OPTIONS LAB
Collaboratory in HIV/STI treatment and prevention science

BIC/FTC/TAF as HIV PEP was well-tolerated with high adherence and no seroconversions

1134

UNITY HEALTH TORONTO

Darrell H. S. Tan[1,2,3], Reva Persaud[1], Attia Qamar[4], Isaac Bogoch[2,5], Arlene Chan[6], Allison Chris[7], Karla Fisher[5], Richard T. Lester[8], John Maxwell[9], James Murray[10], Hong Qian[11], Hubert Wong[11]

1. MAP Centre for Urban Health Solutions, St. Michael's Hospital, Toronto, Canada; 2. Division of Infectious Diseases, St. Michael's Hospital, Toronto, Canada; 3. Department of Medicine, University of Toronto, Toronto, Canada; 4. Scarborough Health Network, Toronto, Canada; 5. Division of Infectious Diseases, Toronto General Hospital; 6. Women's College Hospital, Toronto, Canada; 7. Toronto Public Health, Toronto, Canada; 8. University of British Columbia, Vancouver, Canada; 9. AIDS Committee of Toronto (ACT), Toronto, Canada; 10. AIDS Bureau, Ontario Ministry of Health and Long-Term Care, Toronto, Canada; 11. CIHR Canadian HIV Trials Network, Vancouver, Canada

BACKGROUND

- Integrase strand transfer inhibitors-based regimens have become standard of care for HIV post-exposure prophylaxis (PEP)
- No single tablet regimens recommended in current Canadian guidelines

OBJECTIVES

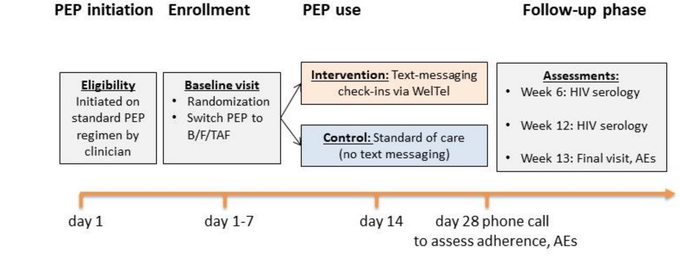
- Describe 1. tolerability and 2. adherence to bictegravir, emtricitabine and tenofovir alafenamide (BIC/FTC/TAF) as HIV PEP in an ongoing clinical trial of text message support vs standard of care

METHODS

- Design: Descriptive analysis of participants enrolled in an RCT of a text-messaging intervention (Weltel) for supporting PEP follow-up
- Eligibility:
  - HIV-negative adults aged ≥18 years
  - Initiated PEP within past 6 days for sexual exposure
  - Able/willing to receive texts via mobile phone
  - Able to communicate in English
- Recruitment (Figure 1):
  - Information cards given to patients receiving PEP in emergency departments
- Study procedures (Figure 2):
  - At enrollment, participants switched to BIC/FTC/TAF to complete 28 days
  - **Adherence** (#days of PEP taken) assessed via telephone call at week 4
  - **Adverse events** assessed at week 4 and week 13 follow-up visits
  - **HIV status** assessed at baseline, week 6, week 12
- Descriptive analysis of
  - Participant characteristics
  - Adverse events, Adherence, HIV seroconversions

Figure 1: Recruitment card

Figure 2: Study design



BIC/FTC/TAF was associated with high tolerability, high adherence and no HIV seroconversions, supporting use of this single tablet regimen as HIV PEP after sexual exposures.

RESULTS

- Of 120 enrolled participants, 1 was HIV seropositive at baseline leaving n=119 included in the analysis.

Table 1: Participant characteristics (n=119)[a]

Characteristic	Value	CharacteristicIC	Value
Age	29.3 (25.8, 34.4)	No. partners in 72h prior to PEP	1 (1,1)[c]
Sexual orientation and gender		Type of condomless exposure[b]	
Men who have sex with men	97 (81)	Anal insertive	40 (34)
Heterosexual men	16 (13)	Anal receptive w ejaculation	36 (30)
Heterosexual women	7 (6)	Anal receptive without ejaculation	21 (18)
Ethnoracial identity		Vaginal insertive	15 (13)
White	16 (20)	Vaginal receptive w ejaculation	4 (3)
Black	8 (10)	Vaginal receptive w/out ejaculation	3 (3)
Asian	34 (43)	Partner's reported HIV status	
Latin American	13 (16)	Positive	12 (10)
Identity other than these or mixed	9 (11)	Negative or unknown	107 (90)
Comorbidities in ≥5% of sample		Initially prescribed PEP regimen	
ADHD	6 (5)	DTG + TDF/FTC	106 (89)
Anxiety/depression	7 (6)	RAL + TDF/FTC	2 (2)
No. times previously used PEP		BIC/FTC/TAF	11 (9)
0	91 (77)	Days of PEP before BIC/FTC/TAF	2 (1, 3)
1	24 (20)	Prior knowledge of PrEP	
2	4 (3)	Unaware	10 (12)
No. with prior diagnosis of STI		Aware but never used PrEP	59 (73)
Gonorrhea	21 (18)	Previously used PrEP	12 (15)
Chlamydia	24 (20)	HIV testing prior to this episode	
Lymphogranuloma venereum	2 (2)	Never	14 (12)
Syphilis	15 (13)	Within past 6 mo	36 ()
Genital warts	7 (6)	Past 6-24 months	2 (5)
Genital herpes	4 (3)	Tested but timing not provided	67 (61)
Hours from exposure to PEP initiation	23 (13, 39)		

[a] Values represent median (1st quartile, 3rd quartile) or frequency (percentage). Values may not all sum to 119 due to missing values.
[b] Highest risk type of sexual exposure reported
[c] Range: 1-6

RESULTS

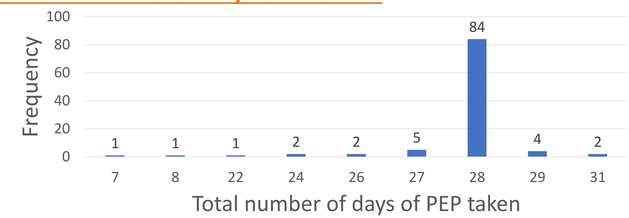
- **Tolerability:** Only 10% experienced adverse events of grade ≥2 severity

Table 2: Adverse events occurring in >3% of participants

Adverse event	Overall N (% of participants)	Severity grade ≥2 N (% of participants)	Any grade, at least possibly related to study drug N (% of participants)
Anorexia	3 (3%)	0 (0%)	3 (3%)
Diarrhea	11(8%)	4 (3%)	10 (8%)
Dizziness	5 (4%)	0 (0%)	5 (4%)
Fatigue	24(20%)	2 (2%)	24 (20%)
Headache	9 (8%)	0 (0%)	9 (8%)
Nausea	14 (12%)	0 (0%)	14 (12%)
Sleep disturbance	6 (4%)	0 (0%)	6 (4%)

- **Adherence:** 90/102 or 88% of participants with available data reported completing ≥28 days of PEP

Figure 3: Total number of days of PEP taken



- No HIV seroconversions among n=66 (55%) of participants tested at week 12
- N=28 (23%) of participants initiated on PrEP by final visit
- N=15 (13%) linked to other primary care/mental health providers

DISCUSSION

- **Limitations:**
  - Biomarkers of PEP adherence not done
  - Some AEs may be related to prior PEP drugs since participants switched to BIC/FTC/TAF after a median of 2 (1,3) days of another regimen
- Findings similar to other reports of BIC/FTC/TAF PEP (n=164 total)
  - JAIDS 2022;90:27-32 and Chinese Med J 2022;135(22)
- **Conclusions:**
  - BIC/FTC/TAF PEP was safe, well-tolerated and associated with high adherence and no HIV seroconversions.
  - BIC/FTC/TAF is an appropriate single tablet INSTI-based HIV PEP regimen

CORRESPONDENCE: darrell.tan@gmail.com

ACKNOWLEDGEMENTS

- We gratefully acknowledge grant funding from the Canadian Institutes of Health Research and the CIHR Canadian HIV Trials Network, and in-kind support from Gilead Sciences Inc.
- DHST holds a Tier 2 Canada Research Chair in HIV Prevention and STI Research

CIHR IRSC · the CTN CIHR Canadian HIV Trials Network · le Réseau Réseau canadien pour les essais VIH des IRSC · GILEAD · Canada Research Chairs www.chairs-chaires.gc.ca