Antiretroviral (ART) Virologic Suppression (VS) and Patient Reported Outcomes (PROs) in the Clinical Opportunities and Management to Exploit Bictegravir/Emtricitabine/Tenofovir Alafenamide (B/F/TAF) as an Asynchronous Connection Key (COMEBACK) Study

Lindsey Roden, MA, MPH; Gregory Huhn, MD, MPHTM; Kody Keckler, BA; Camille E. DeMarco, MPH, CPH; Patricia Cortes Valadez, BSN, RN; Dara Grennan, MD; Kerianne Burke, MPH
The Ruth M. Rothstein CORE CENTER, Cook County Health, Chicago, IL, USA

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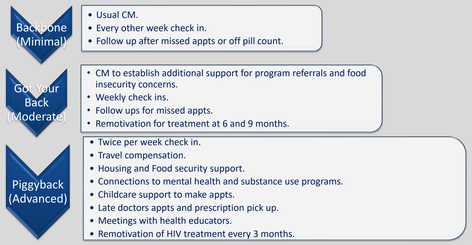
Contact info: ghuhn@cookcountyhealth.org

Background

- Effectively interrupting the source of transmission is a critical step in ending the HIV epidemic.
- Models from the surveillance systems estimate that persons diagnosed with HIV, but not retained in care, account for the largest proportion of HIV transmissions in the US.
- Addressing patients with poor retention with support mechanisms to reengage in care and reinitiate immediate ART may improve retention in care and accelerate virologic suppression as seen in immediate ART models in treatment-naïve patients.
- B/F/TAF is a single-tablet regimen (STR) with high potency and good tolerability that can be safely used in multiple patient groups including activity in patients with a history of multi-class resistance, that may facilitate immediate ART preinitiations among a broad population of patients.
- COMEBACK (NCT04519970) is a 48-week single-center study in Chicago implemented in September 2020, with its main objectives to reengage lost-to-care patients and rapidly reinitiate ART to promote VS and favorable PROs.

Methods

- Adults off ART ≥2 weeks, without history of significant B/F/TAF resistance or renal impairment, were rapidly started on B/F/TAF upon reengagement after same day baseline labs and PROs.
- During 2020 - 2021, forty-nine of the expected N=100 subjects were enrolled and have reached the 48-week timepoint. Baseline, 24 weeks, and 48 weeks endpoints were analyzed
- Direct recruitment at clinics and by Care Team Referrals at the Ruth M. Rothstein CORE Center, a large, urban, safety-net HIV clinic that cares for more than 5,000 PLHW in Cook County.
  - The CORE center defines viral suppression (VS) by Ryan White HRSA Standards with viral load (VL) <200 copies/mL.
  - CORE patients by observational analysis on B/F/TAF during the same time period 2020-2021 had a virologic suppression rate of 78.6% (N=1740/2212)
- COMEBACK primary endpoint W24 and W48 proportion HIV-1 RNA <50 copies/mL (FDA Snapshot).
  - Secondary endpoint for proportion of HIV-1 RNA between 50 and 200 copies/mL.
- Study visits (Baseline, week 4, week 12, week 24, week 36, week 48):
  - Patient Reported Outcomes (PROs)/ Rescreening Validated Tools; Medication adherence and symptoms; CMP, CD4, Viral Load and Genotype (at baseline and as needed); Clinical Exam (if indicated); Medication refill and Appointment check in and follow up.
  - At enrollment patients screen into Case Management (CM) tiers on a minimal (Backbone), moderate (Got Your Back), or advanced (Piggyback) level.



- An acuity assessment tool based on retention and VS was calculated at Week 24 and 48 endpoints to determine CM level of support.
- Participants were assessed on their medication and study visit adherence, ability to complete study components, lab results, other identified challenges (i.e., concurrent health issues [COVID, STIs, etc.]), and whether if increased communication, interim visits, and/or additional resources and/or support was needed. Each category was scored on a scale of 1 to 4 (1- stable, 2- moderate, 3- complex and 4- highest at risk).
- All analyses were performed with Chi-Square using GraphPad Prism Version 8.0.0 for Windows. Alpha <0.05 is statistically significant.

Results

CORE Center & COMEBACK Study Demographics 2020 – 2021

	CORE (N= 2,212)	%	COMEBACK (N=49)	%
Gender				
Male	1637	74	35	71.4
Female	555	25.1	10	20.4
Transgender MtF	19	0.9	3	6.1
Transgender Other / Non-binary	1	0	1	2.1
Age				
24 – 35 y.o.	497	22.5	22	45
36 – 47 y.o.	605	27.4	14	28.5
48 – 59 y.o.	722	32.6	10	20.4
60 – 68 y.o.	388	17.5	3	6.1
Race/Ethnicity				
Black/ African American	1345	60.8	45	91.8
Hispanic	644	29.1	1	2.2
White/Caucasian	177	8	2	4.3
Other	35	2.1	1	2.2
Total	2212	100	49	100

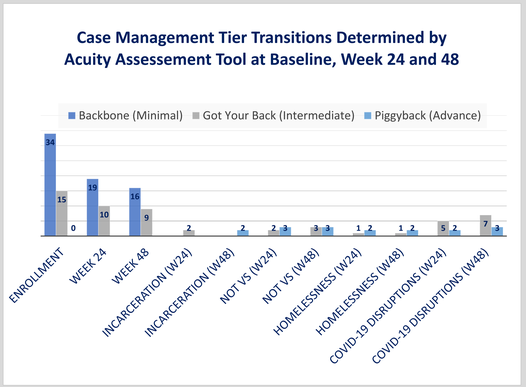
Viral Load and Time off Art at Baseline		**N=49**
	N	%
Viral Suppression	11	22.4
	Range	Median
VL	<40–333,350 copies/mL	7,998 copies/mL
Time off ART	0.5-243 months	2.6 months

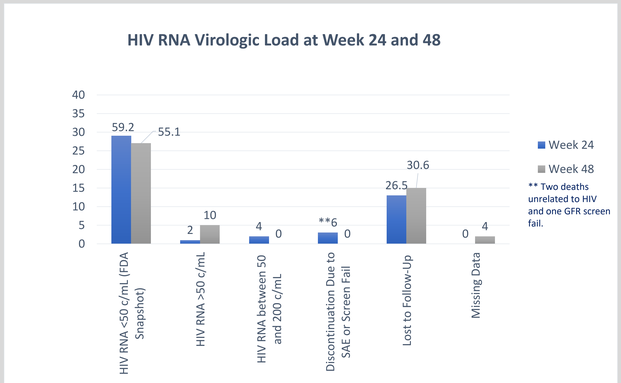
CD4+ Units: cells/mm^3		**N=49**
	Range	Median
Baseline	7-1,625	364
Week 24	9-1,735	497
Week 48	48-1,654	513

Self-Rated Treatment Adherence

Answered on a scale between 0 ("cannot do at all) to 10 ("completely certain can do."), based on the past month. Table includes those who answered 8-10.

	Baseline (N=49)		Week 48 (N=33)		P-value
	N	%	N	%	
1. Stick to your treatment plan even when side effects begin to interfere with daily activities?	**27**	**55.1**	**26**	**78.7**	**0.02**
2. Integrate treatment into your daily routine?	36	73.4	26	78.7	0.58
3. Integrate treatment into your daily routine even if it means taking medication or doing other things in front of people who don't know you are HIV-infected?	23	46.9	22	66.6	0.07
4. Stick to your treatment schedule even when your daily routine is disrupted?	33	67.3	23	69.6	0.82
5. Stick to your treatment schedule when you aren't feeling well?	31	63.2	24	72.7	0.37
6. Stick to your treatment schedule when it means changing your eating habits?	27	55.1	23	69.6	0.18
7. Continue treatment even if doing so interferes with your daily activities?	35	71.4	27	81.8	0.35
8. Continue with treatment plan your physician prescribed even if your T-cells drop significantly in the next three months?	34	69.3	24	72.7	0.74
9. Continue with your treatment even when you are feeling discouraged about your health?	34	69.3	27	81.8	0.20
10. Continue with your treatment even when getting to your clinic appointments is a major hassle?	31	63.2	25	75.7	0.23
11. Continue with your treatment even when people close to you tell you that they don't think that it is doing any good?	37	75.5	27	81.8	0.60
12. Get something out of your participation in treatment, even if the medication you are taking does not improve your health?	32	65.3	25	75.7	0.31





Results

Self-Reported Health

There was a significant increase in the number of participants who reported Good, Very Good, or Excellent health at Week 48 when compared to Baseline (p=0.003), and at Week 48 when compared to Week 24 (p=0.001).

- Thirty-two of 49 participants (65.3%) were retained-in-care at 12 months, with VS in 55.1% (N=27/49) by intention-to-treat.
- Virologic suppression rates by observational analysis in COMEBACK study participants at week 24 was 85.3% (N= 29/34) and week 48 was 84.4% (N=27/32) by comparison to the overall CORE Center population prescribed B/F/TAF (78.6%).
- No resistance to B/F/TAF was detected through 24 weeks and 48 weeks endpoints to date.
- Shifts in CM intensity differs from the HIV adherence self-efficacy PRO completed at 24 and 48 weeks, indicating that at least 50% underestimated their need to integrate and maintain adherence to ART treatment.
- The acuity assessment tool for week 24 and 48 endpoints suggests self-reported undervaluation of support needed in coming back to care as observed with 37% (N= 18/49) patients transitioning one tier up in CM.

Conclusions

- No changes from baseline to week 48 in self-reported treatment adherence to B/F/TAF except a significantly greater proportion of participants at week 48 noted that side effects did not interfere with daily activities
  - Likely reflects favorable tolerability on B/F/TAF once beyond the "start up" phenomenon of reinitiating ART.
- Retained-in-care VS was high but lapses in retention and shifts toward more intense CM are likely due to social determinants of health challenges, including incarceration, homelessness, and COVID-19-related disruptions in healthcare.
- Detrimental social determinants of health can be entrenched, at least for the first 6 to 12 months, and the VS achieved for those retained in care is in large part due to the work and success of the retention specialist and our quantified intervention model.

Limitations

- Due to COVID-19 challenges, recruitment has prolonged study completion.
- Sample enrollment may not be representative of our full facility due to language barriers, specifically 15-20% of our patient population is monolingual Spanish speaking.
- An in-depth analysis to understand variance between patient responses to PROs at Baseline, Week 24 and Week 48 were not evaluated and findings presented here will be further analyzed upon study completion.

Special thanks to all the CORE center patients who participated in this study.

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