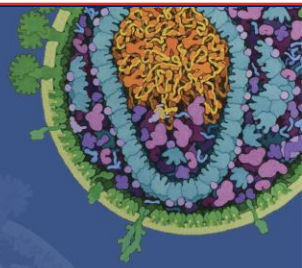
AETC AIDS Education & Training Center Program Mountain West

virtual CROI 2021
Conference on Retroviruses and Opportunistic Infections
March 6-10, 2021



CROI Update: HIV Co-Infections and Comorbidities

Adrienne Shapiro, MD, PhD, MSc
Acting Assistant Professor, Departments of Global Health & Medicine
(Division of Allergy & Infectious Diseases)

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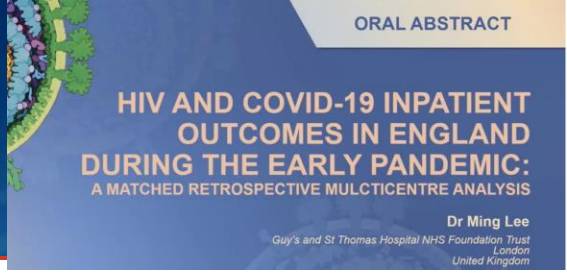
Disclosures

Grant funding: Vir Biotechnology

HIV & COVID-19

HIV & COVID-19



- **#142 Lee (UK):** Multicenter retrospective matched cohort of PLWH hospitalized with PCR+ COVID-19 in the UK, Feb-May 2020. (N=68)
- Matched up to 3:1 to persons without HIV hospitalized with COVID-19 on hospital site, gender, 5-year age band, SARS-CoV-2 test date week, socioeconomic index. (N=181)
- Outcome: time to improvement or discharge
- PLWH more likely to have CKD, ESRD, liver disease; less likely to have rheumatologic disease vs PLwoH
- PLWH had longer time to improvement/discharge (HR 0.57, 95%CI 0.39-0.85, p=0.005) vs PLwoH in crude analysis, but attenuated difference & significance after adjusting for comorbidities, age, and race/ethnicity. (HR 0.7, 95% CI 0.43,1.17, p=0.18).
- No difference in mortality seen
- **Conclusion: Among people hospitalized with COVID-19 in the UK, PLWH did not have significantly different outcomes vs. PLwoH after adjusting for other comorbidities**

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HIV & COVID-19

ORAL ABSTRACT

COVID-19 HOSPITALIZATION AMONG PEOPLE WITH HIV OR SOLID ORGAN TRANSPLANT IN THE U.S.

Jing Sun, MD, PhD
Johns Hopkins University
Baltimore, MD, USA

#103 Sun (USA): National Covid Cohort Collaborative – routinely collected clinical data from 39 centers across US. PCR+ COVID between Jan 2020-Feb 2021

Odds of **hospitalization** in people with immuno-suppression, defined as HIV or SOT

Immunosuppression groups	Crude estimates		Adjusted estimates [a]		Adjusted estimates [b]	
	OR (95% CI)	P-value	OR (95% CI)	P-value	OR (95% CI)	P-value
HIV- / SOT- (N=501,416)	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
HIV+ alone (N=2,932)	2.14 (1.99, 2.30)	<0.01	1.63 (1.5, 1.76)	<0.01	1.32 (1.22, 1.43)	<0.01
SOT+ alone (N=4,633)	4.00 (3.77, 4.25)	<0.01	3.07 (2.88, 3.27)	<0.01	1.69 (1.58, 1.81)	<0.01
HIV+ / SOT+ (N=111)	5.37 (3.57, 8.06)	<0.01	3.50 (2.27, 5.42)	<0.01	1.65 (1.06, 2.56)	0.03

[a]Model adjusted for age, sex, race and ethnicity (Black non-Hispanic, white Hispanic, white non-Hispanic, others), and study

Odds of **invasive mechanical ventilation** in hospitalized patients with immuno-suppression, defined as HIV or SOT

Immunosuppression groups	Crude estimates		Adjusted estimates [a]		Adjusted estimates [b]	
	OR (95% CI)	P-value	OR (95% CI)	P-value	OR (95% CI)	P-value
HIV- / SOT- (N=153,310)	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
HIV+ only (N=1,421)	1.93 (1.63, 2.28)	<0.01	1.73 (1.45, 2.06)	<0.01	1.86 (1.56, 2.22)	<0.01
SOT+ only (N=2,956)	2.66 (2.40, 2.96)	<0.01	2.02 (1.81, 2.25)	<0.01	1.96 (1.74, 2.12)	<0.01
HIV+ / SOT+ (N=78)	4.35 (2.54, 7.45)	<0.01	3.92 (2.21, 6.96)	<0.01	3.73 (2.08, 6.67)	<0.01

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HIV & COVID-19 Lightning round

 # 548 Yendewa (USA): Large commercial healthcare database cohort: 297,194 COVID-19 cases, including 1638 (0.6%) PLWH (83% on ART, 48% virally suppressed). In this cohort, propensity score-matched **PLWH had higher odds of hospitalization** (OR 1.26; 95% CI(1.04,1.53), **ICU and/or invasive mech vent** (OR 1.32, 95% CI 1.10, 1.58), **vs PLwoH**; comparable mortality at 30d (2.9% vs 2.3% p=0.12).

 # 547 Moran (USA): N=180 adults with HIV. Risk of hospitalization among PLWH with PCR+ COVID-19 is associated with # of comorbidities in a dose-dependent fashion. Age-adjusted OR for hospitalization (95% CI) of each additional comorbidity: 1.25 (1.01-1.53)

#543 Shapiro (USA): CNICS Cohort of PLWH (N=15,969); N=582 (3.6%) COVID-19 cases identified Mar-Dec 2020. Disproportionate # of COVID-19 cases in Black, Hispanic PLWH. Female, diabetes, BMI>=30 (but not CD4 count) associated with having COVID-19 among PLWH. **Increased adjusted relative risk (95% CI) of hospitalization** for PLWH w/ COVID-19 and:

Age >=60	1.78 (1.25, 2.54)	p=0.001	**ASCVD risk score**	Per 10% incr 1.41 (1.25, 1.60)	p<0.001
CD4 <=350	2.29 (1.63, 3.22)	p<0.001	**DM2**	1.45 (1.02, 2.06)	p=0.038
HCV	1.53 (1.04,2.25)	p=0.03	**eGFR<60**	2.28 (1.61, 3.24)	p=<0.001

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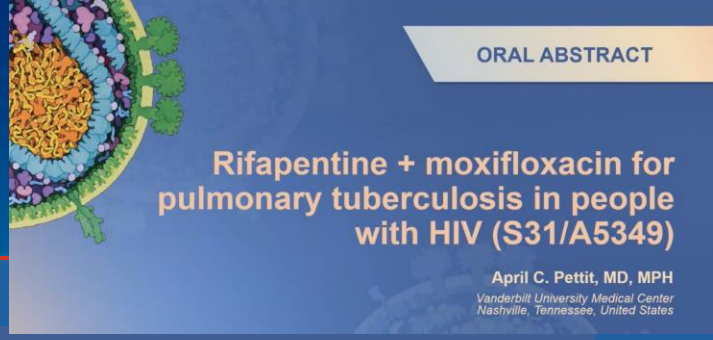
HIV & TB

TB & HIV



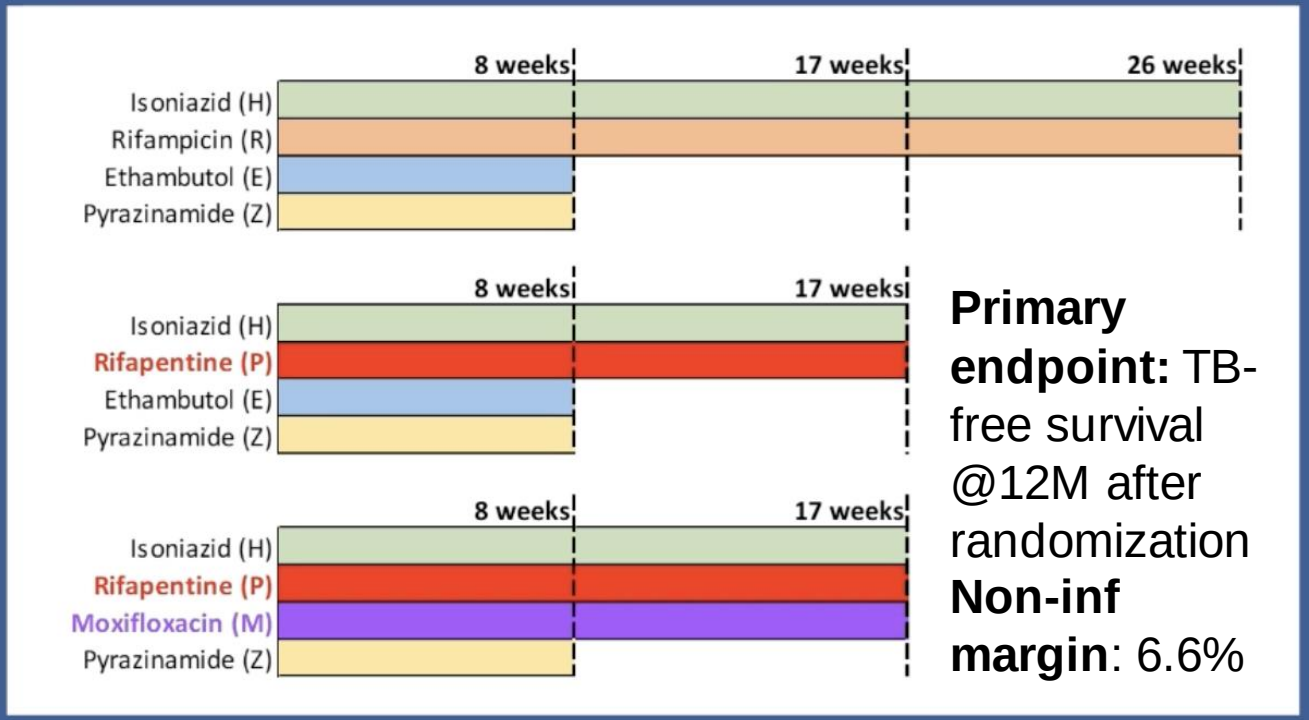
Methods-Study 31/A5349 Design

International, randomized, open-label, phase 3, non-inferiority trial

2HRZE / 4HR "Control"

2HPZE / 2HP "RPT"

2HPZM / 2HPM "RPT-MOX"



Primary endpoint: TB-free survival @12M after randomization

Non-inf margin: 6.6%

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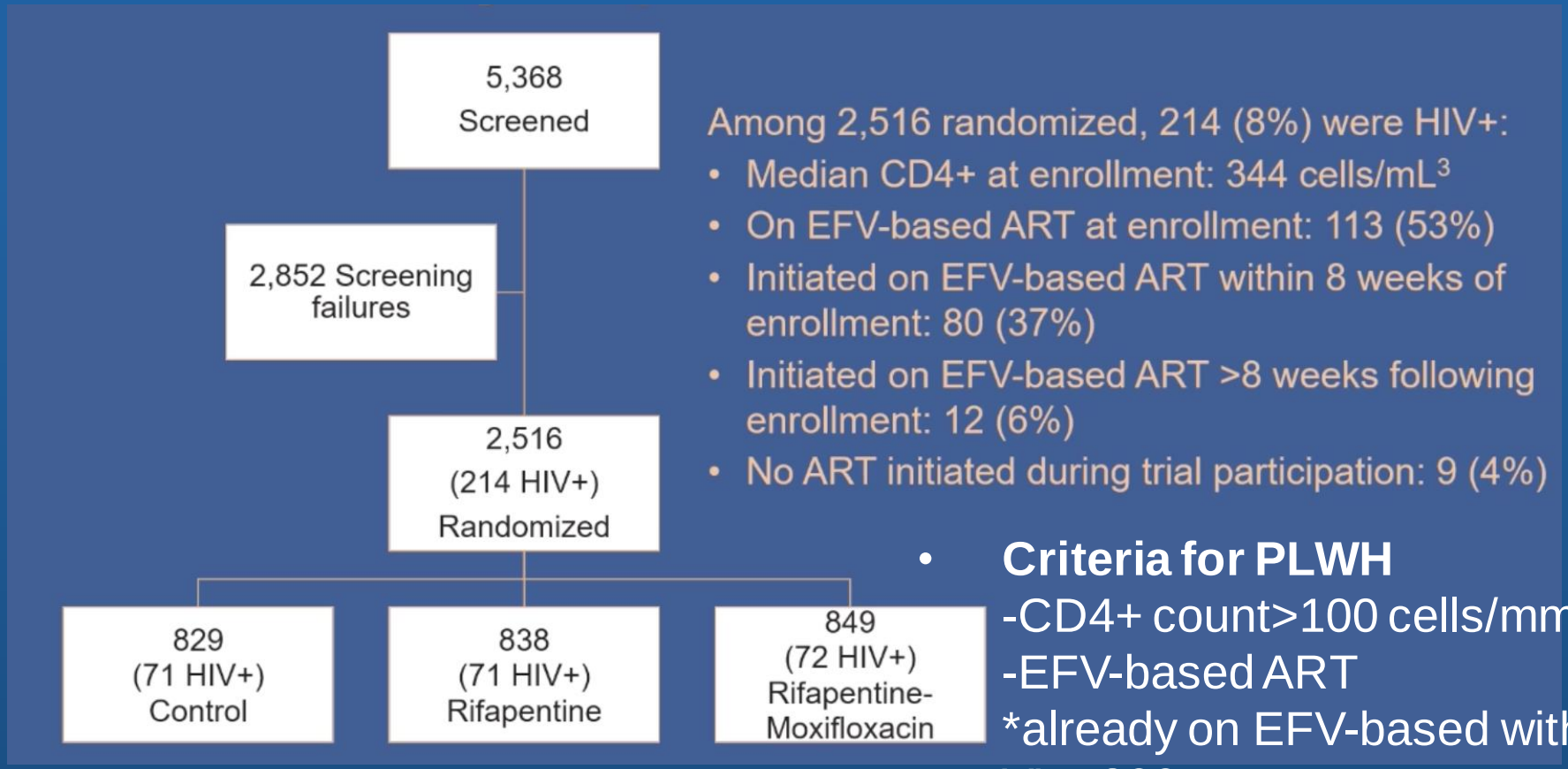
TB & HIV



- **Criteria for PLWH**

-CD4+ count>100 cells/mm3
-EFV-based ART
*already on EFV-based with VL <200
*starting EFV-based ART within 8 weeks of TB tx

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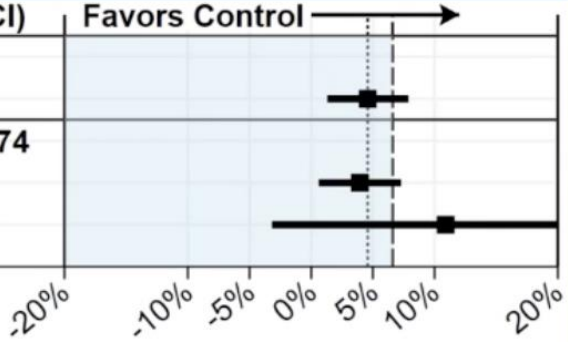
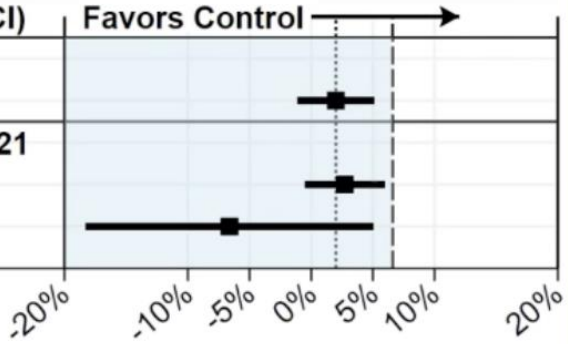
Results-Efficacy (Assessable population)

	Rifapentine	Control	Unadj. diff. (95% CI)
Overall			
	107 (14.2%) / 752	70 (9.6%) / 726	4.6 (1.3, 7.9)
HIV Status			**Interaction p = 0.574**
Negative	90 (13.1%) / 687	61 (9.2%) / 666	3.9 (0.6, 7.3)
Positive	17 (26.2%) / 65	9 (15.3%) / 59	10.9 (-3.2, 25.0)



	Rifapentine-Moxifloxacin	Control	Unadj. diff. (95% CI)
Overall			
	88 (11.6%) / 756	70 (9.6%) / 726	2.0 (-1.1, 5.1)
HIV Status			**Interaction p = 0.121**
Negative	83 (11.9%) / 698	61 (9.2%) / 666	2.7 (-0.5, 6.0)
Positive	5 (8.6%) / 58	9 (15.3%) / 59	-6.6 (-18.3, 5.0)



First two columns show unfavourable outcomes N(%) / participants in Primary: Assessable analysis population.
Dashed lines indicate overall unadjusted difference (short dashes) and margin of non-inferiority (6.6%, long dashes).

4M RPT-MOXI non-inferior to 6M SOC in PLWH

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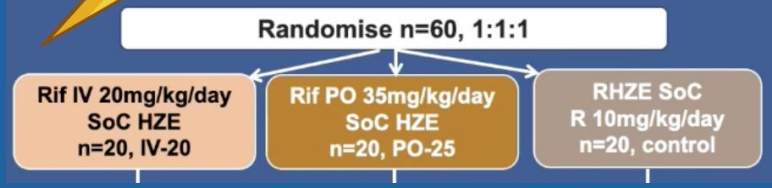
TB & HIV Lightning Round



#131 Cresswell (Uganda):
Phase II TB Meningitis tx w/ high-dose RIF
-90% participants had HIV, median CD4+=50
-SOC RIF reached detectable CSF levels in <50%, vs 94% in both intensified arms
-No excess toxicity with high-dose RIF (not powered for clinical endpoints)

#132 Sun (Taiwan): BIC/TAF/FTC with 1HP for LTBI in PLWH with VL <200
- N=50 started, 1 discontinued
-16 had VL rebound during 1HP, all re-suppressed at 3 & 6 months post-1HP

#178 Gupta (multi): Pregnancy outcomes in PLWH receiving 9M INH for prevention of TB
N=128 women with known pregnancy outcomes while on study
Increased risk of non-live birth (RR 1.92 (1.11, 3.33)) and other adverse pregnancy outcome in INH-exposed 1st trimester

HIV & HCV

Hep C

#135

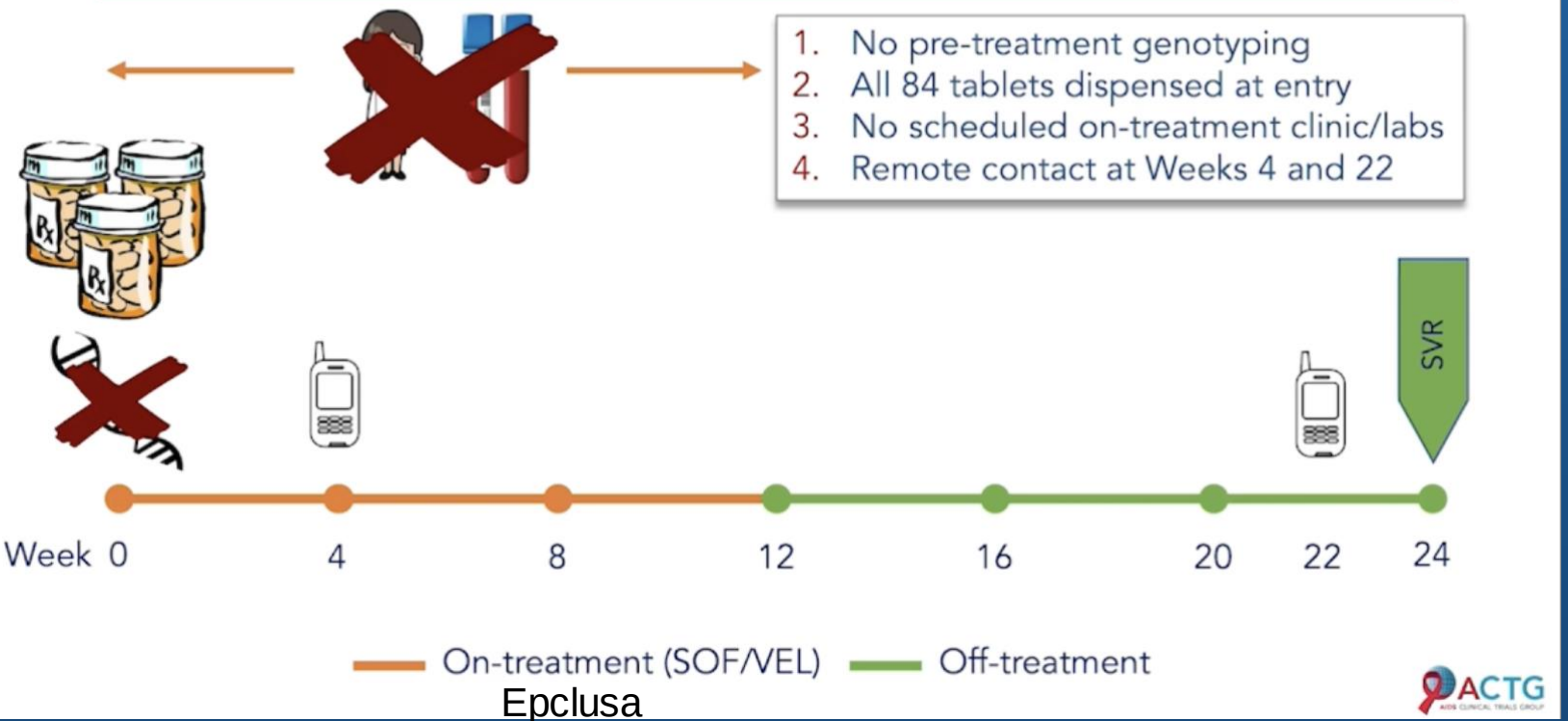
ORAL ABSTRACT

A SIMPLE AND SAFE APPROACH TO HCV TREATMENT: FINDINGS FROM THE ACTG 5360 (MINMON) TRIAL

Sunil S Solomon

Johns Hopkins University School of Medicine
Baltimore, MD

The "MINMON" Approach



Epclusa

Baseline Characteristic	N=399
Median age in years (Range)	47 (20 – 82)
Female sex at birth, n (%)	139 (35)
Identity across transgender spectrum, n (%)	22 (6)
Race/Ethnicity, n(%)	
Non-Hispanic White	99 (25)
Non-Hispanic Black	57 (14)
Non-Hispanic Asian	113 (28)
Hispanic, any race	95 (24)
History of substance use*, n (%)	
Current	56 (14)
Previous	170 (43)
Never	171 (43)
Cirrhosis (FIB-4 ≥ 3.25), n (%)	34 (9)
HIV co-infection, n(%)	166 (42)
*On cART, HIV RNA<400 copies/ml, n (%)****	164 (99)
Median HCV RNA in log10 IU/ml (IQR)	6.1 (5.6 – 6.6)
HCV Genotype**, n(%)	
Genotype 1	249 (62)
Genotype 2	26 (7)
Genotype 3	80 (20)
Genotypes 4, 5, 6, 7	41 (10)

Exclusion:

- De-compensated cirrhosis
- Pregnancy
- Chronic HBsAg+

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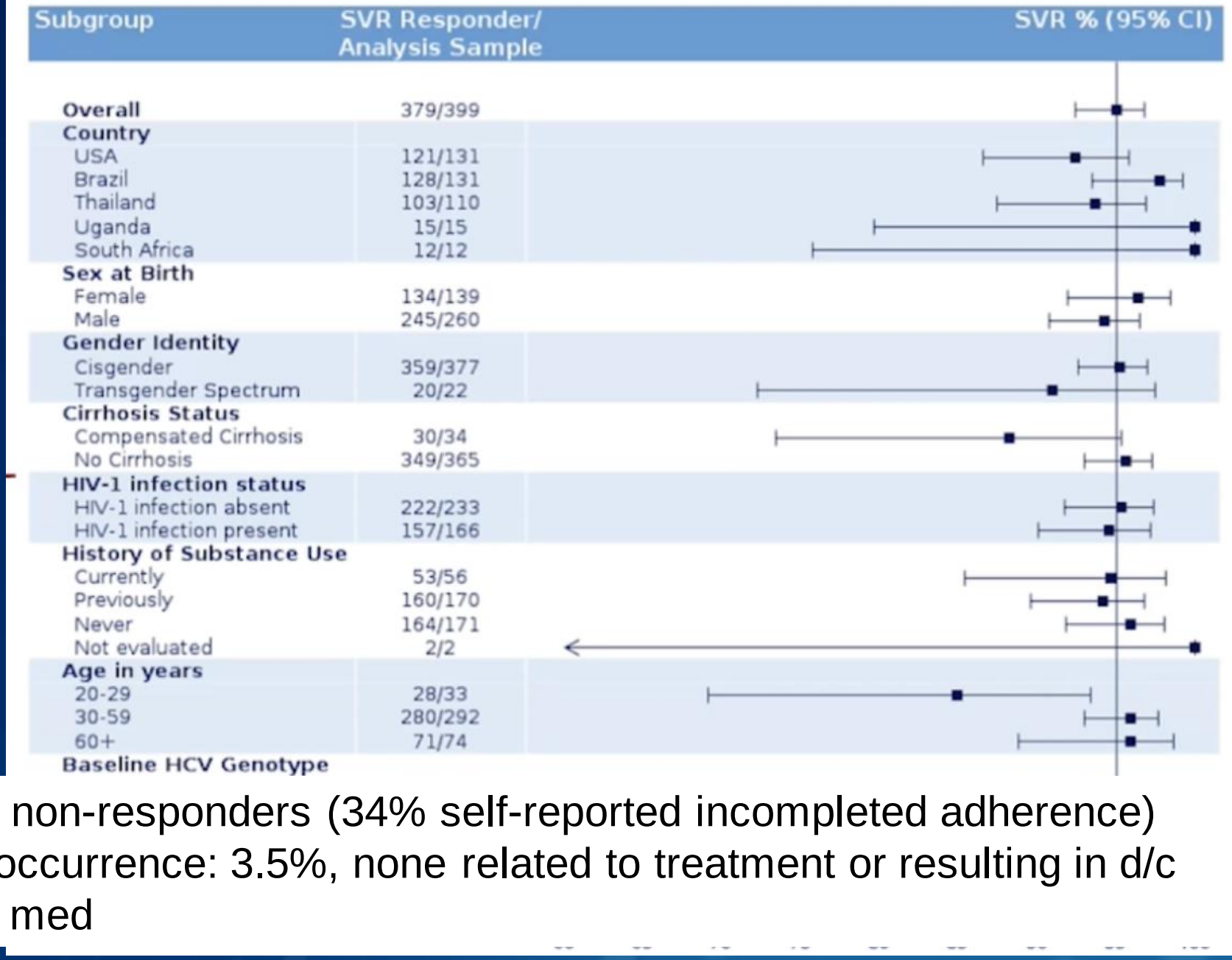

N=20 non-responders (34% self-reported incompleted adherence)
SAE occurrence: 3.5%, none related to treatment or resulting in d/c study med

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Conclusions

Multi-month dispensing, minimal-interaction HCV treatment safe and effective for treatment-naïve persons without decompensated cirrhosis

Limitations:
-No control group
-Not fully generalizable – PLWH limited to persons with VL<400 → may be more adherent
-Sequence data needed to determine non-response/relapse vs reinfection

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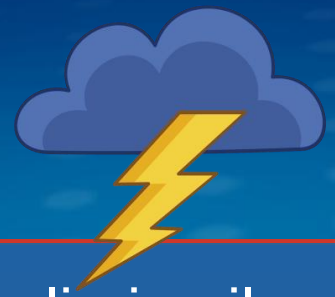
HCV Lightning Round



#446 Reipold: Self-testing for HCV is acceptable and preliminarily feasible in multi-country study using an OraQuick HCV rapid antibody test.
N=775 PWID and MSM in Georgia, Kenya, Vietnam, China (unassisted ST), and gen pop in Egypt (assisted)
High acceptability (>90%) would use, variable ease of use & reliability of results.

#440 Martin: Cost-effectiveness modeling to determine testing frequency to achieve HCV elimination in MSM in the US (90% reduction in incidence by 2030):
q6M for MSM with HIV; annually for MSM using PrEP; at time of HIV testing for non-PrEP-using MSM
Modestly Increased frequency vs CDC/IDSA/AASLD guidelines
ICER: $35,000/QALY gained (WTP $100,000/QALY gained)

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