Innovative Programs to End the HIV Epidemic: **ART Rapid Start**

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Southeast AIDS Education & Training Center (SEATEC) Webinar

January 22, 2020

Disclosures

- (CME) Integritas Communications: Funded through Gilead
- (CME) Vindico CME – Funded through ViiV Healthcare

Objectives

1. Describe the Data Pertaining to Rapid ART Start with focus on programs in Southeast
2. Advocate for Rapid Start Approach in Context of Equity
3. Review clinical considerations when initiating rapid ART
4. Identify Potential Hurdles to Implementation

Ending the HIV Epidemic

GOAL

75%
reduction in new HIV infections in 5 years and at least
90%
reduction in 10 years

Diagnose all people with HIV as early as possible after infection.

Treat the infection **RAPIDLY** and effectively to achieve sustained viral suppression.

Protect people at risk for HIV using potent and proven prevention interventions, including PrEP, a medication that can prevent HIV infections.

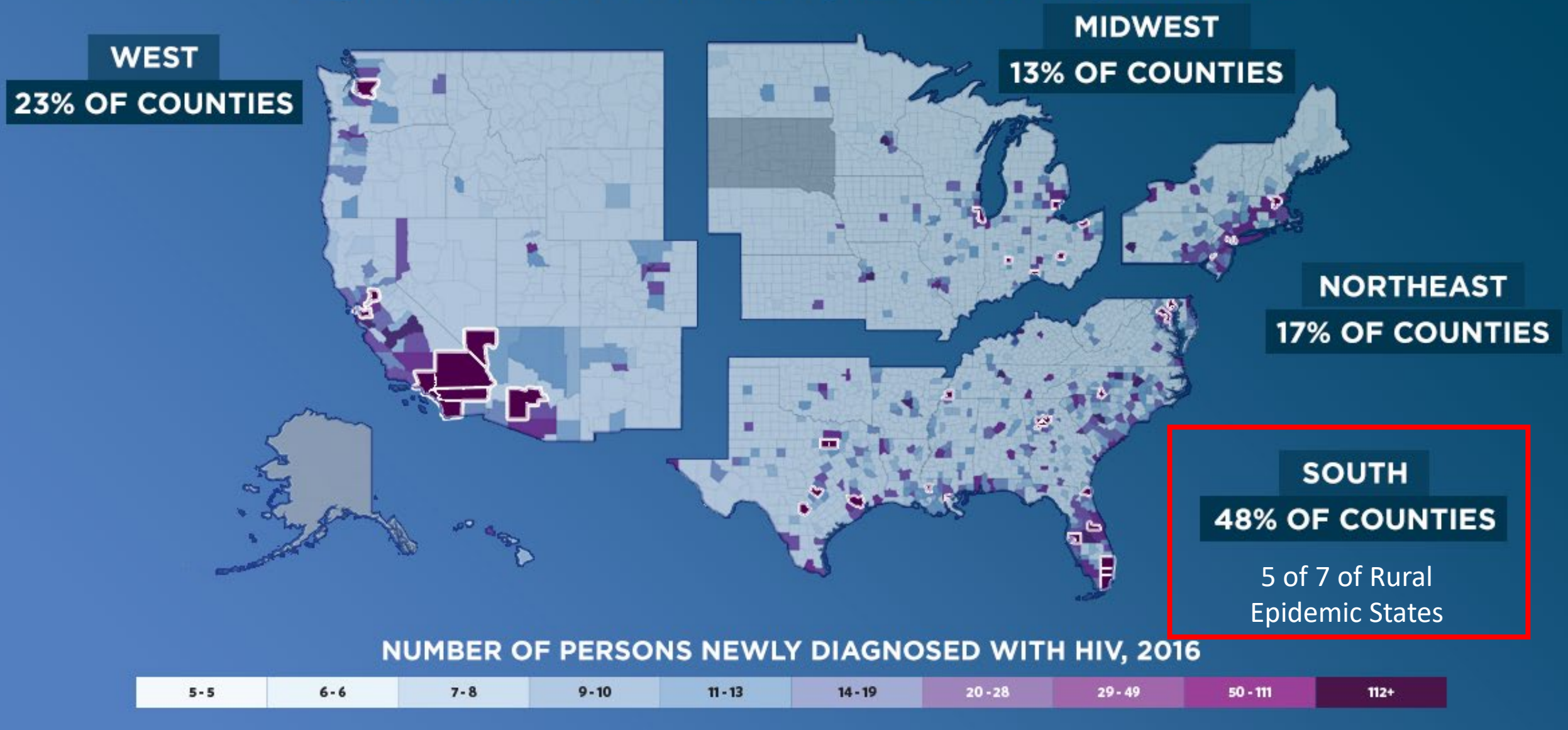
Respond rapidly to detect and respond to growing HIV clusters and prevent new HIV infections.

HIV HealthForce will establish local teams committed to the success of the Initiative in each jurisdiction.

DHHS. Ending the HIV Epidemic: A Plan for America. 2019.

Ending the HIV Epidemic: A Plan for America

Regional Breakdown of the 48 Highest Burden Target Counties

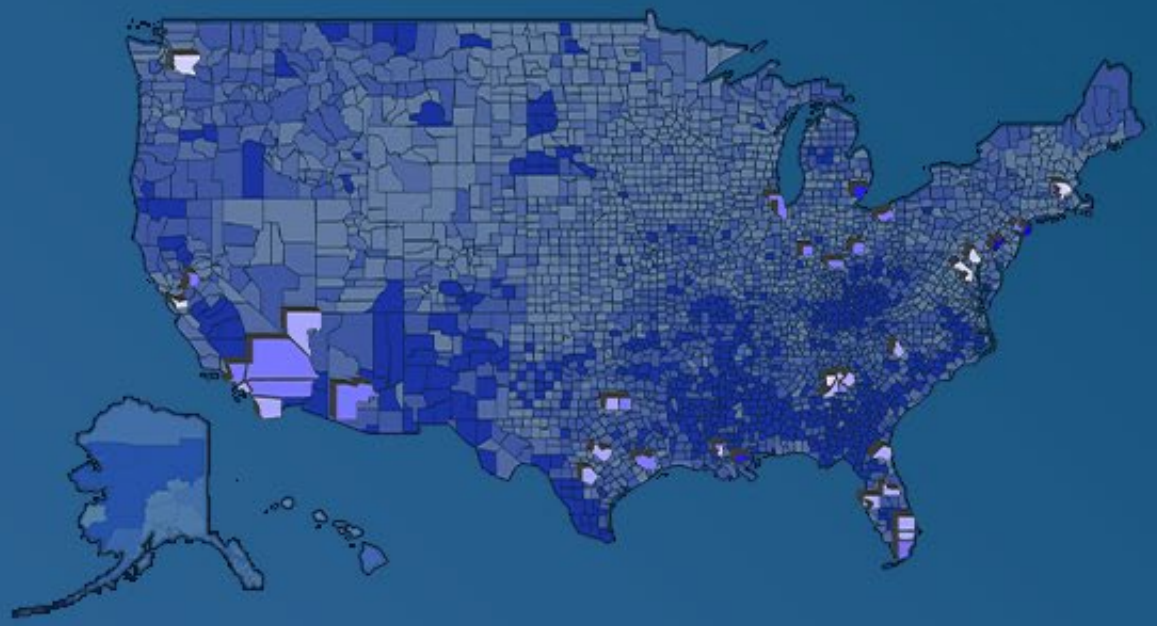


SOURCE: U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

Ending the HIV Epidemic: A Plan for America

48 Highest Burden Counties and D.C.

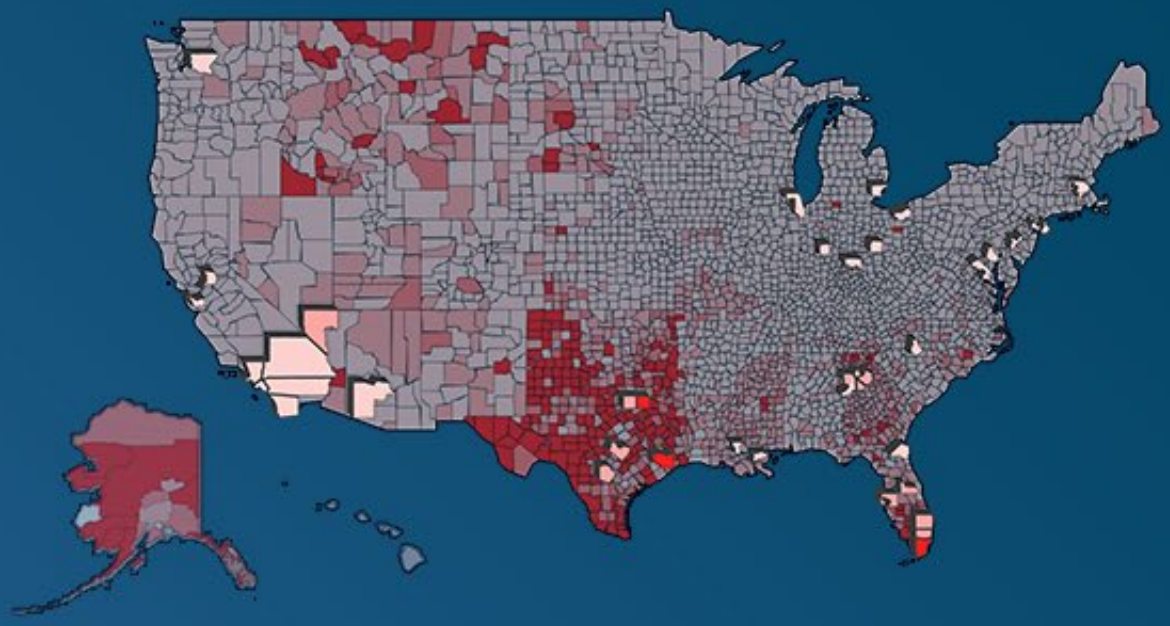
In **67%** of the 48 target counties and D.C., the percent of people **living in poverty** is **higher** than the national average (**14.7%**)



PERCENT OF POPULATION LIVING IN POVERTY, 2015

0 - 12.0	12.1 - 15.0	15.1 - 18.0	18.1+

In **73%** of the 48 target counties and D.C., the percent of people **uninsured** is **higher** than the national average (**9.4%**)

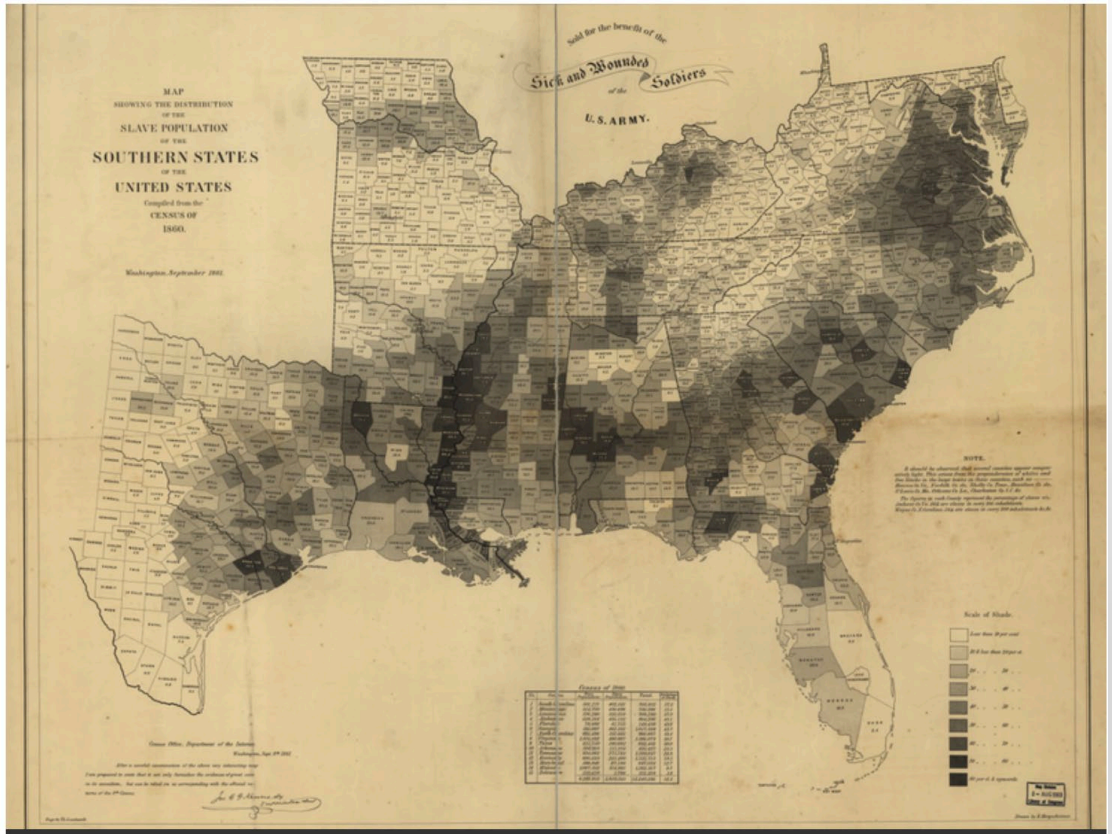


PERCENT OF POPULATION LACKING HEALTH INSURANCE, 2015

0 - 12.0	12.1 - 16.0	16.1 - 20.0	20.1+

Structural Racism

Slavery Expansion



The U.S. Coast Survey map calculated the number of slaves in each county in the United States in 1860. (Library of Congress)

https://www.smithsonianmag.com/history/maps-reveal-slavery-expanded-across-united-states-180951452/

Failing to Remember

#RobertRayford

Article

October 14, 1988

Documentation of an AIDS Virus Infection in the United States in 1968

Robert F. Garry, PhD; Marlys H. Witte, MD; A. Arthur Gottlieb, MD; et al

» Author Affiliations

JAMA. 1988;260(14):2085-2087. doi:10.1001/jama.1988.03410140097031

Guidelines Endorse

DHHS[1]

- ART to be started immediately or as soon as possible after diagnosis (AII)

IAS-USA[3]

- Start ART as soon as possible, **including immediately after diagnosis,** if patient is ready

WHO[2]

- Recommended where feasible same day

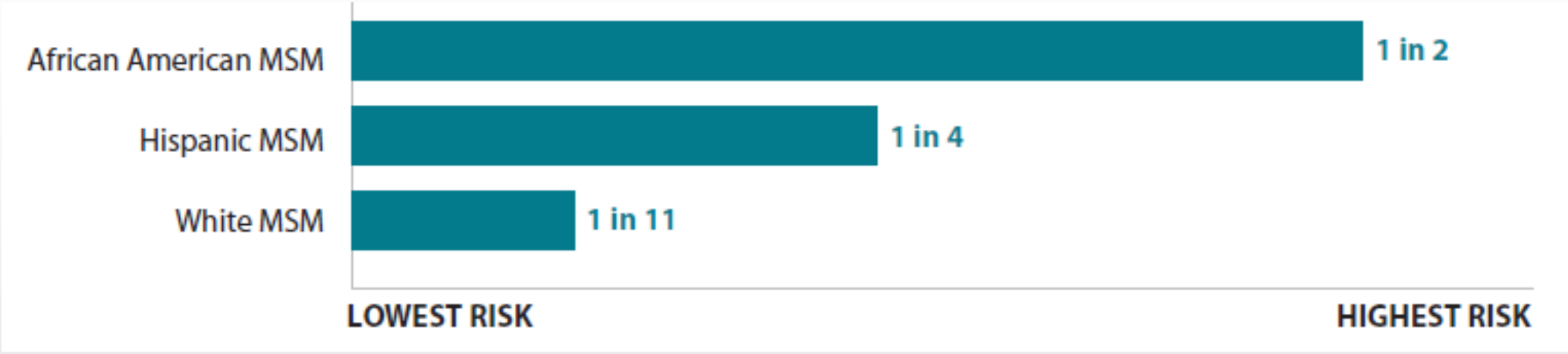
NY State DOH[4]

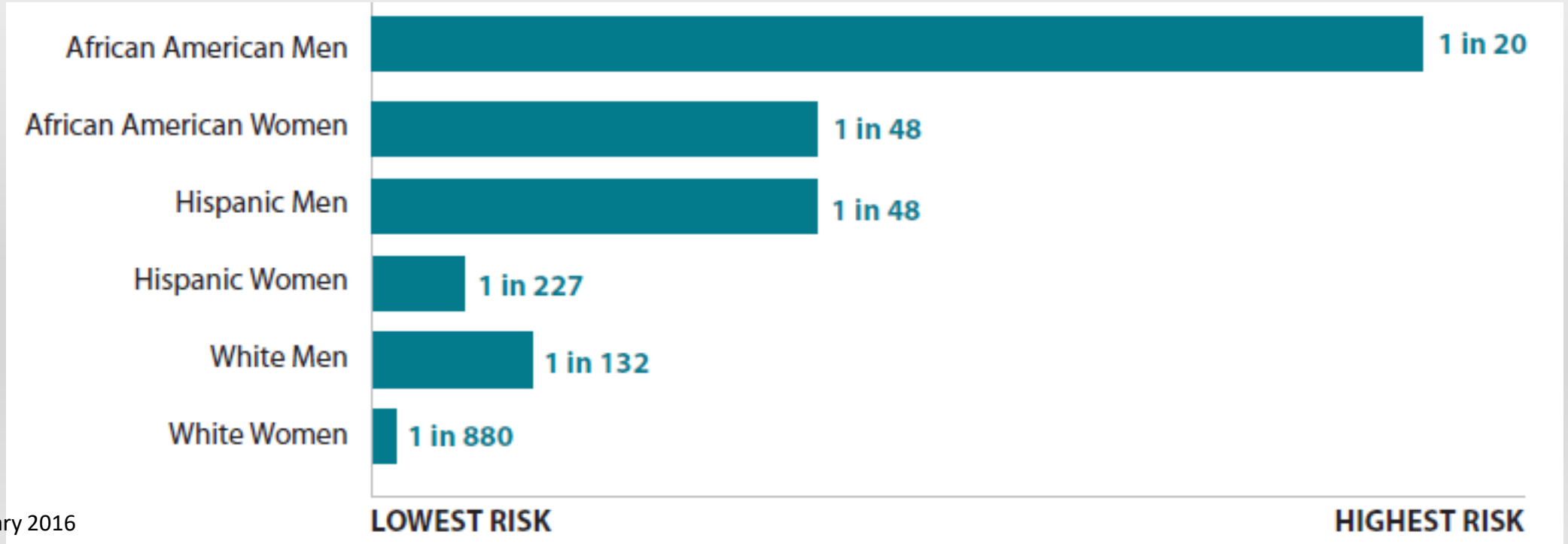
- Offer rapid initiation of antiretroviral therapy (ART)—preferably on the same day (A1) or within 96 hours of diagnosis

1. DHHS Guidelines. December 2019. 2. WHO Guidelines. July 2017. 3. Saag. JAMA. 2018;320:379. 4. Radix A et al. NYSDOH AIDS Institute. 2019


U=U
UNDETECTABLE
=
UNTRANSMITTABLE
A PERSON LIVING WITH HIV WHO HAS AN UNDETECTABLE VIRAL LOAD DOES NOT TRANSMIT THE VIRUS TO THEIR PARTNERS.
IAS
The International AIDS Society is proud to endorse the U=U consensus statement of the Prevention Access Campaign.

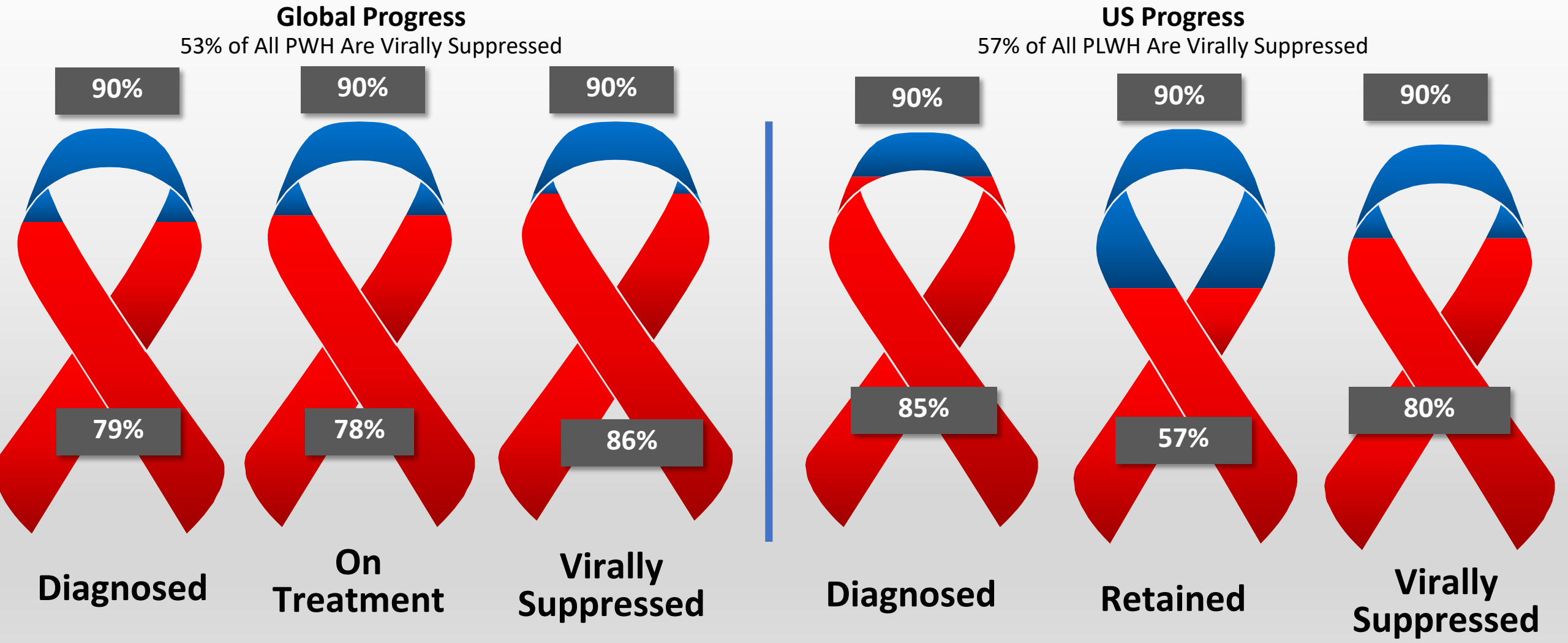
Lifetime Risk of HIV Infection…





CDC. February 2016

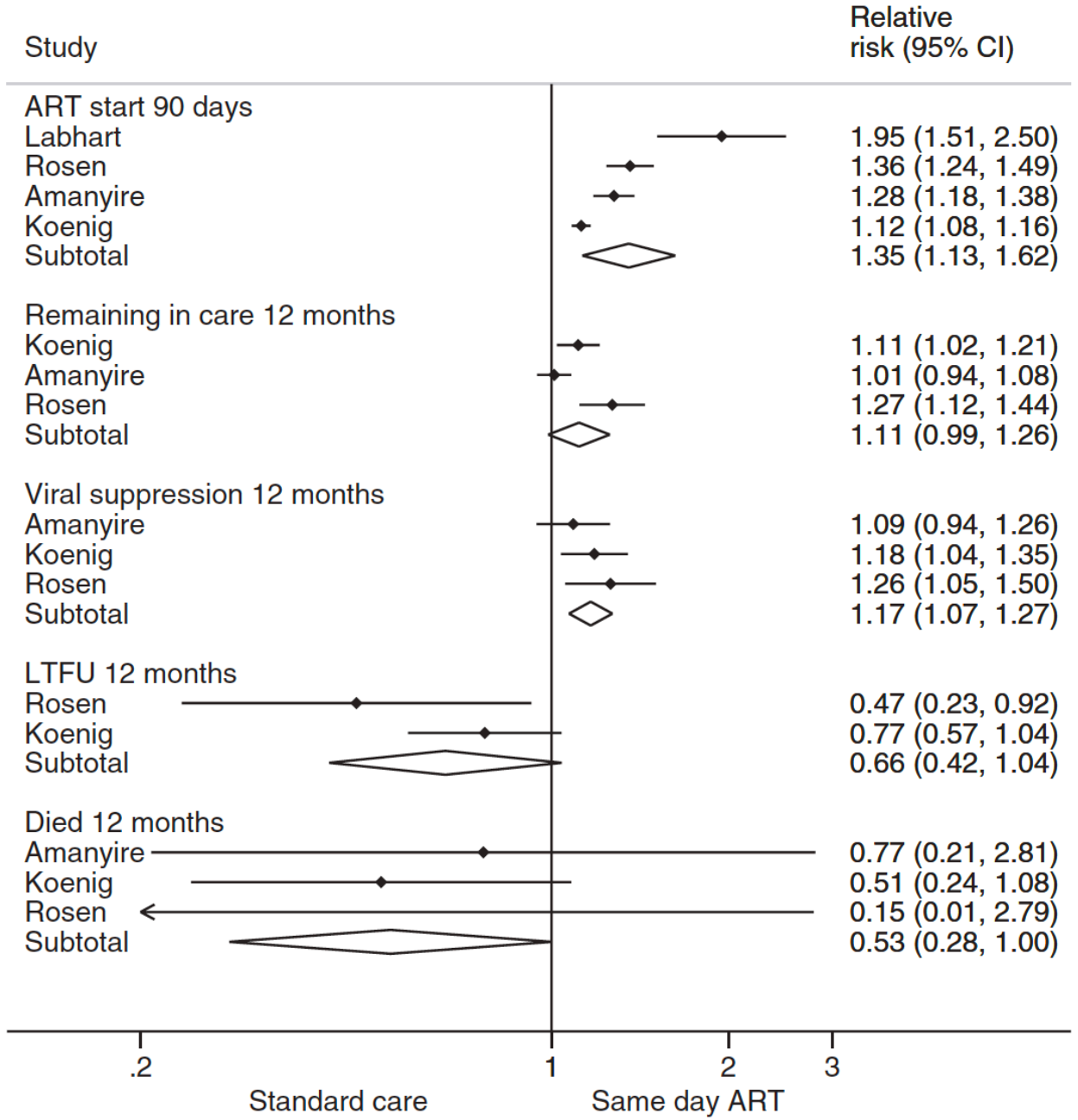
Interpret Outcomes in Context of Setting



Marsh K et al. Global Regional and County Level 90-90-90 estimates for 2018. *AIDS* 2019.
CDC. 2017. HIV Surveillance Supplemental Report. 2017;22(2). https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Accessed May 3, 2018.

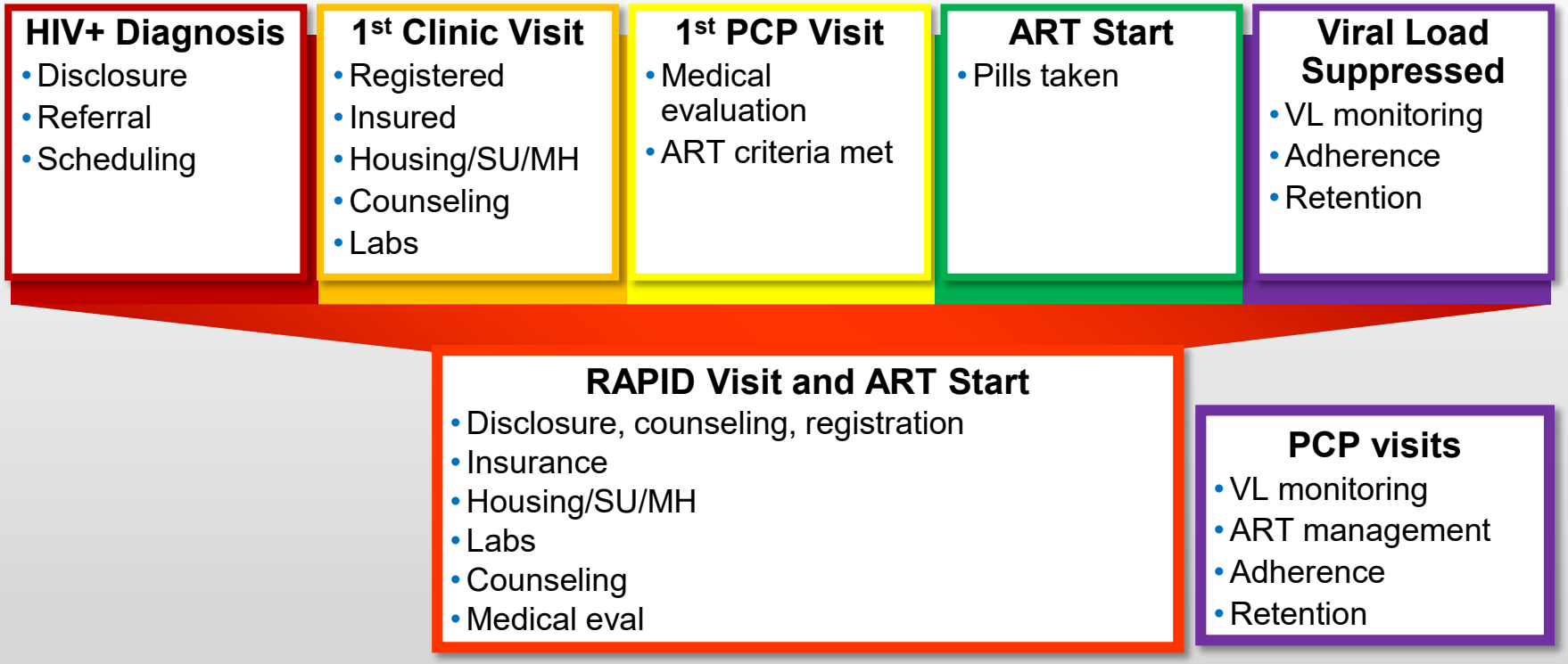
Adapted from Carlos del Rio

RCTs: Global Setting



Ford N et al. *AIDS* 2018

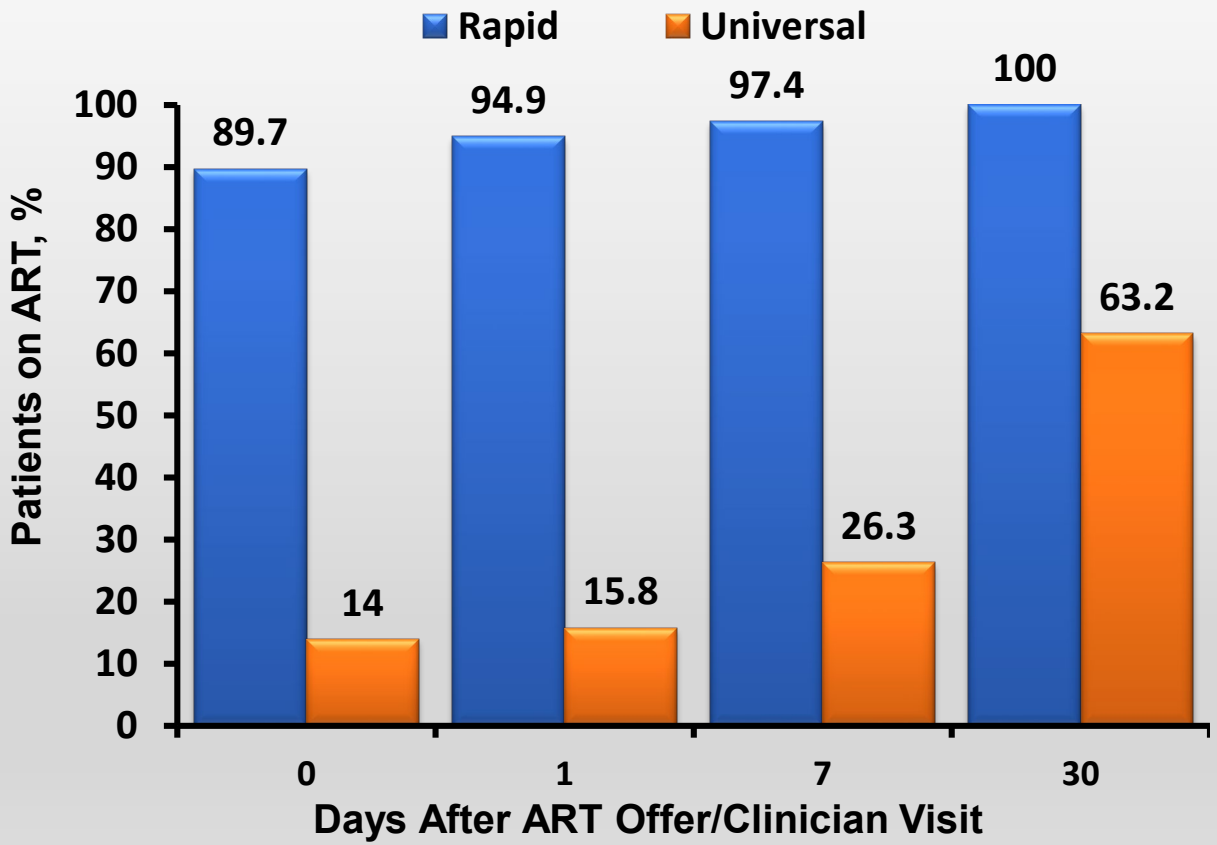
SFGH RAPID Model



MH, mental health; PCP, primary care provider; SU, substance use.

Pilcher CD, et al. *J Acquir Immune Defic Syndr.* 2017;74(1):44-51.

SFGH: RAPID – Uptake of Same day ART

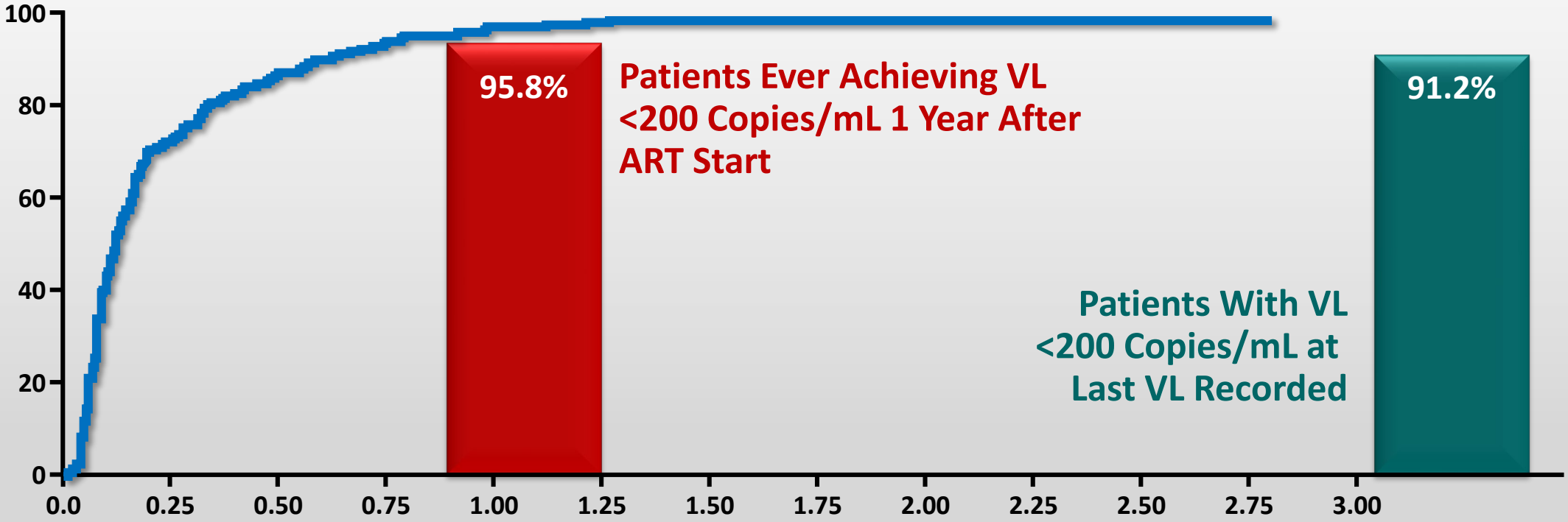


Key Sociodemographics

	RAPID n=39	Universal n=47
Homelessness	11 (28%)	13 (25%)
Uninsured	39 (100%)	47 (100%)
Illicit Substance Use	18 (46%)	18 (38%)

Pilcher CD, et al. *J Acquir Immune Defic Syndr*. 2017;74(1):44-51.

RAPID: Quick and Durable Viral Suppression 2013 – 2017 SF DPH



N = 255

Coffey S, et al. *AIDS*. 2019;33(5):825-832.

Grady Infectious Disease Program: The Ponce de Leon Center

Who do we serve?

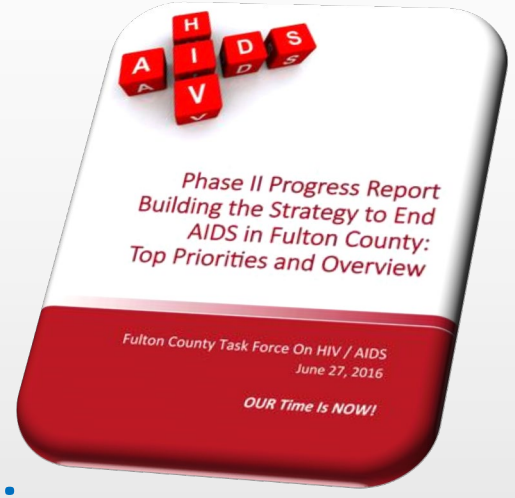
- 71% Male, 28% Female, <1% Transgender
- 84% Black/African American, 9% White, 5% Latino
- 14% <= 24, 35% 25-44, 51% >=45 years of age
- 32% < FPL, 60% < 2X FPL
- 42% uninsured, 26% Medicaid, 21% Medicare
- 64% Stage 3 (AIDS)

Medicaid NONEXPANSION State

REACH: Rapid Entry and ART in Clinic for HIV

Goals

1. Clinician visit and ART access within 72 hours of clinic presentation
2. Decrease time to viral suppression



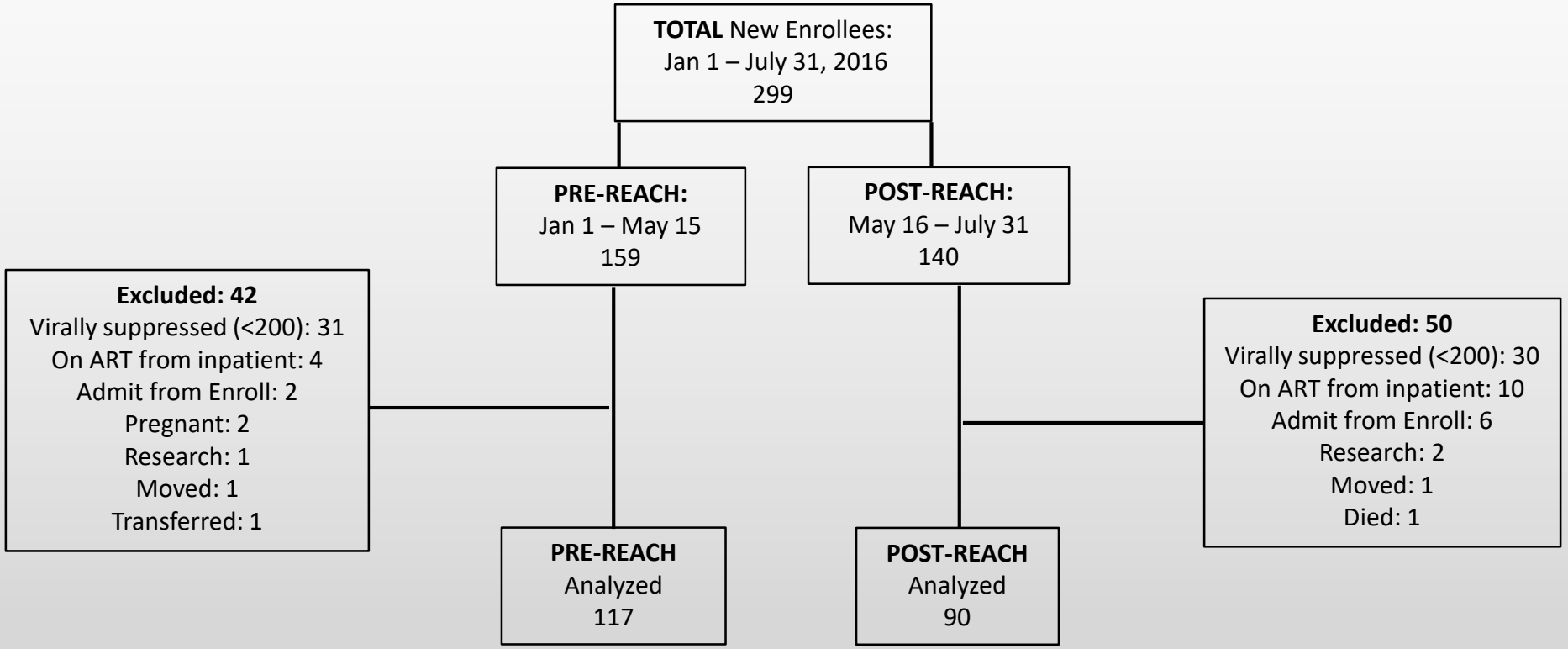
Health System Changes to Facilitate Program Implementation

ACTION	LEVEL
Remove eligibility restrictions for clinic enrollment	**EMA Ryan White office**
Loosen administrative requirements for clinic enrollment	EMA Ryan White office; **hospital system**
Remove TB skin test as requirement for clinic enrollment	**Clinic administration**
Enhance access to *New Patient* provider visits	Hospital system; clinic administration
Enhance provider education on *Rapid Starts*	**Clinician**
Enhance support for accessing ART, regardless of payer	**Pharmacy administration**
Continue access to ongoing ART-adherence education	**Nursing**

EMA, eligible metropolitan area; TB, tuberculosis.

Colasanti J, et al. *Open Forum Infect Dis.* 2018;5(6):ofy104.

Figure 1


TOTAL New Enrollees:
Jan 1 – July 31, 2016
299
PRE-REACH:
Jan 1 – May 15
159
POST-REACH:
May 16 – July 31
140
Excluded: 42
Virally suppressed (<200): 31
On ART from inpatient: 4
Admit from Enroll: 2
Pregnant: 2
Research: 1
Moved: 1
Transferred: 1
Excluded: 50
Virally suppressed (<200): 30
On ART from inpatient: 10
Admit from Enroll: 6
Research: 2
Moved: 1
Died: 1
PRE-REACH
Analyzed
117
POST-REACH
Analyzed
90

REACH Cohort Characteristics, N=207

	Characteristic	Median *or* n(%)
Young Black Men	Age	35 (25-45)
	African American	188 (91%)
	Male	165 (80%)
Socioeconomic Challenges	Uninsured (Ryan White only)	118 (57%)
	Unstable housing	126 (61%)
	Income	$8,796
Psychosocial Challenges	Active substance use	91 (44%)
	Mental health disorders	54 (26%)
Biomedical Complexity	CD4 count	146 cells/μL
	ART experienced	83 (40%)

All patients newly enrolled in the clinic from January 1–July 31, 2016: **N=299**
Patients in 6 week REACH pilot: **N=90**

SCALE IS A CHALLENGE

Colasanti J, et al. *Open Forum Infect Dis*. 2018;5(6):ofy104.

ARVs During Rapid Entry

	Pre-REACH N (%)	Post-REACH N (%)
Initiated ART	111 (95)	85 (94)
Anchor		
TDF	67 (60)	36(47)
TAF	16 (14)	22 (24)
ABC	27 (24)	26 (29)
AZT	1 (1)	--
NRTI sparing		1 (1)
Backbone		
DTG	55 (49)	49 (59)
EVG	27 (24)	22 (26)
DRV	27 (24)	12 (14)
EFV	1 (0.8)	1 (1.2)
Lop/r	1 (0.8)	--
RPV	--	1 (1.2)

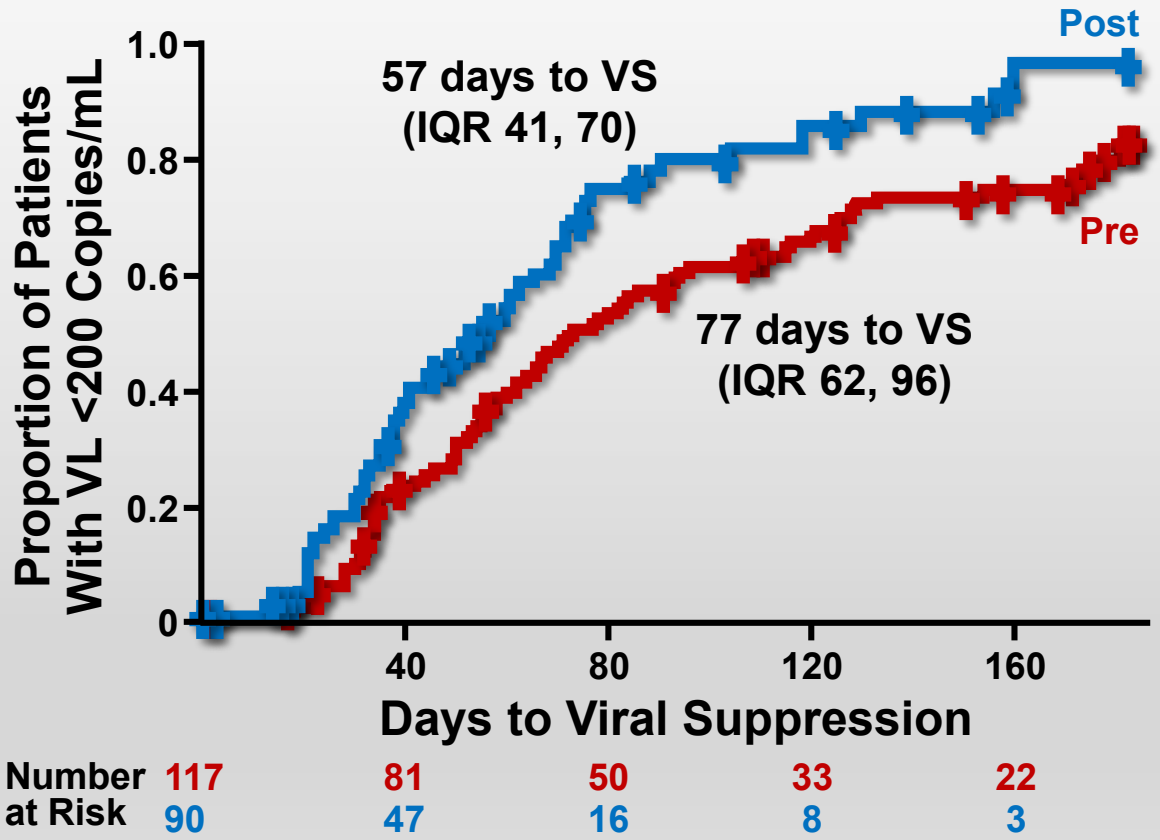
Colasanti J, et al. *Open Forum Infect Dis.* 2018;5(6):ofy104. Supplemental material

Results: Process Improvement ↓ Time to VS

Days to Clinical Events

	Pre-REACH N=117	Post-REACH N=90	
Event	**Mean (95% CI) *or* n(%)**	**Mean (95% CI)**	***P* value**
Days to 1st scheduled provider visit	14.0 (11.9, 16.2)	3.7 (1.1, 6.2)	<0.0001
Days to 1st attended provider visit	12.1 (6.4, 22.8)	2.1 (0.9, 4.4)	<0.0001
Days to ART start	22.0 (12.7, 38.1)	4.4 (2.3, 8.4)	<0.0001
Attended 1st scheduled visit	85 (73)	73 (81)	NS
Viral suppression	87 (74)	61 (68)	NS

Days to Viral Suppression



ICI, confidence interval; QR, interquartile range.

Colasanti J, et al. *Open Forum Infect Dis.* 2018;5(6):ofy104.

Late Presenters Need More

	Early			Late		
	≤ 90 days after diagnosis			> 90 days after diagnosis		
	Pre-REACH n = 47	Post-REACH n = 29		Pre-REACH n = 70	Post-REACH n = 61	
Outcomes	**Median (IQR) or n (%)**		***P* value**	**Median (IQR) or n (%)**		***P* value**
Days to 1st scheduled provider visit	12 (4, 19)	4 (2, 7)	<.0001	17 (9, 21)	4 (1, 7)	<.0001
Days to 1st attended provider visit	14 (6, 20)	5 (2, 7)	0.0003	20 (10, 29)	4 (2, 10)	<.0001
Attended 1st scheduled visit	37 (79)	26 (90)	0.3480	48 (69)	47 (77)	0.2783
Days to ART initiation	17 (11, 27)	5 (3, 10)	0.0002	24 (13, 41)	7 (3, 22)	<.0001
Viral Suppression	41 (87)	24 (83)	0.7392	46 (66)	37 (61)	0.5489

86% **64%**

Colasanti J, et al. *Open Forum Infect Dis.* 2018;5(6):ofy104.

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86% **64%**

Colasanti J, et al. *Open Forum Infect Dis.* 2018;5(6):ofy104.

More needed…Especially Re-entry

Cox proportional hazard model: Time to VS

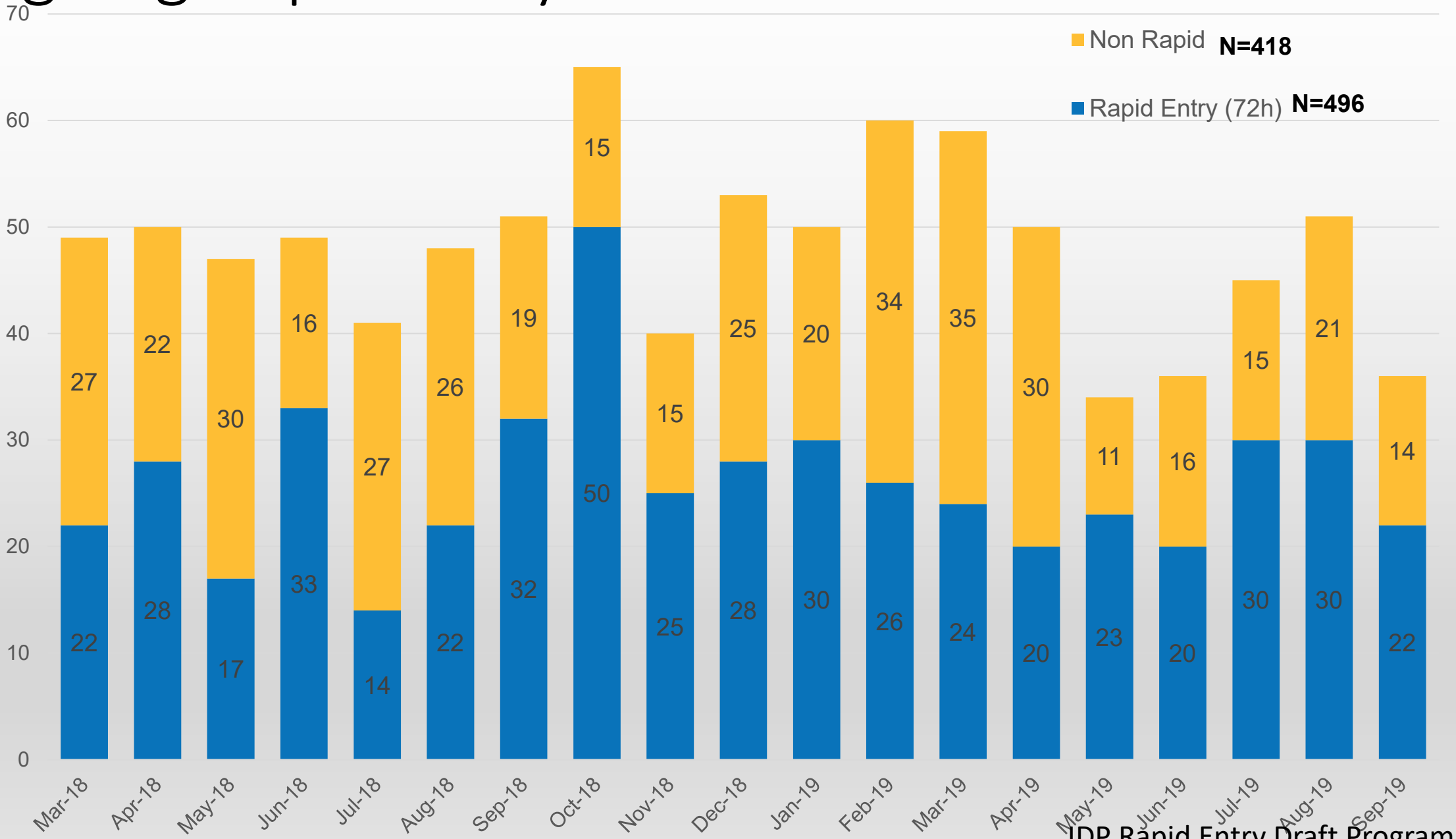
Variable	Adjusted Hazard Ratio	95% Confidence Interval		P value
Post-REACH	1.825	1.276	2.609	0.001
ART Naïve	1.733	1.192	2.518	0.004
INSTI use	1.477	0.925	2.358	0.103
Baseline VL	0.842	0.711	0.997	0.046

Adjusted Logistic Regression: Achieving VS

Variable	Adjusted Odds Ratio	95% Confidence Interval		P value
Post-REACH	0.821	0.418	1.611	0.5661
ART Naïve	2.231	1.131	4.400	0.0205
INSTI use	2.606	1.204	5.641	0.0150
Baseline VL	1.243	0.871	1.773	0.2303
Black/African American	0.484	0.127	1.852	0.2894

Colasanti J, et al. *Open Forum Infect Dis.* 2018;5(6):ofy104. Supplemental material

Ongoing Rapid Entry at IDP



IDP Rapid Entry Draft Programmatic data

CrescentCare Start Initiative December 2016

- FQHC (started as ASO) w/ robust support services available
- Medicaid EXPANSION

CrescentCare Start Initiative (CCSI):
Patients newly diagnosed with HIV are seen by a provider within 72 hours (optimally same-day) and provided 30 days of ART.

Early Intervention Services (EIS):
Same protocol but patients contacted our clinic over 72 hours since diagnosis.
Range: 4 days – 25 years

Adapted from: J. Halperin

Procedures/Evaluation

Medical Provider Visit:

- HIV Lifecycle, importance of adherence, U=U discussed
- Comorbidities assessed
- Physical Examination
- TAF/FTC/DTG recommended by medical leadership (30 day-supply)
- Provider option to not rx, alter medications if suspected resistance
- First Dose DOT

Post-Provider Visit:

- Enroll in insurance programs
- Intake Labs obtained
- Social Work services for those with urgent needs

- Inclusion:
  - Enrolled 12/2016 – 2/2018
  - 6 month lab f/u at crescent care
- CCSI 126
  - 4 lost to f/u
- EIS 69
  - 1 died after hospital D/C
  - 1 declined ART on day #1

Adapted from: J. Halperin

CrescentCare START: Baseline

	CCSI (n=126)	EIS (n = 69)
Age, median	29	29
Female	27 (21.4)	10 (14.5)
African American	81 (64.3)	48 (69.9)
Latinx	15 (11.9)	7 (10.1)
MSM	73 (57.9)	42 (60.9)
STI at entry	48 (38.1)	32 (46.4)
<100% FPL	49 (39)	25 (36)
Uninsured	65 (52)	38 (56)
Mental health Dx	***25 (20)***	***23 (33)***
Baseline CD4	***444 (265, 640)***	***271 (124, 459)***

P < 0.05

Halperin J et al. *OFID*. 2019

CD4 Count, Viral Suppression, Transmitted Resistance

CCSI

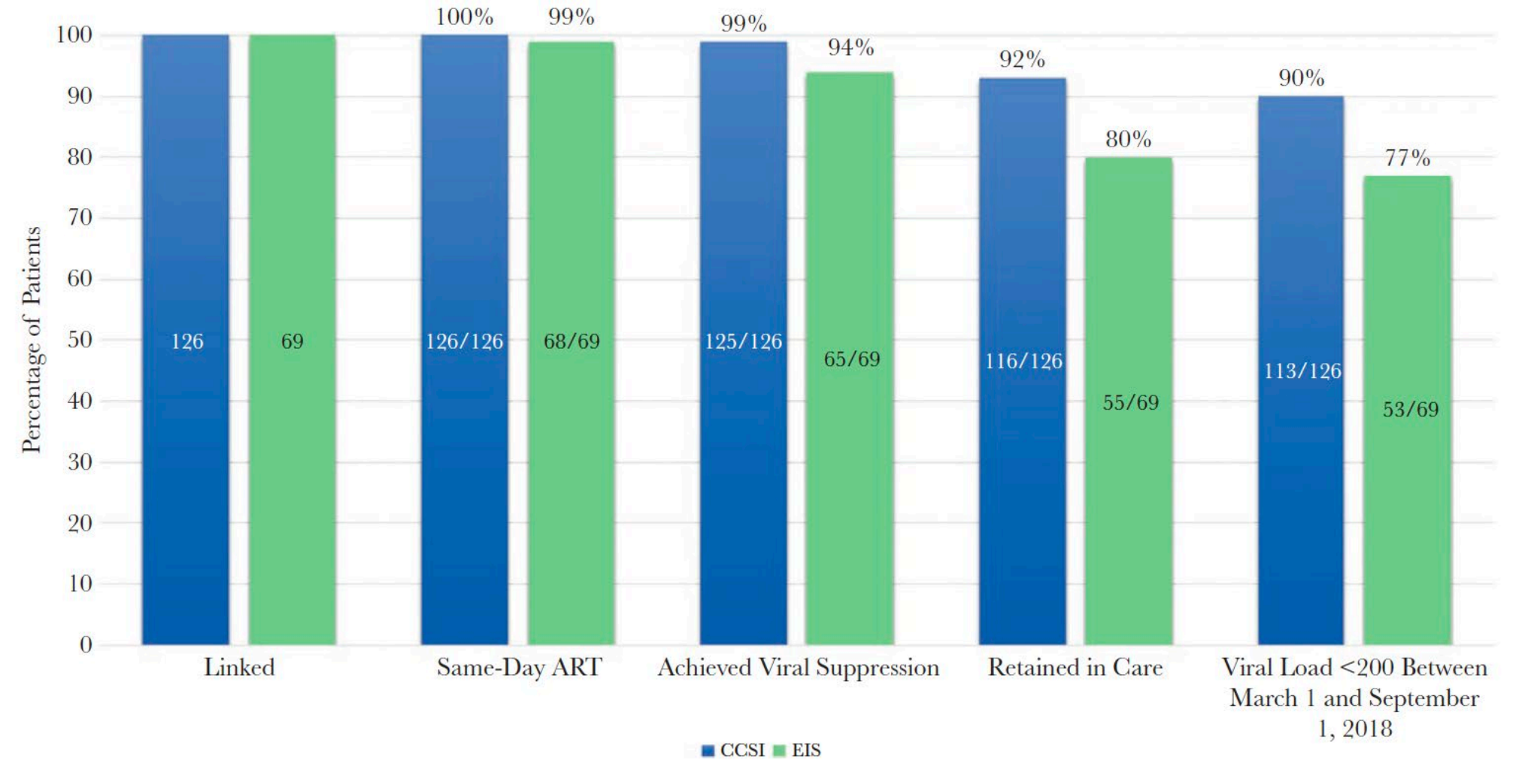
- All but two patients received TAF/FTC + DTG
- 118/126 genotypes were performed and reviewed.
- 22/118 (19%) with transmitted resistance
- 18 with NNRTI resistance
- 3/22 with M184V/I with two previously on PrEP
- 4/22 with multiple PI mutations including L90M
- All patients with transmitted resistance achieved viral suppression.
- No ART changes due to renal/hepatic toxicity

EIS

- All but three patients received TAF/FTC + DTG
- 63/69 genotypes were performed
- 6/63 (9.5%) with transmitted resistance.
- 5 with NNRTI mutations
- 2/6 with M184V/I no previous PrEP exposure
- All patients with transmitted resistance achieved viral suppression
- No ART changes due to renal/hepatic toxicity

Adapted from: J. Halperin

CCSI Continuum of Care



Halperin J et al. *OFID*. 2019

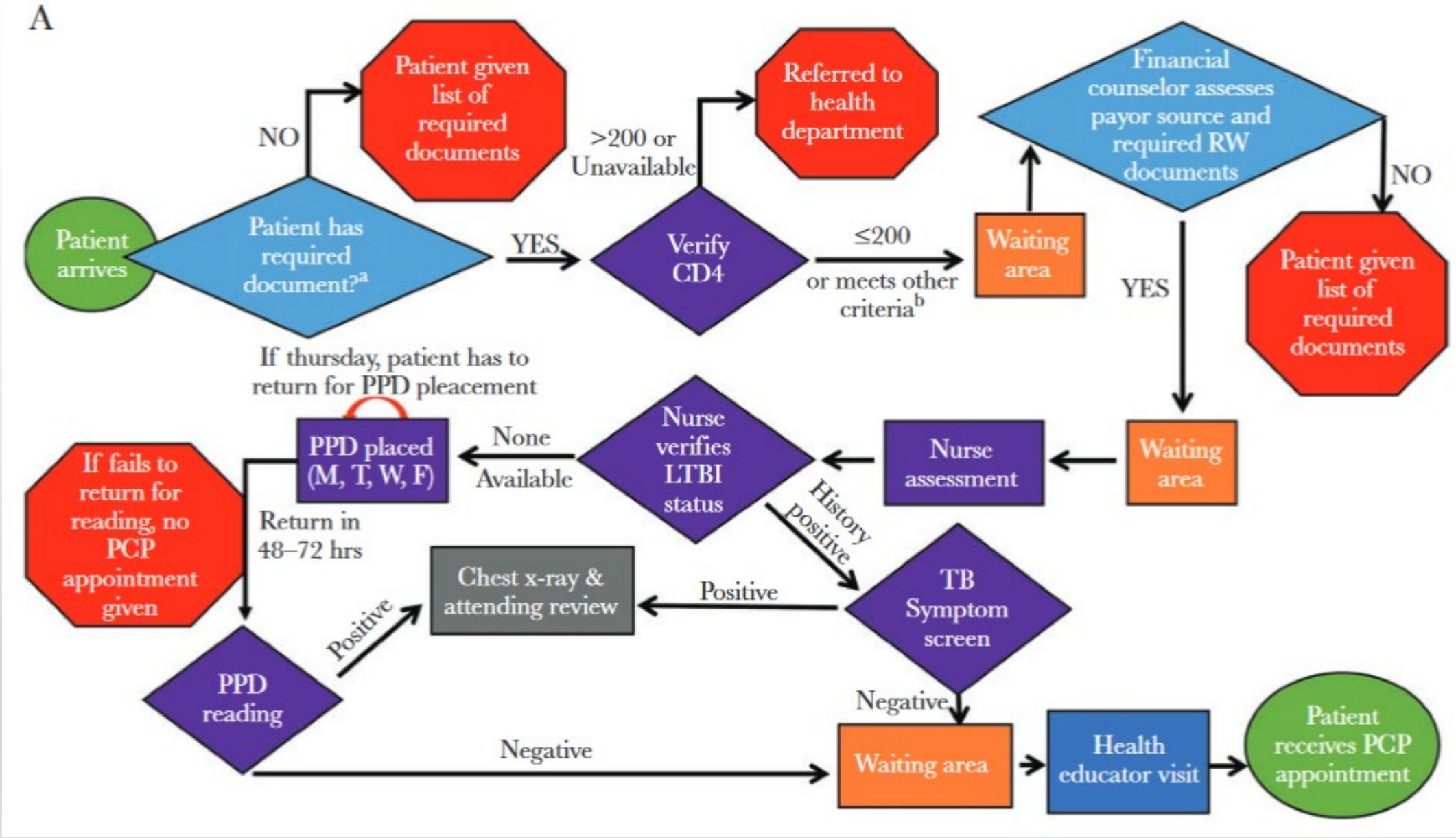
Barriers to Implementation

- **Structural/systemic**
  1. HIV testing/diagnosis occurs off-site; ie, referral to clinic
  2. Complex eligibility criteria - eg, CD4 count, income, residence
  3. Access to medications without payer source
  4. Scheduling and provider availability

- **Provider/staff beliefs**
  1. “That’s how we’ve always done it.”
  2. Preparatory lab results must be known; ie, serum creatinine, hepatitis B and C serology, genotype
  3. Latent TB infection screening must be performed first

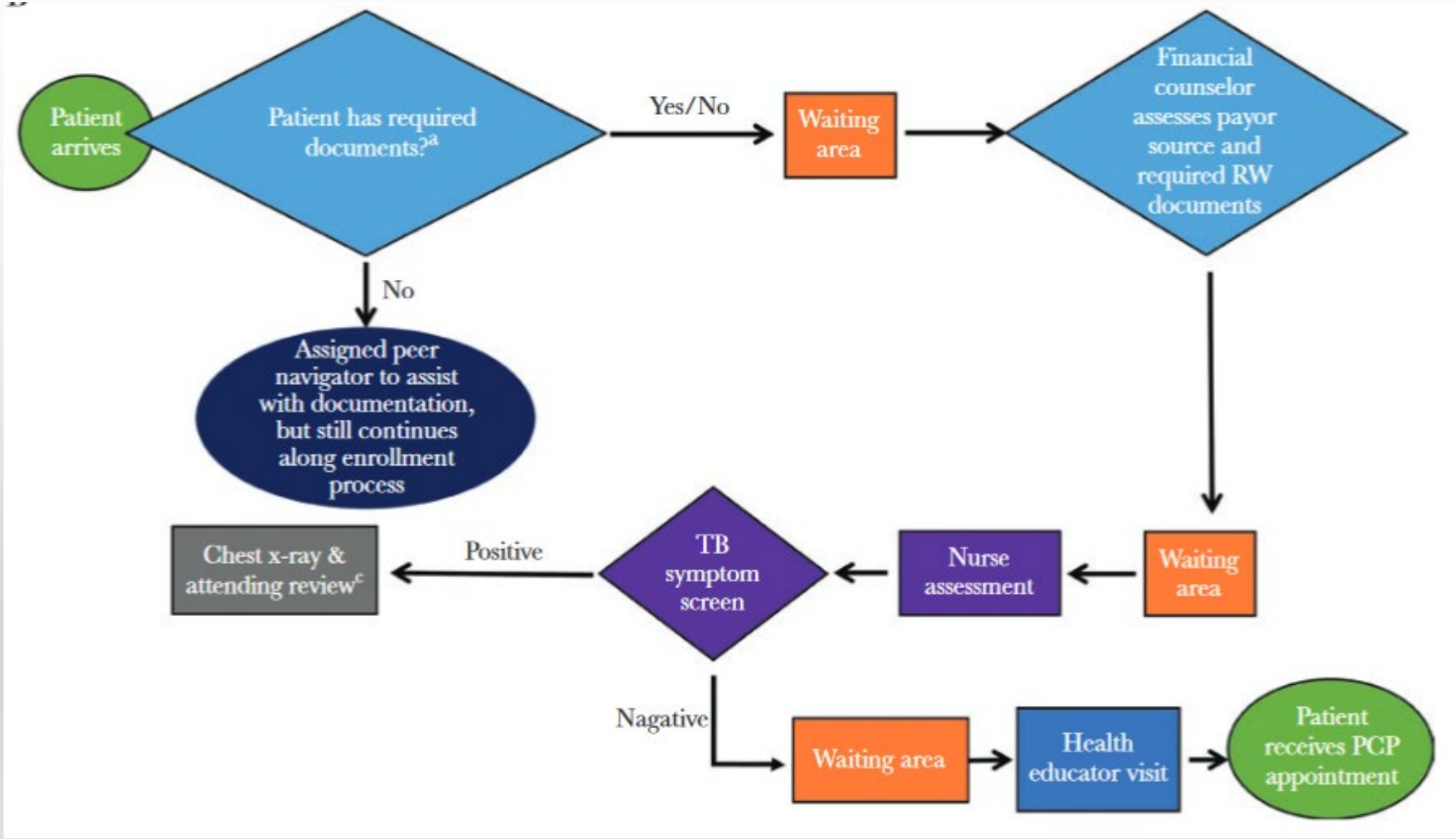
- **Patients’ attitudes and beliefs**
- **Patients’ psychosocial comorbidities**
  1. Unstable housing
  2. Food insecurity
  3. Mental illness
  4. Substance use

Pre-Rapid Entry Implementation

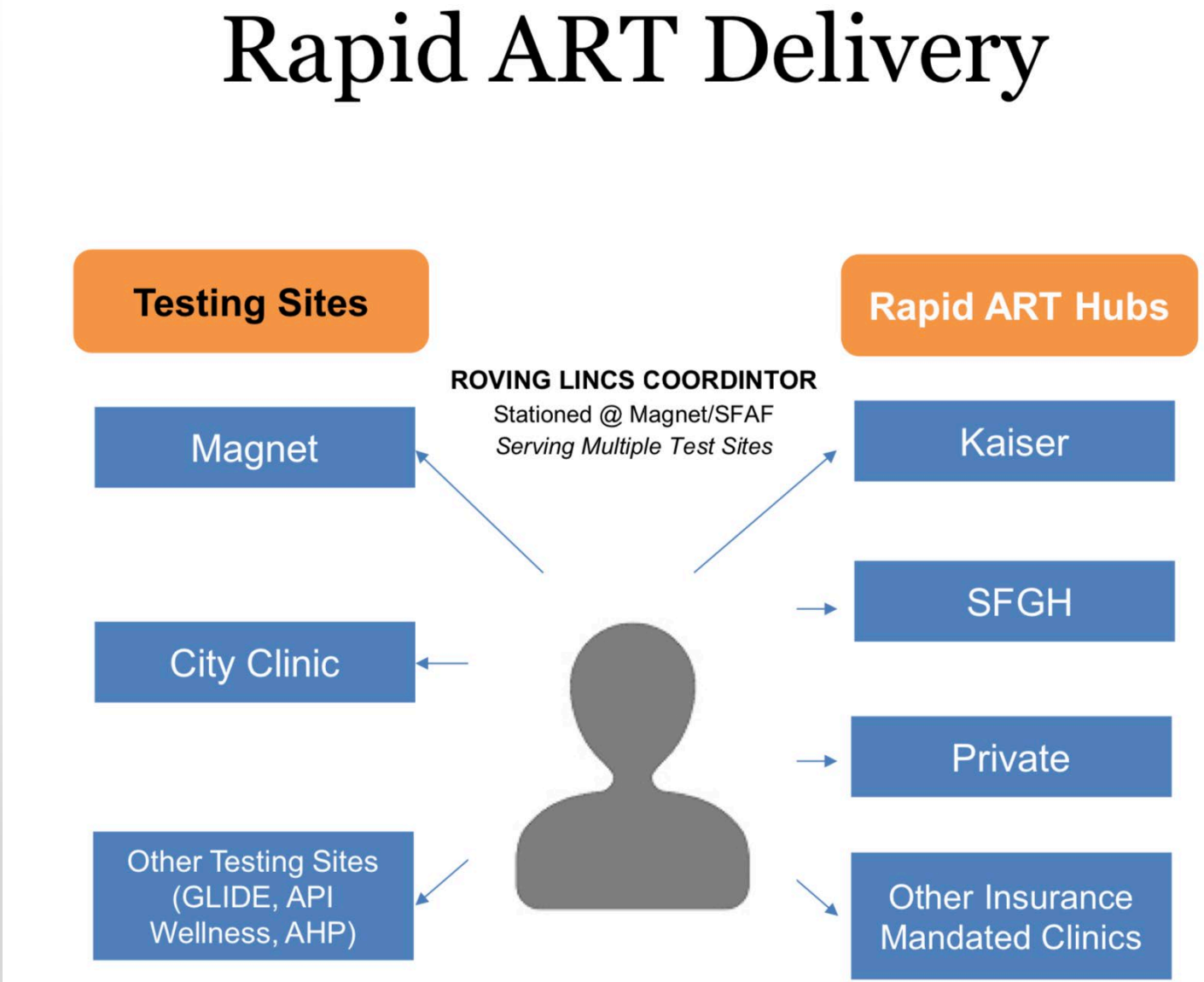


= Step in enrollment process when patient could be turned away and not given PCP appt until step completed

Post Implementation Patient Enrollment



SF DOH: Community-wide coordination

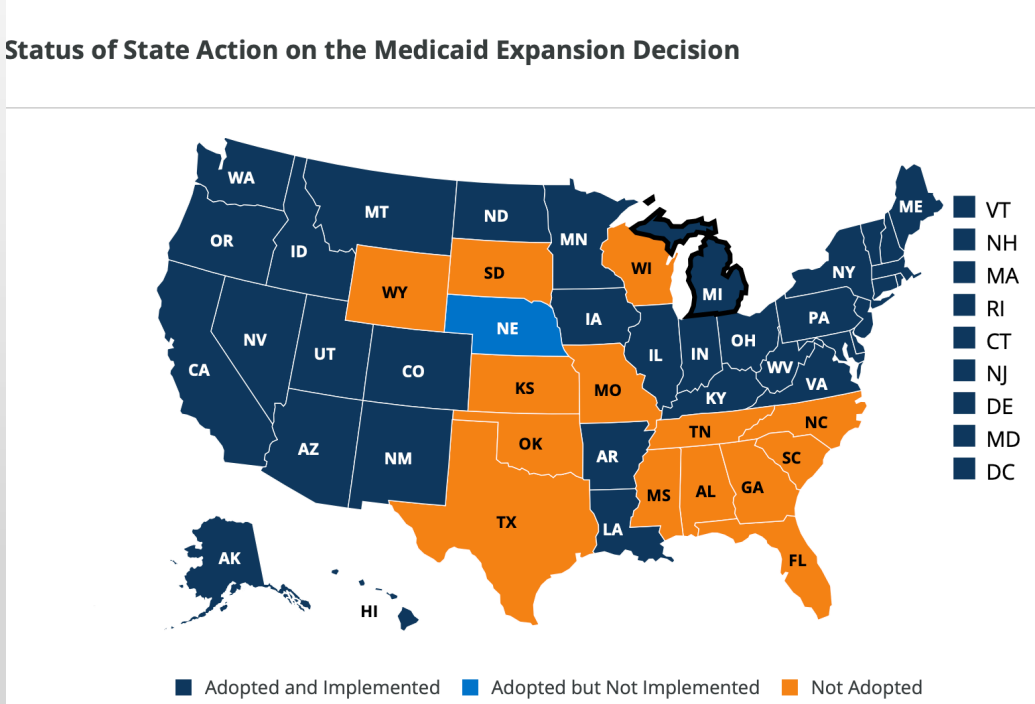


LINCS – linkage, integration, navigation, comprehensive services

Slide: adapted from Buchbinder S. Getting to Zero: https://www.sfdph.org/dph/files/sfchip/GettingToZero-HIV.pdf

How to get Antiretrovirals

- No payer source and no documentation to enroll in Ryan White (RW)
  - Manual patient assistance program
    - Can be time intensive, but not impossible
  - Starter packs: need to find funding source for this
    - Expedited insurance applications (eg, San Francisco)
- Enrolled in RW, but awaiting *AIDS Drug Assistance Program* (ADAP) application completion
  - Stop-gap medications
  - Co-pay cards
- Medicaid expansion (eg, Louisiana)
  - "…a gift from the heavens." −*Halperin*



KFF 2019: state of Medicaid expansion

Clinical Guidance – what to start

DHHS[1]

- Avoid NNRTI-based regimens
- Recommended regimens[a]
  - BIC/FTC/TAF
  - DTG + tenofovir[c]/FTC
  - DRV/r or DRV/c[b] + tenofovir[c]/FTC

IAS-USA[3]

- Recommend unboosted INSTI regimens (other than DTG/ABC/3TC) as initial therapy
  - BIC/FTC/TAF ***or*** DTG + FTC/TAF

1. DHHS Guidelines. December 2019. . Saag. JAMA. 2018;320:379

Key Facilitators of RAPID Intervention

- Same-day appointments
- Flexible provider scheduling (on call backup)
- ART-regimen preapproval prior to genotyping or lab testing
- Availability of ART starter packs
- Patient navigator
- Accelerated process for health insurance initiation
- Observation of first ART dose in clinic (recommended)
- Guarantee sustained access to ART

Some fearful of rapid entry – it's all about context

Too fast to stay on track? Shorter time to first anti-retroviral regimen is not associated with better retention in care in the French Dat'AIDS cohort

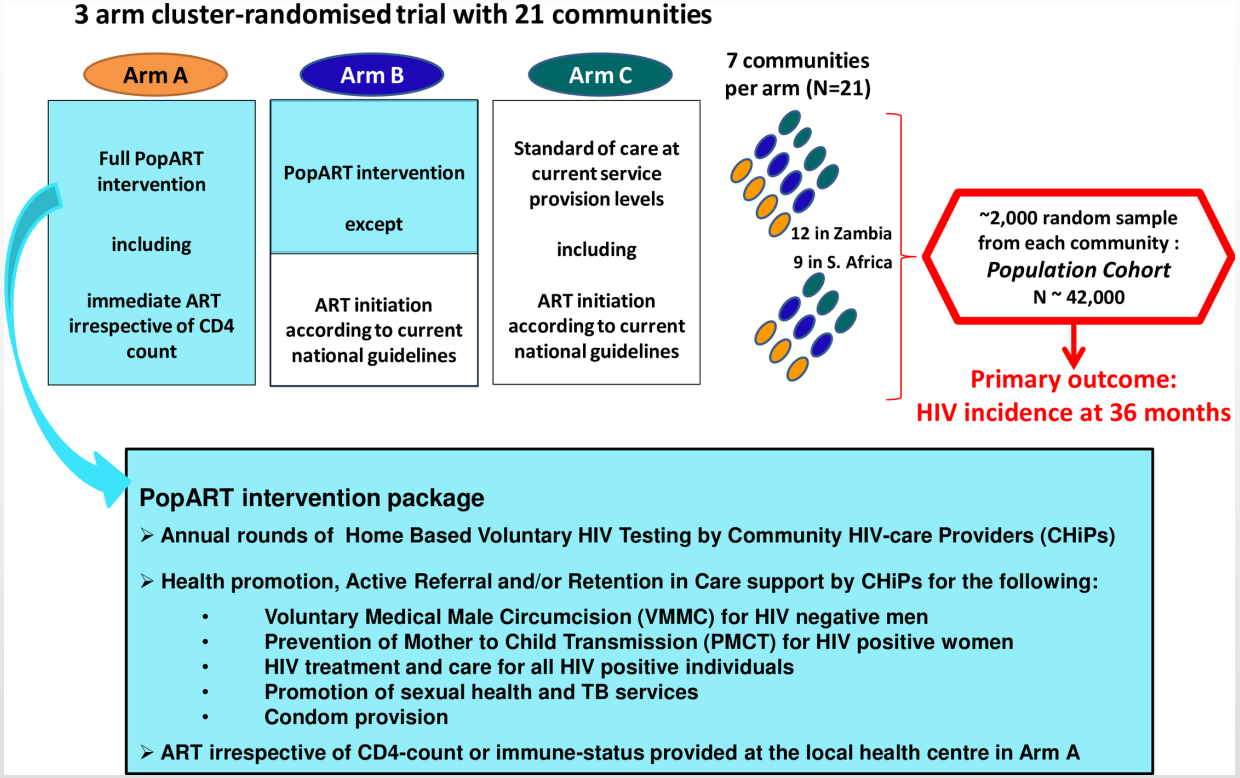
L. Cuzin, L. Cotte, C. Delpierre, C. Allavena, M-A. Valantin, D. Rey, P. Delobel, P. Pug on behalf of the Dat'AIDS Study group

Published: September 6, 2019 • https://doi.org/10.1371/journal.pone.0222067

CD4 cell count at HIV diagnosis/ µL		<200 N = 1594	200–350 N = 1589	350–500 N = 1593	>500 N = 1588	P
Age at diagnosis (Years, median, IQR)		41 (33–51)	37 (29–47)	34 (27–44)	34 (27–43)	<0.0001
End of study (%)	In care	75.2	76.4	75.5	77.8	<0.0001
	Changed place of care	7.7	9.2	10.7	9.3	
	Lost to follow-up	11.8	12.6	12.9	12.3	
	Dead	5.3	1.8	0.9	0.6	
Sex and way of acquisition (%)	MSM[a]	15.8	23.8	29.1	31.3	<0.0001
	MSW[b]	37.7	25.6	20.1	16.7	
	Women	29.6	26.4	22.4	21.6	
	Trans gender M>W	19.5	29.3	31.7	19.5	
ART 3rd drug (%)	bPI[c]	69.7	58.0	51.2	44.2	<0.0001
	NNRTI[d]	8.5	22.0	25.7	30.7	
	INSTI[e]	13.7	14.5	17.2	20.1	
From diagnosis to first visit (days, median IQR)		9 (3–19)	12 (6–22)	12 (5–22)	13 (6–27)	<0.0001
Time from first visit to ART (days, median, IQR)		14 (7–27)	21 (7–56)	42 (14–144)	80 (18–364)	<0.0001
From diagnosis to undetectable VL (days, median IQR)		228 (150–300)	212 (132–336)	239 (140–419)	289 (142–634)	<0.0001

Time from first medical visit to first ART (days)		< 9 N = 1881	9–27 N = 1784	28–90 N = 1800	> 90 N = 1780	P
Alive and in care at month 12 after ART prescription (%)		79.9	84.5	85.9	85.2	<0.0001
Time from diagnosis to undetectable VL (days; median, IQR)		194 (108–351)	210 (130–361)	232 (152–357)	527 (311–924)	<0.0001
Length of first ART (months; median, IQR)		14 (5–32)	17 (7–35)	21.5 (7–39)	22 (7–42)	<0.0001
End of study situation	Dead (%)	2.2	3.1	1.9	0.9	0.002
	LTFU (%)	14.3	12.4	13.4	12.5	0.002
VL < 50 copies/mL after 6 months of ART (%)		72.1	69.8	78.9	79.6	<0.0001
VL < 50 copies/mL after 12 months of ART (%)		78.0	81.5	84.1	81.4	0.12
VL < 50 copies/mL after 18 months of ART (%)		83.7	85.5	86.9	87.9	0.15

HPTN 071: PopART -= Universal Test and Treat

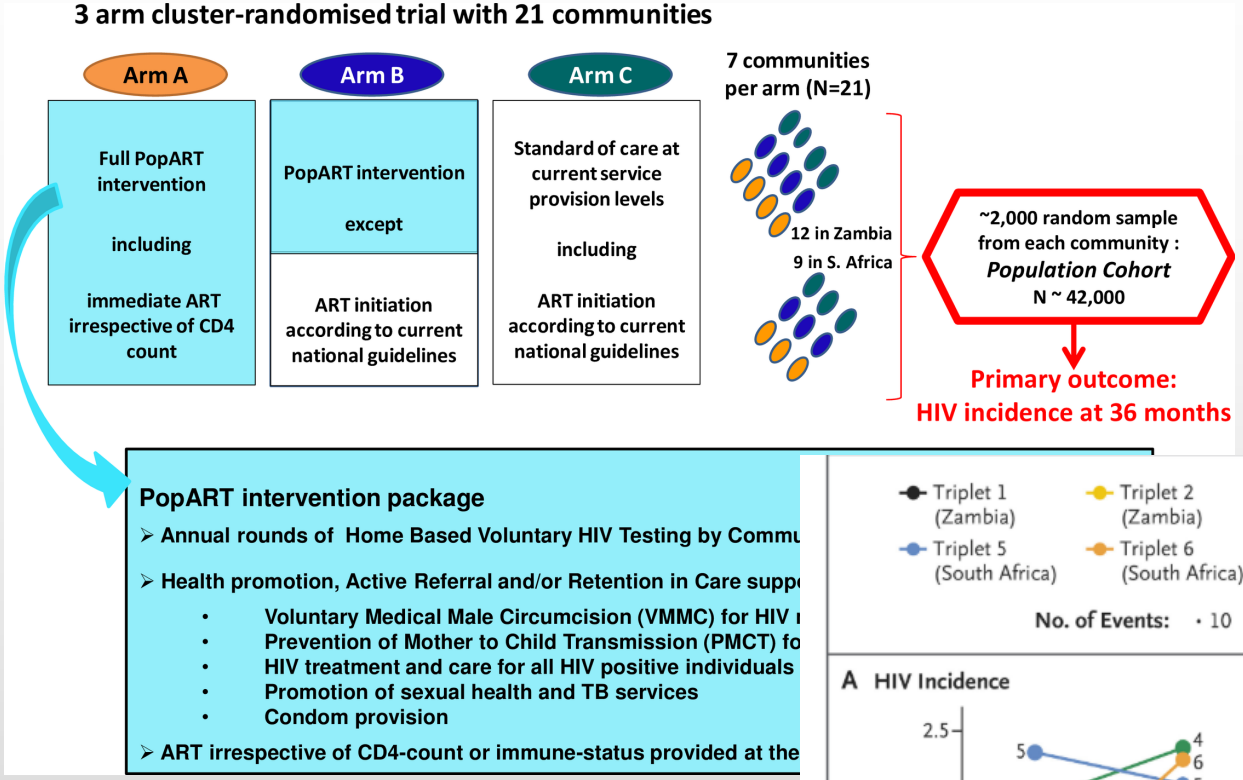


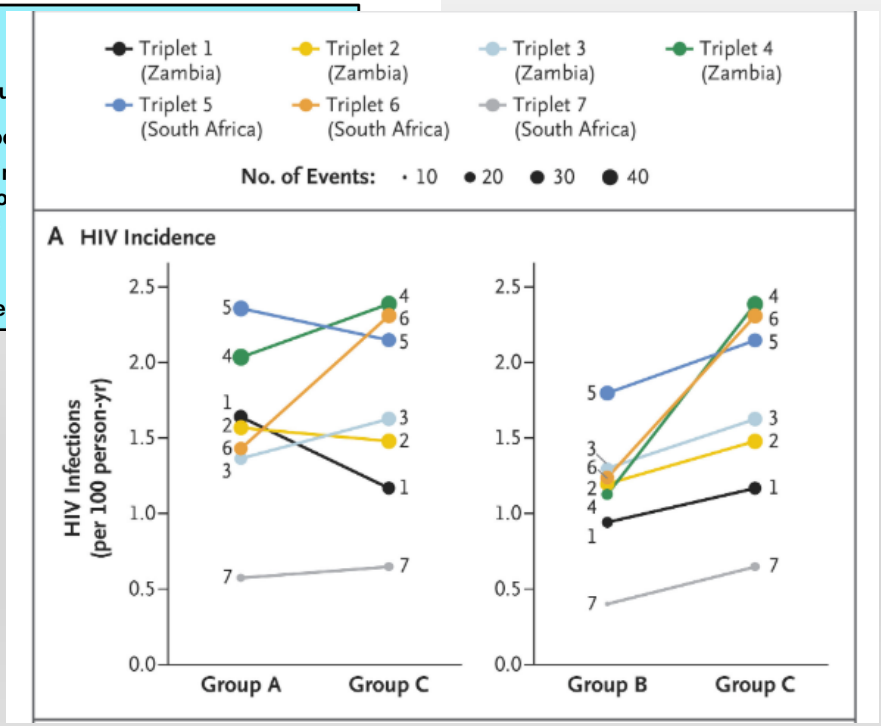
Time from diagnosis to ART: 10 mo → 6 mo (7 communities)

- Group c

Hayes r et al NEJM 2019; Seeley J et al. AIDS Behav 2019

HPTN 071: PopART -= Universal Test and Treat





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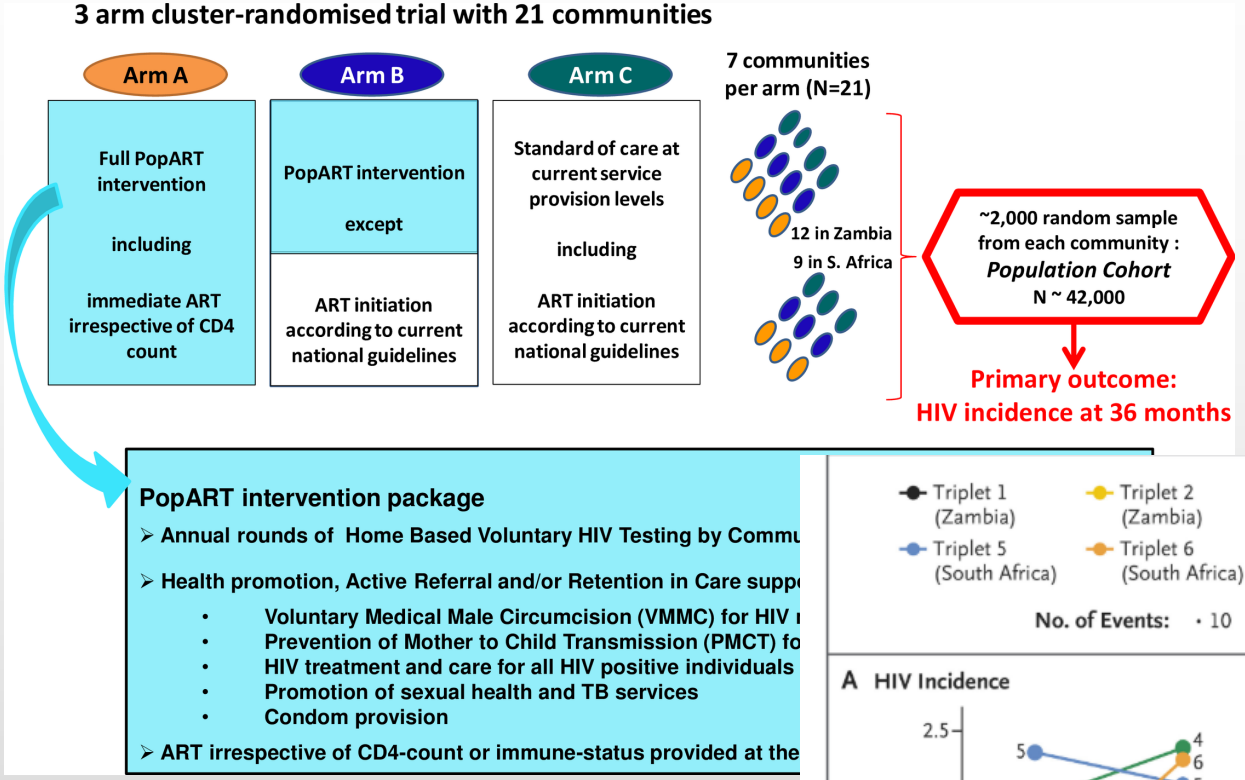
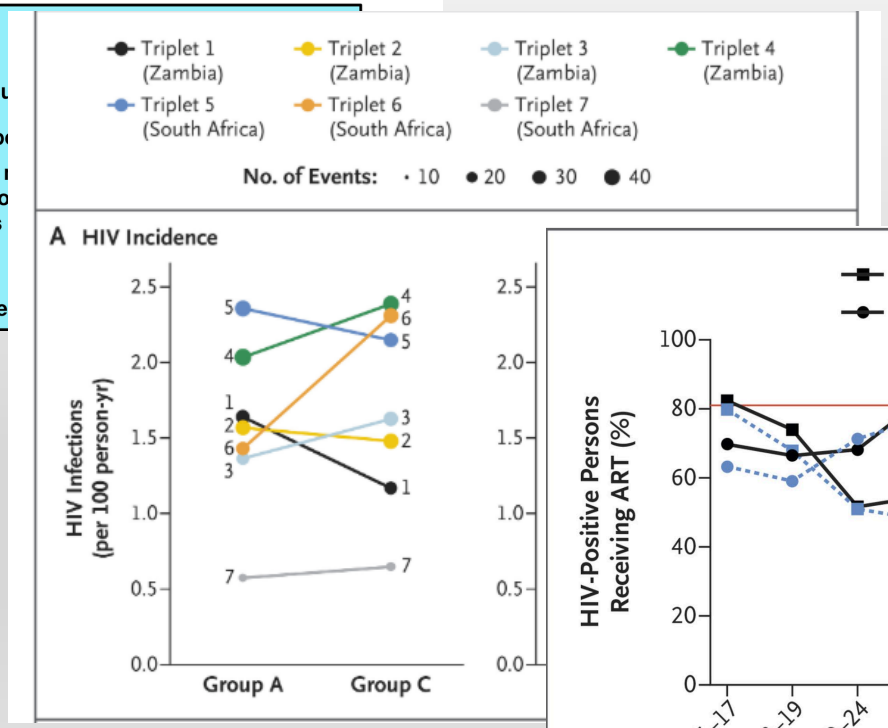
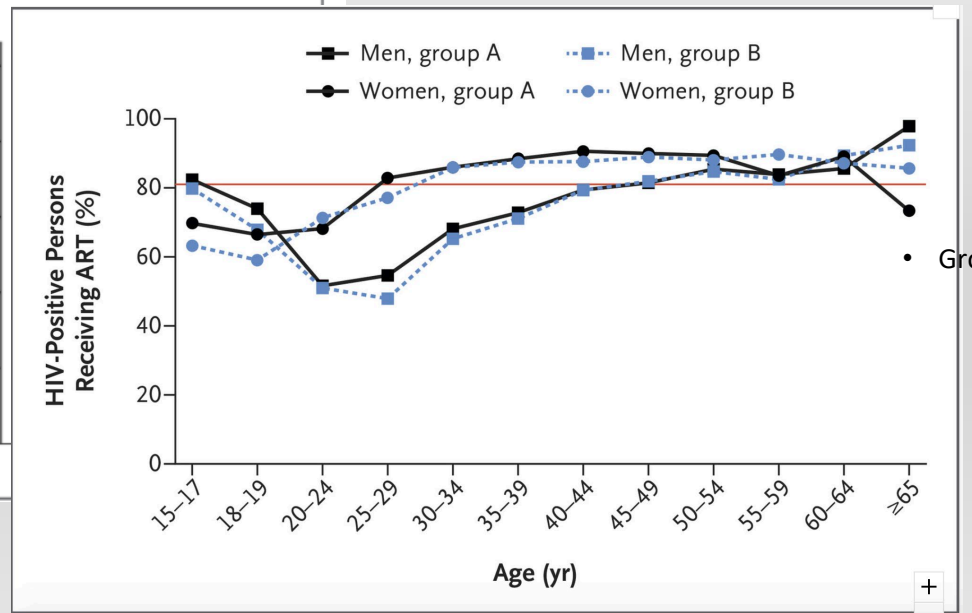




Time from diagnosis to ART: 10 mo → 6 mo (7 communities)



- Group c

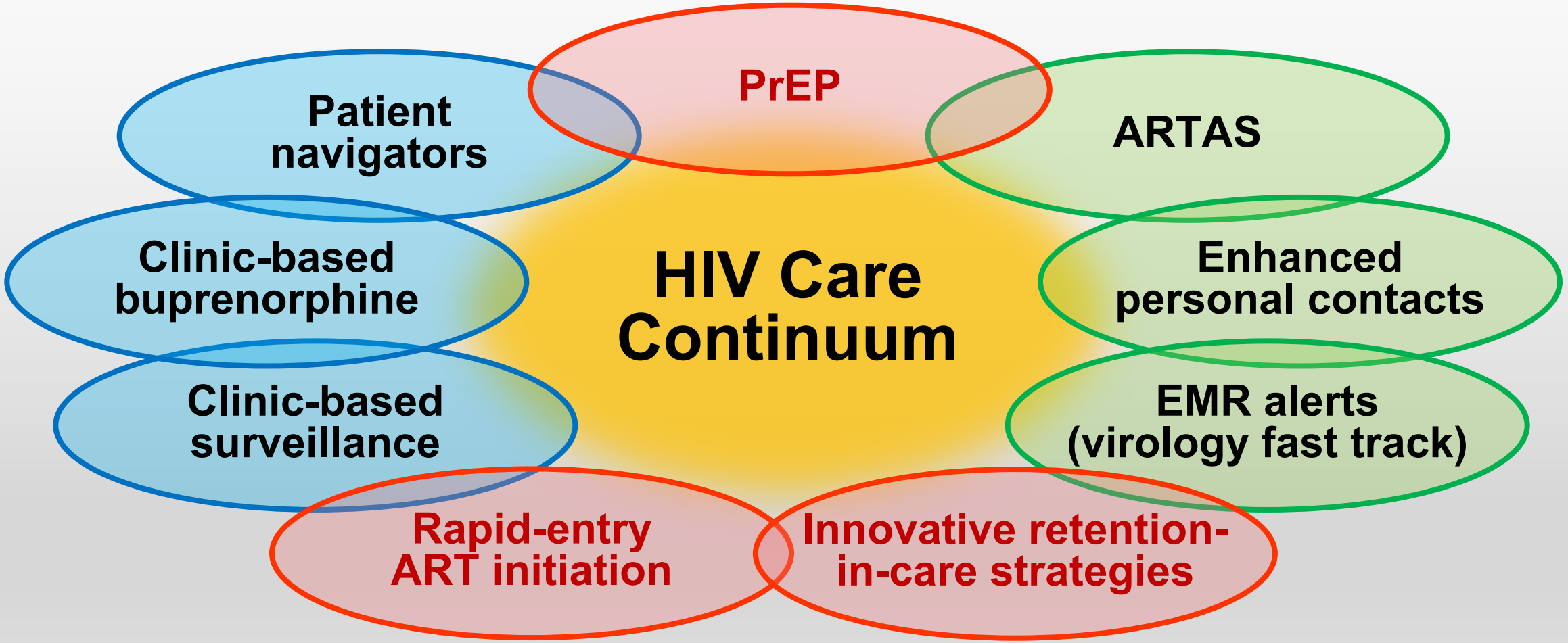
Hayes r et al NEJM 2019; Seeley J et al. AIDS Behav 2019

Rapid Start Supports Equity

- AA men are more likely to have delays in ART initiation even after seeing a prescribing provider.
- No better demonstration of commitment to a community than same-day immediate access to a provider.
- Dazon 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 .”

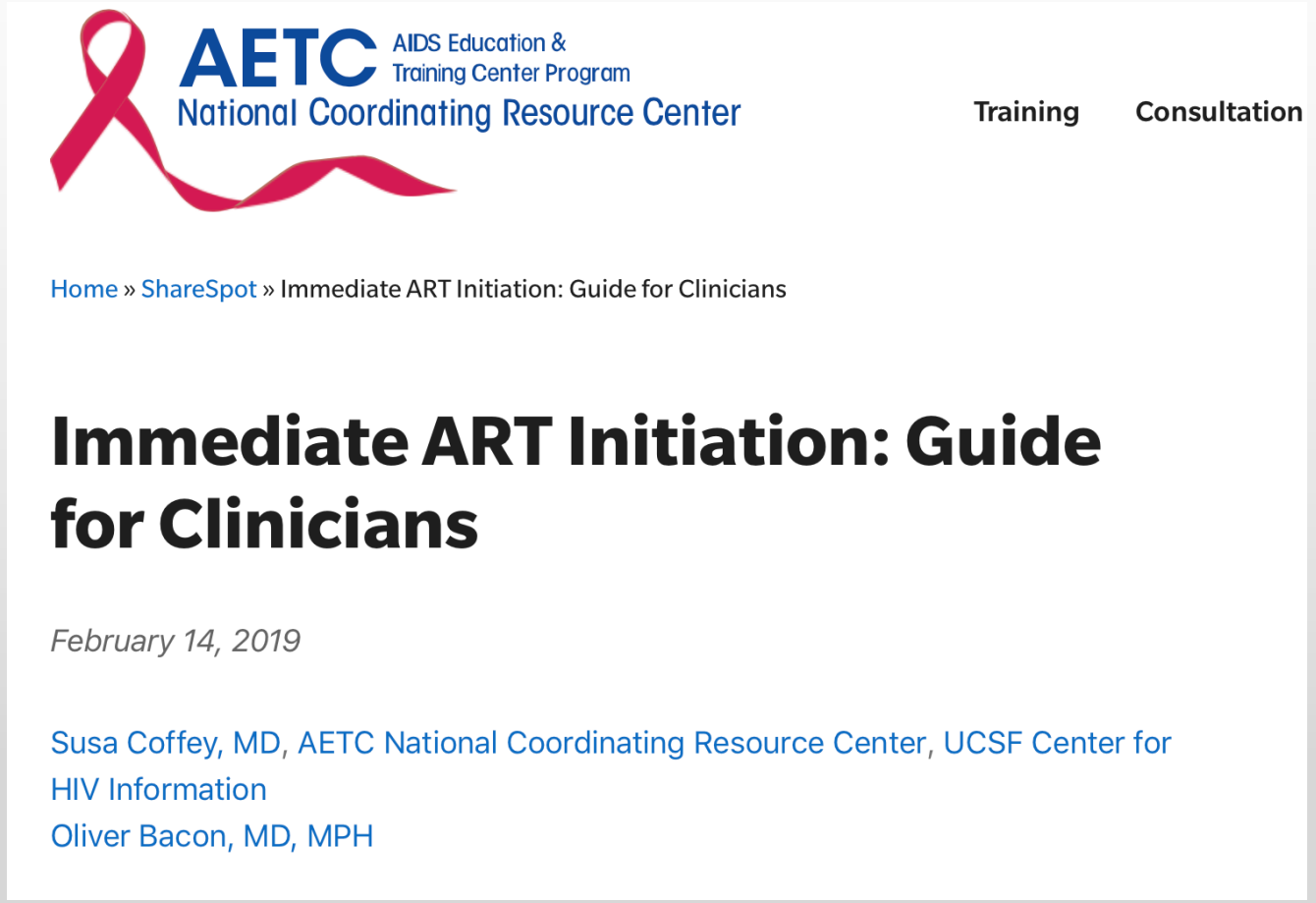
Mgbere O JIAPAC 2018;

Rapid Entry is Part of a Package



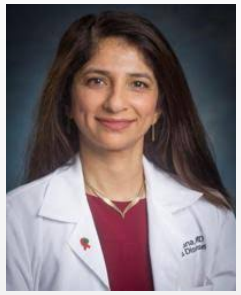
CDC LRC Compendium

Guide for Clinicians



https://aidsetc.org/blog/immediate-art

Domestic Rapid Start Consortium

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- Atlanta
- Miami
- New Orleans
- Baton Rouge
- Orlando
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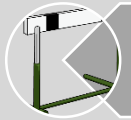
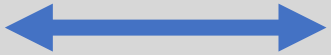
- Austin
- Houston
- Alexandria
- Birmingham
- Washington D.C.
- San Francisco
- Phoenix
- Tucson
- Albuquerque
- Los Angeles
- Chicago


Best Practices


Logistical Hurdles


Research



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