

BACKGROUND

- Identification of HTE PWH in clinical settings is challenging due to disparate definitions.
- This retrospective study characterized PWH in clinical practice meeting various HTE criteria, focusing on demographic and clinical characteristics including virologic control at baseline of HTE-qualifying antiretroviral (ART) regimen.

METHODS

- In Trio Health HIV Network EMR and dispensing data we identified HTE PWH ≥18 years dispensed ART after January 2015 with baseline viral load (within 12-months prior to first HTE-qualifying regimen) using 2 definitions.
- Definition 1: resistance ≥2 classes **OR** drug used in HTE setting (maraviroc [MVC], etravirine [ETR], ibalizumab [IBA], enfuvirtide [ENF], fostemsavir [FTR], dolutegravir [DTG] BID or darunavir [DRV] BID) **OR** failed 2 consecutive regimens and viremic starting 3rd **OR** viremic starting 4th regimen.
- Definition 2: Above limited to viremic at HTE baseline. Univariate comparisons of virally suppressed (VS) PWH from definition #1 versus PWH from definition #2 were conducted via chi-square for categorical and t-test for continuous variables.

RESULTS

- Of 29844 patients, 865 (3%) satisfied definition 1 and 435 (1.5%) satisfied definition 2 [Figure]. Of HTE Definition 1, 53% were age >50, 73% male, 46% black, 35% commercially insured.
- Only 24% had historic genotypic tests; of those with available results, 8% were resistant to ≥2 classes.
- Clinically, 20% presented with baseline CD4 <200 cells/mm³, 50% with normal eGFR, 70% with normal ALT; 26% were viremic on all regimens [Table].
- Approximately half of definition 1 PWH were virally suppressed at baseline HTE-qualifying regimen (n=430).
- Viremic patients (definition 2) were more likely to have historic genotypic tests, to be female, black, age 26-50, on Medicaid, underweight, with baseline CD4 <200 cells/mm³, normal eGFR and ALT.
- Viremic patients received more known regimens overall, but fewer once qualified as HTE, and had shorter time on first HTE-qualifying regimen with more failures.
- Viremic PWH were less likely to receive FTR, ETR, MVC, DRV BID, more likely to be taking BIC- and DTG-containing regimens.

CONCLUSIONS

- HTE PWH represent a small but important population. HTE PWH viremic at baseline differ from virally suppressed PWH by baseline characteristics and treatment patterns and are more likely to fail in HTE setting.
- Genotype testing is underutilized among HTE PWH.

Figure. HTE Definition

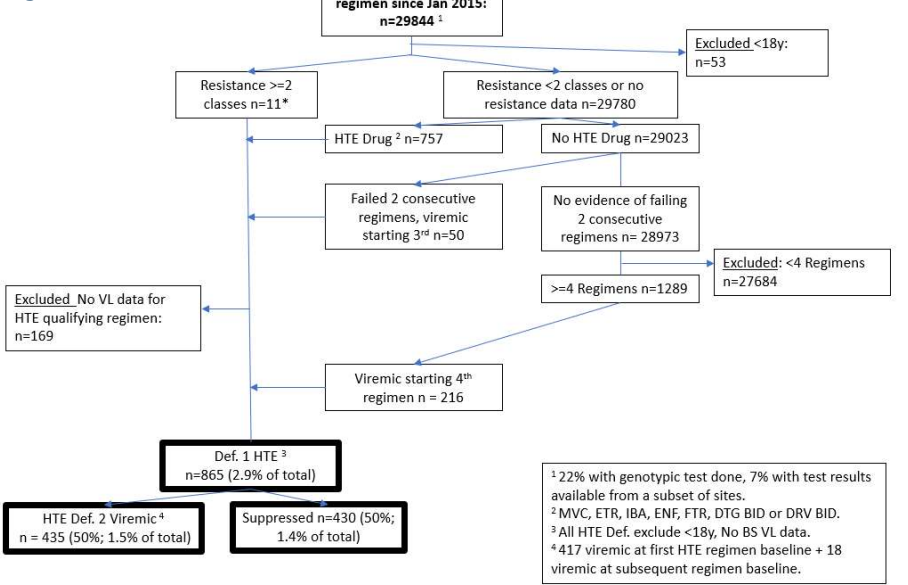


Table. HTE Characteristics by Definition

	N (%) unless specified. Note: variable categories are limited to those with significant differences (p<.05), p-values are for viremic vs suppressed at baseline of HTE-qualifying regimen	HTE Definition 1	HTE Definition 2	Suppressed at HTE baseline
		Total n=865	Viremic at HTE baseline n=435	n=430
Age	18-25: 27 (3) 26-50: 383 (44) >50: 455 (53)	15 (3) 226 (52) [#] 194 (45)	12 (3) 157 (37) 261 (61) [#]	
Gender	Male: 634 (73) Female: 164 (19) Transgender: 13 (2) Unknown: 54 (6)	305 (70) 101 (23) [*] 10 (2) 19 (4)	329 (77) [*] 63 (15) 3 (1) 35 (8) [*]	
Race	White: 384 (44) Black: 402 (46) Asian, American Indian, Pacific Islander: 47 (5) Unknown: 32 (4)	161 (37) 241 (55) [#] 22 (5) 11 (3)	223 (52) [#] 161 (37) 25 (6) 21 (5)	
Payer	Commercial: 305 (35) Medicare: 184 (21) Medicaid: 182 (21) Ryan White: 13 (2) Other plan or self-pay: 92 (11) Unknown: 89 (10)	146 (34) 76 (17) 118 (27) [#] 7 (2) 52 (12) 36 (8)	159 (37) 108 (25) [*] 64 (15) 6 (1) 40 (9) 53 (12) 47 (11)	
Baseline CD4 <200 cells/mm ³	172 (20)	125 (29) [#]	47 (11)	
Baseline BMI	Underweight <18.5 kg/m ² : 25 (3) Normal 18.5-24.9 kg/m ² : 291 (36) Overweight 25-30 kg/m ² : 284 (35) Obese >30 kg/m ² : 202 (25)	18 (4) [*] 160 (39) 128 (32) 100 (25)	7 (2) 131 (33) 156 (39) [*] 102 (26)	
Baseline eGFR (mL/min/1.73m ²)	<60: 101 (12) 60-89: 306 (38) 90+: 409 (50)	48 (11) 139 (32) 242 (56) [#]	53 (14) 167 (43) [*] 167 (43)	
Baseline ALT > upper limit of normal (ULN)	243 (30)	109 (26)	134 (35) [*]	
Follow-up (yrs), mean (SD)	7.9 (4.4) n=865	7.9 (4.2) n=435	7.8 (4.6) n=430	
Follow-up since HTE baseline start (mo), mean (SD)	39.4 (24.2) n=865	34.1 (22) n=435	44.8 (25.2) n=430 [*]	
Prior known regimens, mean (SD)	1.3 (1.5) n=865	2.1 (1.5) n=435 [*]	0.5 (1.1) n=430	
HTE regimens, mean (SD)	1.9 (1.2) n=865	1.8 (1.2) n=435	2 (1.3) n=430 [*]	
Duration of baseline HTE regimen (mo), mean (SD)	14.5 (15.6) n=865	13.3 (13.5) n=435	15.8 (17.4) n=430 [*]	
Suppressed at last available observation on baseline HTE regimen (<200 copies/ml)	372 (68)	143 (49)	229 (90) [#]	
Failure at any time on baseline regimen (2 consecutive viral loads >200 copies/ml)	152 (18)	115 (26) [#]	37 (9)	
Viremic on all HTE regimens	158 (26)	132 (42) [#]	26 (9)	
Ibalizumab-containing (IBA) ¹	2 (0)	0 (0)	2 (0)	
Fostemsavir (FTR) ¹	17 (2)	3 (1)	14 (3) [*]	
Maraviroc (MVC) ¹	147 (17)	30 (7)	117 (27) [#]	
Etravirine (ETR) ¹	317 (37)	75 (17)	242 (56) [#]	
Enfuvirtide (ENF) ¹	2 (0)	1 (0)	1 (0)	
Bictegravir (BIC) ¹	84 (10)	77 (18) [#]	7 (2)	
Dolutegravir + Rilpivirine (DTG + RPV) ¹	164 (19)	88 (20)	76 (18)	
DTG (not including DTG+RPV) ¹	111 (13)	68 (16) [*]	43 (10)	
DTG BID ¹	63 (7)	33 (8)	30 (7)	
Darunavir (DRV) ¹	281 (32)	125 (29)	156 (36) [*]	
DRV BID ¹	93 (11)	32 (7)	61 (14) [*]	
DRV+ DTG BID ¹	13 (2)	9 (2)	4 (1)	
With historic genotypic test	208 (24)	137 (31) [#]	71 (17)	
With genotypic result available	113 (13)	79 (18) [#]	34 (8)	
Resistant to ≥2 classes	9 (8)	5 (6)	4 (12)	

¹ First HTE regimen; [#]p<.001; ^{*}.001≤p<.05



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