 did not return for follow-up.
- No HIV seroconversions have been detected in the study.
- Compared to historical PEP regimens, BIC/FTC/TAF was significantly less likely to cause product-related symptoms, notably less likely to be associated with diarrhea, fatigue, and headaches than the Quad Pill.

**Regimen completion rates among BIC/FTC/TAF users versus those using other PEP regimens, Fenway Health, Boston, 2000–2020.**

| | AZT/3TC/PI (N = 119) % | TDF/FTC+RAL (N = 100) % | EVG/c/FTC/TDF (N= 100) % | BIC/FTC/TAF (N = 48) % |
|---|---|---|---|---|
| **Completed as Prescribed** | 38.8 **** | 57.0*** | 71.0 ^ | 85.4 |
| **Stopped or Modified** | 14.0 | 28.0** | 15.0 | 10.4 |
| **Lost to Follow-Up** | 47.3**** | 15.0 (15)^ | 14.0 | 4.2 |

BIC/FTC/TAF = referent group
AZT/3TC/PI = Zidovudine/Lamivudine/Protease Inhibitor
TDF/FTC+RAL = Tenofovir disoproxil fumarate coformulated with emtricitabine plus raltegravir bid
EVG/c/FTC/TDF = tenofovir disoproxil fumarate, emtricitabine, elvitegravir, cobicistat coformulated

****p = 0.0001
***p = 0.001
**p = 0.01
*p = 0.02
^p = 0.05

**Most commonly reported adverse events among BIC/FTC/TAF PEP users versus those using other PEP regimens, Fenway Health, Boston, 2000–2020.**

| | AZT/3TC/PI (N = 119) % | TDF/FTC+RAL (N = 100) % | EVG/c/FTC/TDF (N= 100) % | BIC/FTC/TAF (N = 48) % |
|---|---|---|---|---|
| **Recruited** | Jan 2000 – May 2004 | Mar 2008 – Mar 2010 | May 2013 – Nov 2015 | May 2018 – Dec 2019 |
| **Diarrhea** | 58.8**** | 21.0 * | 38.0**** | 6.0 |
| **Fatigue** | 48.5**** | 14.0 | 28.0*** | 6.0 |
| **Nausea/vomiting** | 58.8**** | 27.0 | 28.0 | 15.0 |
| **Headache** | 11.8*** | 15.0**** | 14.0**** | 0.0 |
| **Dizziness/Lightheadedness** | 8.4** | 10.0 ** | 6.0* | 0.0 |
| **Body/Muscle/Joint Pain or Aches and/or Overall Discomfort** | 10.9 | 8.0 | 2.0 | 2.0 |

BIC/FTC/TAF = referent group
AZT/3TC/PI = Zidovudine/Lamivudine/Protease Inhibitor
TDF/FTC+RAL = Tenofovir disoproxil fumarate coformulated with emtricitabine plus raltegravir bid
EVG/c/FTC/TDF= tenofovir disoproxil fumarate, emtricitabine, elvitegravir, cobicistat coformulated

****p = 0.0001
***p = 0.001
**p = 0.01
*p = 0.02

## Conclusions

- This was the first evaluation of single tablet combination of BIC and TAF when used in combination with FTC for PEP.
- This regimen was safe and well-tolerated when used as PEP, with occasional mild gastrointestinal side effects and fatigue, and limited, reversible lab abnormalities.
- Daily BIC/FTC/TAF for PEP compares very favorably with historical regimens, including other integrase strand transfer inhibitors.
- The excellent safety profile and the high completion rates suggest that BIC/FTC/TAF should be considered for use as PEP.

## Acknowledgements

The study was made possible by an unrestricted research grant from Gilead Sciences. The assistance of Mary Childs in the preparation of this poster is greatly appreciated. The study team thanks the staff of Fenway Health for referrals and to the participants for their engagement in this study, particularly the study coordinators, Mo Drucker and Val Rugulo.