15th International Conference on HIV TREATMENT AND PREVENTION ADHERENCE

Making HIV Universal Test-and-Treat a Reality to Achieve SDG 3.3: The Role of Rapid Start of Antiretroviral Therapy

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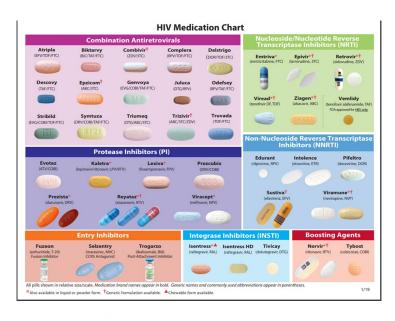
WHO Sustainable Development Goals





Ensure healthy lives and promote well-being for all at all ages

- Target 3.3: By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases
- Indicator 3.3.1: Number of new HIV infections per 1,000 uninfected population, by sex, age and key populations



The NEW ENGLAND JOURNAL of MEDICINE

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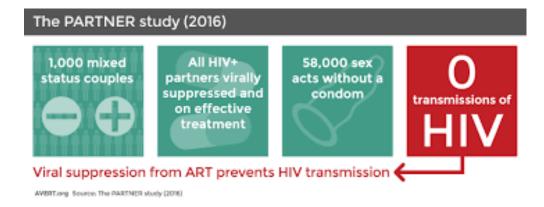
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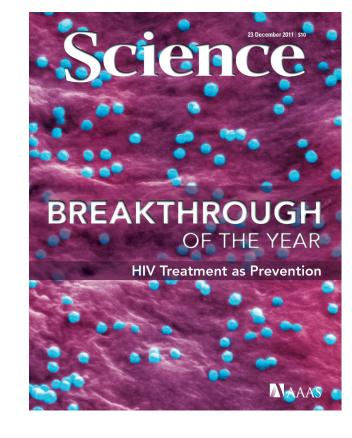
OL. 365 NO.

Prevention of HIV-1 Infection with Early Antiretroviral Therapy

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- 1. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV, DHHS 2019
- 2. Initiation of ART in Early Symptomatic HIV infection. *NEJM* 2015
- 3. Cohen et al NEJM 2011; Cohen. NEJM. 2016;375:830.
- 4. PARTNER and Partner 2 Study, JAMA 2016; Partner 2 Rodger. Lancet. 2019;393:2428.
- 5. Pre-exposure Chemoprophylaxis for HIV Prevention in Men who Have Sex with Men. NEJM 2011; On Demand PrEP in Men at High Risk for HIV Prevention, NEJM 2015



February 5, 2019

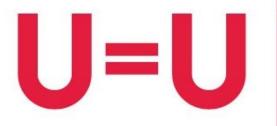
Volume 321 Number 5

Viewpoint

HIV Viral Load and Transmissibility of HIV Infection

Undetectable Equals Untransmittable

RW Eisinger, CW Dieffenbach, and AS Fauci



UNDETECTABLE = UNTRANSMITTABLE

Effects of a multicomponent intervention to streamline initiation of antiretroviral therapy in Africa: a stepped-wedge cluster-randomised trial

Gideon Amanyire ¹, Fred C Semitala ¹, Jennifer Namusobya ¹, Richard Katuramu ¹, Leatitia Kampiire ¹, Jeanna Wallenta ², Edwin Charlebois ², Carol Camlin ², James Kahn ², Wei Chang ², David Glidden ², Moses Kamya ¹, Diane Havlir ², Elvin Geng ³

Initiating Antiretroviral Therapy for HIV at a Patient's First Clinic Visit: The RapIT Randomized Controlled Trial

Sydney Rosen^{1,2}*, Mhairi Maskew², Matthew P. Fox^{2,3}, Cynthia Nyoni², Constance Mongwenyana², Given Malete², Ian Sanne², Dorah Bokaba⁴, Celeste Sauls², Julia Rohr¹, Lawrence Long²



Same-day HIV testing with initiation of antiretroviral therapy versus standard care for persons living with HIV: A randomized unblinded trial

Serena P. Koenig^{1,2}*, Nancy Dorvil¹, Jessy G. Dévieux³, Bethany L. Hedt-Gauthier⁴, Cynthia Riviere¹, Mikerlyne Faustin¹, Kerlyne Lavoile¹, Christian Perodin¹, Alexandra Apollon¹, Limathe Duverger¹, Margaret L. McNairy^{5,6}, Kelly A. Hennessey¹, Ariadne Souroutzidis⁷, Pierre-Yves Cremieux⁷, Patrice Severe¹, Jean W. Pape^{1,5}

March 20, 2018

Effect of Offering Same-Day ART vs
Usual Health Facility Referral During
Home-Based HIV Testing on Linkage to
Care and Viral Suppression Among
Adults With HIV in Lesotho
The CASCADE Randomized Clinical Trial

Niklaus D. Labhardt, MD^{1,2,3}; Isaac Ringera, RN⁴; Thabo I. Lejone, MIH⁴; Thomas Klimkait, PhD⁵; Josephine Muhairwe, MD⁴; Alain Amstutz, MD^{1,2,3}; Tracy R. Glass, PhD^{1,2}

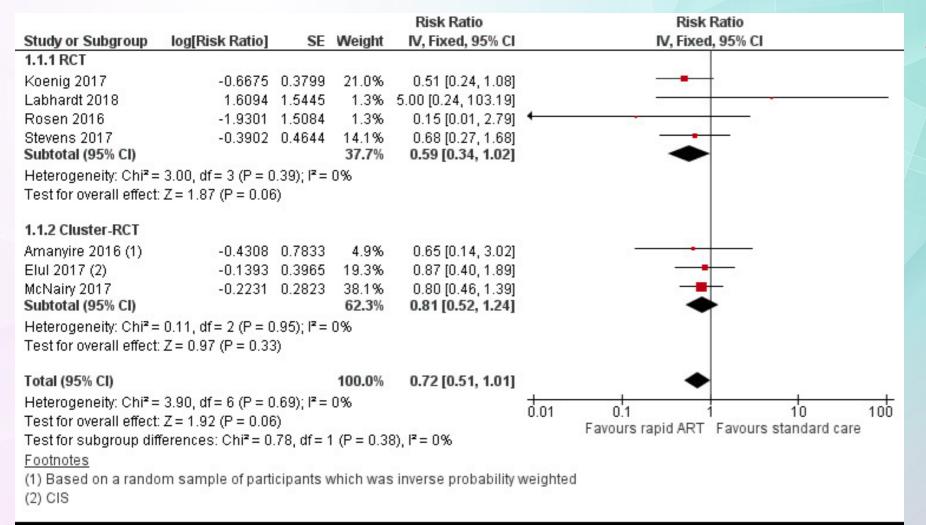
Rapid ART versus SOC: Virologic Suppression



Analysis 2.2. Comparison 2 Rapid ART versus standard care: subgroup analysis by time of ART initiation, Outcome 2 Virological suppression at 12 months.

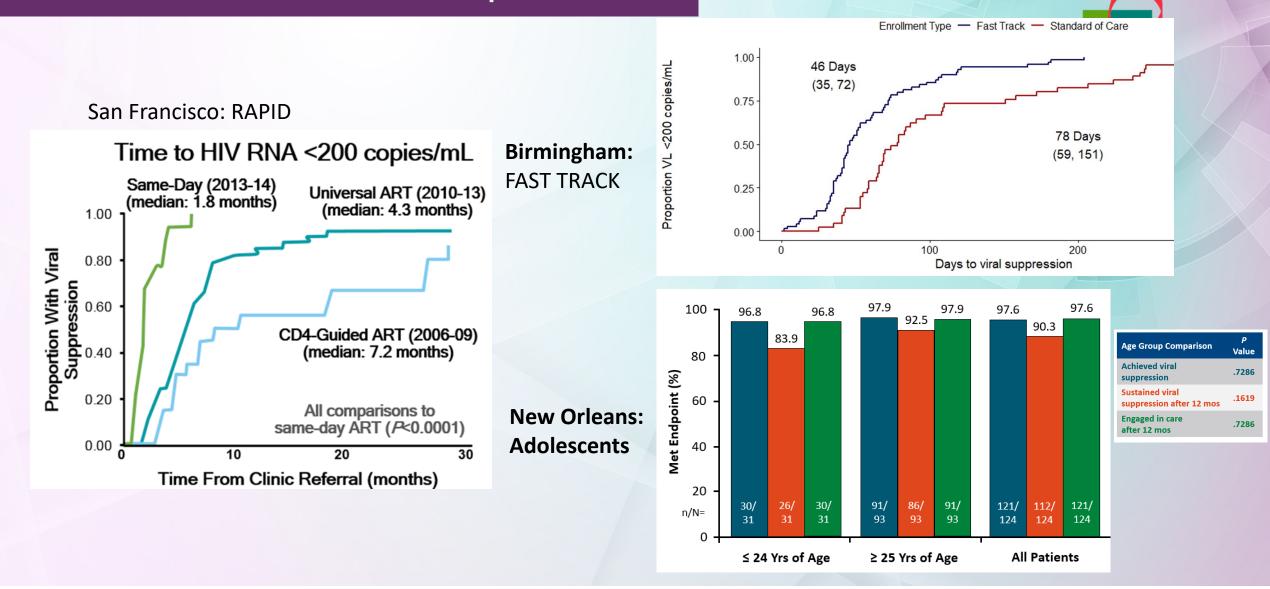
Study or subgroup	Rapid ART	Standard of care	log[Risk Ratio]	Risk Ratio	Weight	Risk Ratio
	N	N	(SE)	IV, Fixed, 95% CI		IV, Fixed, 95% CI
2.2.1 Same-day ART						
Koenig 2017	0	0	0.2 (0.067)	-	57%	1.18[1.04,1.35]
Labhardt 2018	0	0	0.4 (0.146)		12.01%	1.47[1.1,1.95]
Rosen 2016	0	0	0.2 (0.091)		30.99%	1.26[1.05,1.5]
Subtotal (95% CI)				•	100%	1.24[1.12,1.37]
Heterogeneity: Tau ² =0; Chi ² =1.89, d	f=2(P=0.39); I ² =09	6				
Test for overall effect: Z=4.22(P<0.00	001)					
2.2.2 ART offered within 14 days						
Amanyire 2016	0	0	0.1 (0.052)		100%	1.13[1.02,1.25]
Subtotal (95% CI)				•	100%	1.13[1.02,1.25]
Heterogeneity: Not applicable						
Test for overall effect: Z=2.34(P=0.02	2)					
Test for subgroup differences: Chi ² =	1.56, df=1 (P=0.21	1), I ² =35.95%				
		Favours	standard care	0.5 0.7 1 1.5 2	Favours rap	id ART

Rapid Start vs SOC: Mortality





The US Experience



RAPID ART BY THE GUIDELINES



- Encourage rapid initiation of ART, including same-day start if feasible
- Avoid ABC, DTG/3TC, and NNRTIbased regimens during rapid start
- Recommended regimens
 - BIC/FTC/TAF
 - DTG + (3TC or FTC) + (TAF or TDF)
 - DRV/(RTV or COBI) + (3TC or FTC) + (TAF or TDF)

WHO[3]



- Immediate ART for all PWH
- Initiation should be considered within 7 days of diagnosis, ideally on the same day

Considerations

- Transmitted NNRTI or NRTI resistance more likely than PI or INSTI resistance
- Empiric HBV coverage
- Treatment suitable for patients with CrCl ≥ 30 mL/min
- Ols (Cryptococcal meningitis, TB meningitis)
- Pregnancy [4, 5], Retention [6]

1. DHHS Guidelines. December 2019 2. Saag et al. *JAMA*. 2020; 3. WHO Guidelines for Managing Advanced HIV Disease and Rapid Initiation of Antiretroviral Therapy. 2017; 4. Chan et al. J Int AIDS Soc 2016; 5. Mitiku et al, *J Int AIDS* Soc 2016.; 6. Cuzin *Plos One* 2019.

Rapid Start in Practice

1st Primary Care **ART Start** ART Management **HIV+ Diagnosis** 1st Clinic Visit **Provider Visit** Prescription Disclosure Viral load Registered · Pharmacy pick-up HIV education Medical evaluation monitoring Insurance Counseling · Assess housing, Assess preparedness Adherence Referral Retention substance use. Scheduling mental health needs HIV education Counseling Labs **RAPID Visit: ART Start**

Primary Care Provider Visits:

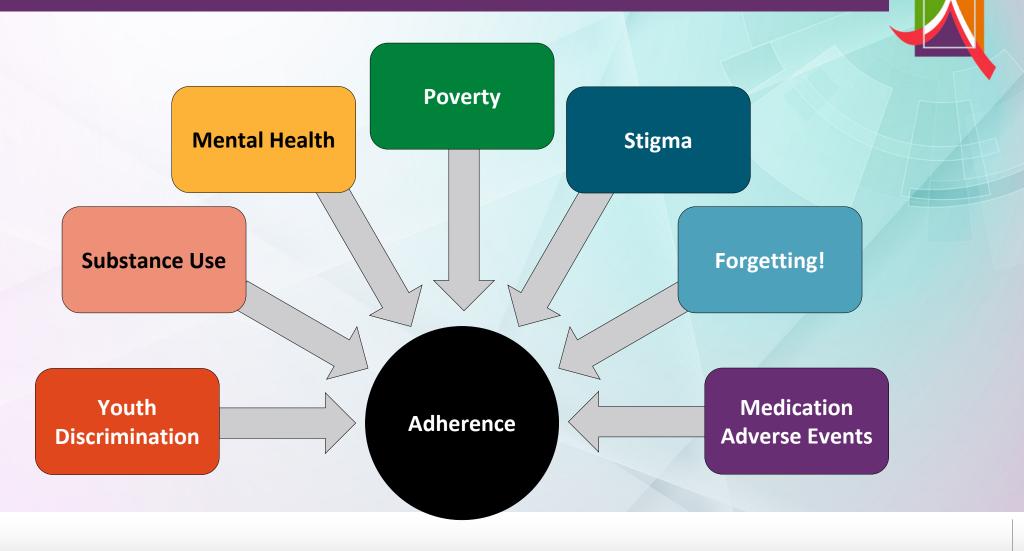
ART Management

- Viral load monitoring
- Art management
- Adherence
- Retention

- Disclosure, councelling
- Registration
- Insurance
- · Assess housing, substance use, mental health needs
- Labs
- HIV education
- Counseling
- Medical evaluation
- Assess preparedness
- ART dispensed
- Telephone follow-up



Assessing Barriers to Care and Treatment



RAPID START PROMOTES EQUITY

- Black men are more likely to experience delays in ART initiation even after seeing a prescribing provider [1]
- Hispanic/Latino persons significantly less likely to receive ART after meeting clinical indications for treatment vs whites [2]
- Same-day immediate access to a provider can demonstrate commitment to a community
- Dázon Dixon Diallo from Sister Love: "See my brothers and sisters as your own. If you do, then of course you will see patients same-day, start same-day, and love same-day."

The Patient Perspective: New Orleans



"When I was first diagnosed, my first thought was not, 'Am I going to die?' because you know everyone is going to die. It was, 'Can I give this to my boyfriend?' That terrified me. I started medication on the day I was diagnosed, and I am now undetectable so the answer is: 'No, I cannot'."

"U=U was the message I took home to my family. Ten yrs ago I came out; 5 yrs ago I was diagnosed. Over Christmas, I told my family that I was undetectable, on medication, and showed the U=U video. I feel good with my family, and I have not in a long time."

"I have not had sex in 17 yrs, since the day I was diagnosed. U=U changes how I see myself and my risk to others. I just went on my first date."

Increased Diagnoses of Acute HIV through Routine ED Screening and Rapid LTC and initiation of ART during the COVID-19 Pandemic



Year	AHI Dx	AHI Dx ED	New Dx	New Dx ED
2016	7	5	41	19
2017	7	7	37	22
2018	4	4	39	28
2019	9	9	56	39
2020 (through 8/17/2020)	9	9	35	31
Update 10/16/20	12	12		

- Of the 9 AHI patients, 7 were men (6 identified as MSM) and 2 were cisgender women
- Median age was 25 years (range 21 to 28 years)
- The median viral load was > 6 million (range 115,000 to > 6 million) copies/mL
- Eight of 9 patients presented with an illness indistinguishable from COVID-19
 - Including 1 patient with co-infection
- All 9 patients were notified, LTC, and initiated on ART
 - Median of 1 day (0-38 days) from result of confirmatory PCR
 - Median 3 days (range 1-41 days) from presentation as a result of delayed reflex PCR testing due to high demands on lab personnel and scarcity of reagents due to COVID-19 testing volumes

CRITICAL COMPONENTS TO RAPID ART

Planning, coordination, teamwork, and funding critical to program design

- Cooperation and rapport between testing and rapid ART sites
- Warm hand-offs and accessible linkage coordinators
- Early and sustained access to ART
- Expedited insurance/payer source and clinic enrollments
- Same-day clinician visits
- Accessible education on beginning ART in advance of genotype/lab results
- Follow-up with continued education, patient navigation efforts, and contact with retention teams

