VIRTUAL
2020 NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

Rapid Start: Is the South ready? A Conversation on How It Can Be Done

Discussion Panel and Presentation by:
Amneris Luque, MD - Medical Director UTSW Faculty;
Ellen Kitchell, MD - Associate Medical Director UTSW Faculty;
Jeremy Chow, MD - UTSW Faculty; Kristina Schmidt, MSN, APRN, FNP-BC - iSTAT Provider;
Piper Duarte, MPH - Performance Improvement Analyst; Cindy Zoellner, PharmD, BCPS-AQID - Senior Clinical Pharmacy Specialist

RW Session 15995

Questions? Email Piper.Duarte@phhs.org to connect you to our program

Learning Objectives

VIRTUAL 2020 NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

- Describe the demographics and challenges to recognize when establishing a Rapid Entry Program
- Share the processes and plan to meet the need of newly diagnosed and vulnerable return-to-care populations
- Discuss initial outcomes that support replication and expansion of Rapid Entry Programs beyond new diagnosis

Dallas County Hospital

- Parkland Health & Hospital System is part of the Dallas County Hospital District and is a safety net system for indigent healthcare

- Parkland HIV Services Department consists of 4 HIV clinics located throughout Dallas County serving nearly 6,000 HIV patients
  - Amelia Court HIV Clinic located near downtown in the medical district is the primary clinic staffed with UTSW ID faculty, ID fellows, and midlevel providers
  - 3 additional clinics at 2 Parkland community oriented primary care clinics (COPCs) in areas of Dallas County with high HIV prevalence
  - all sites have robust teams of nurses, medical assistants, social workers, case managers, clerical staff, and access to a Parkland Pharmacy

Parkland HIV Testing

- HIV testing in emergency department (ED) and urgent care center (UCC) settings for patients presenting for medical problems unrelated to sexual health further extends the 2006 CDC testing recommendation

- Parkland implemented routine testing in the ED and UCC in 2009 using the CDC testing algorithm which helps identify acute HIV infection prior to antibody formation

Category	January 2020	February 2020	March 2020
Total Number of HIV Tests	5,466	4,542	3,921
New HIV Diagnosis	22	22	23
Percentage of New Positive Results	0.4%	0.5%	0.6%

Our Rapid Start Story

- 61% linkage to care (Intake to 1st Medical Visit) <30 days
- 37 day average from case management intake to new patient initial medical service visit (ISV) with a medical provider
- 60% of HIV patients initiating care at Parkland with case management attended their ISV
- Existing process for same day acute care visits for established patients but no same day visits for new patient visits
- We faced challenges to rapid start that your clinic may be facing too
- Today we want to share with you how we addressed those challenges and made rapid start a reality for Parkland HIV Services

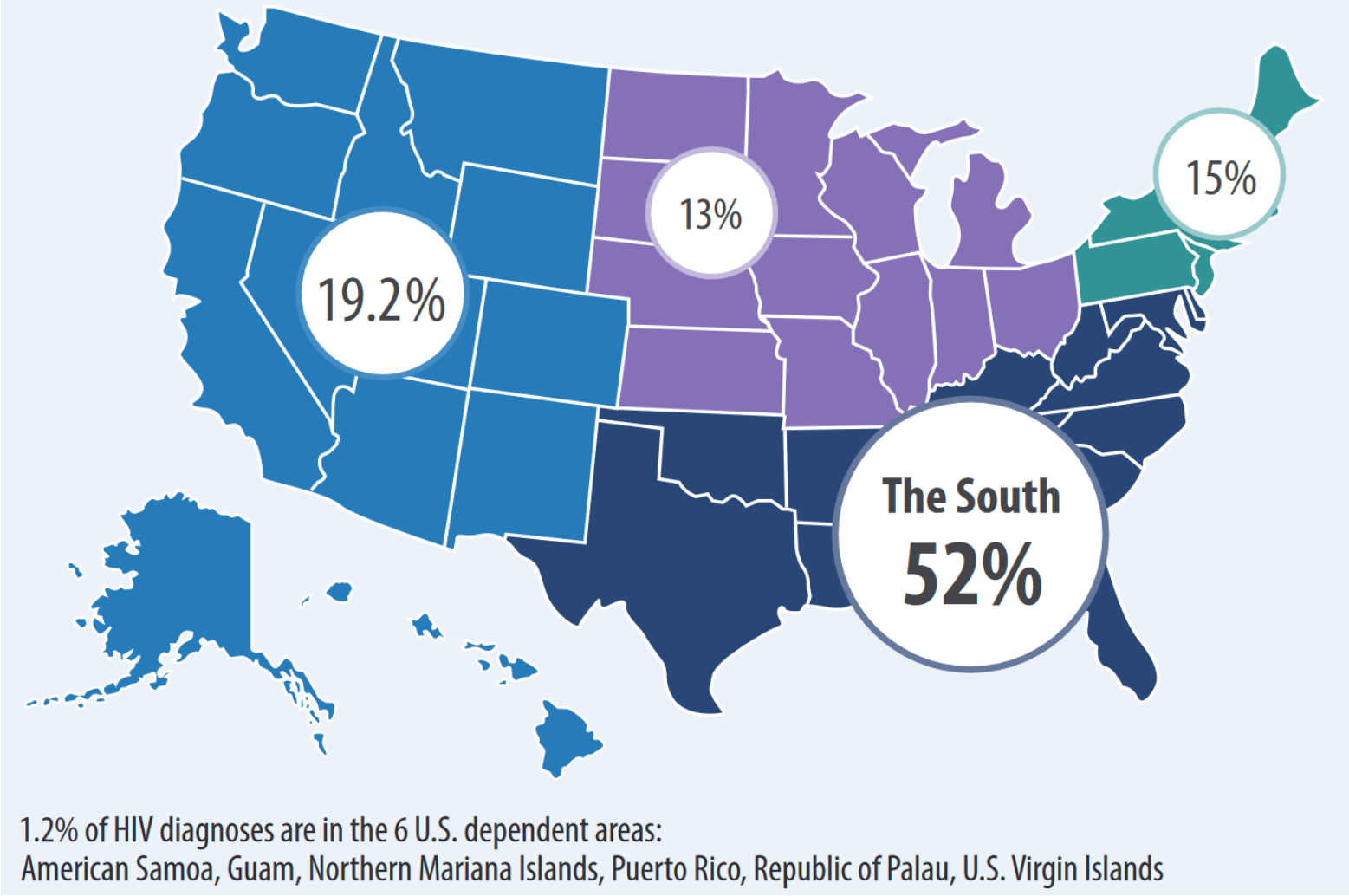
Outline

- Unique challenges of HIV landscape in the South
- Treatment as Prevention (TASP) or Undetectable = Untransmittable (U=U)
- Pioneer efforts in rapid initiation of antiretroviral therapy (ART)
- Our rapid start story – iSTAT Clinic at Parkland HIV Services Dallas, Texas
- Case Examples & Lessons Learned

The Story of HIV in the South

- Describe demographics and challenges to recognize when establishing a Rapid Entry Program

New HIV Diagnosis



1.2% of HIV diagnoses are in the 6 U.S. dependent areas:
American Samoa, Guam, Northern Mariana Islands, Puerto Rico, Republic of Palau, U.S. Virgin Islands

Source: CDC. Diagnoses of HIV infection in the United States and dependent areas, 2018. *HIV Surveillance Report* 2019;30

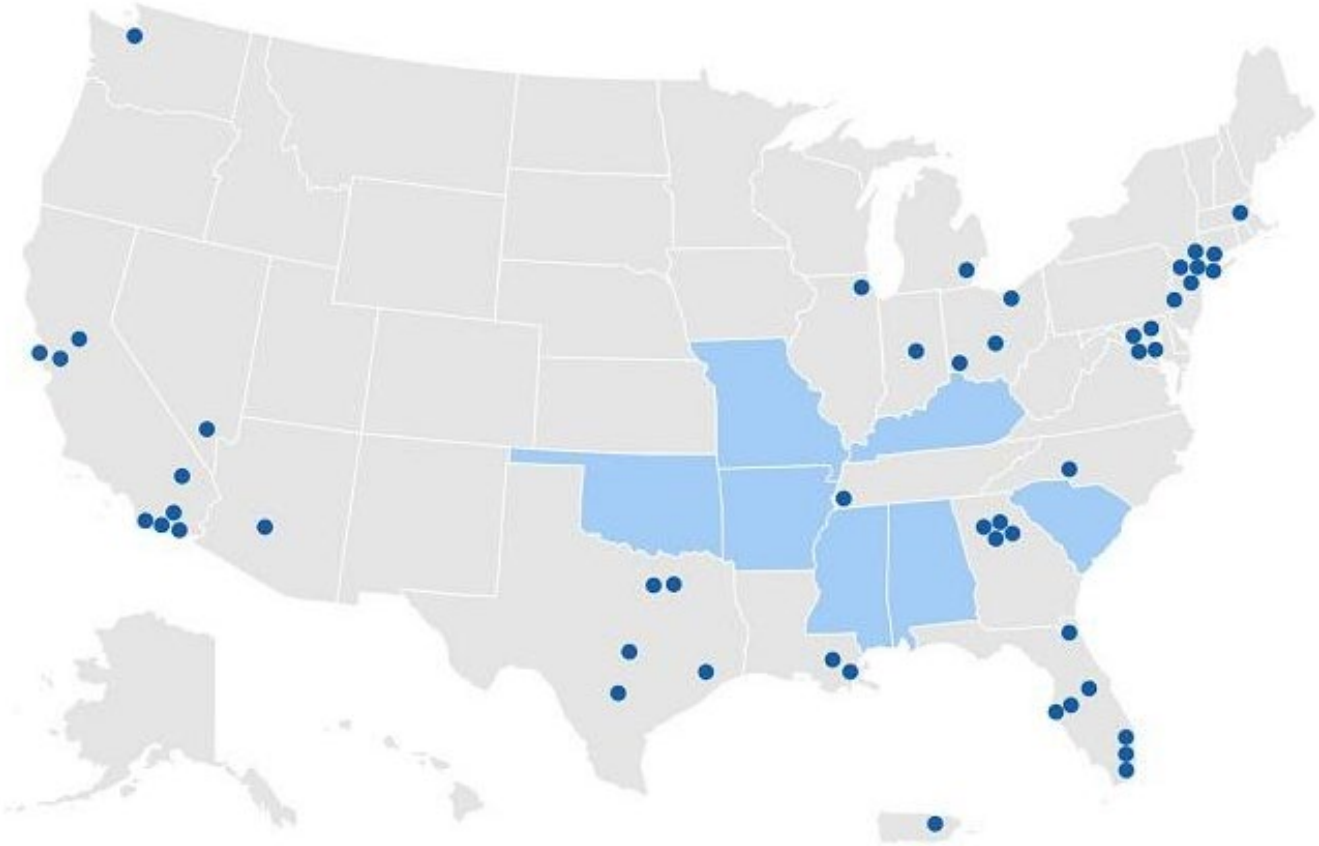
Top 10 states or dependent areas reporting the highest number of new HIV diagnoses in 2018:

State	Number of Diagnoses of HIV Infection, 2018
Florida	4,683
Texas	**4,483**
California	4,398
Georgia	2,552
New York	2,470
Illinois	1,352
North Carolina	1,200
New Jersey	1,044
Pennsylvania	1,002
Louisiana	986

http://www.cdc.gov/hiv/statistics/basics/index.html https://www.kff.org/hivaids/state-indicator/hiv-diagnoses-adults-and-adolescents

Dallas HIV Incidence

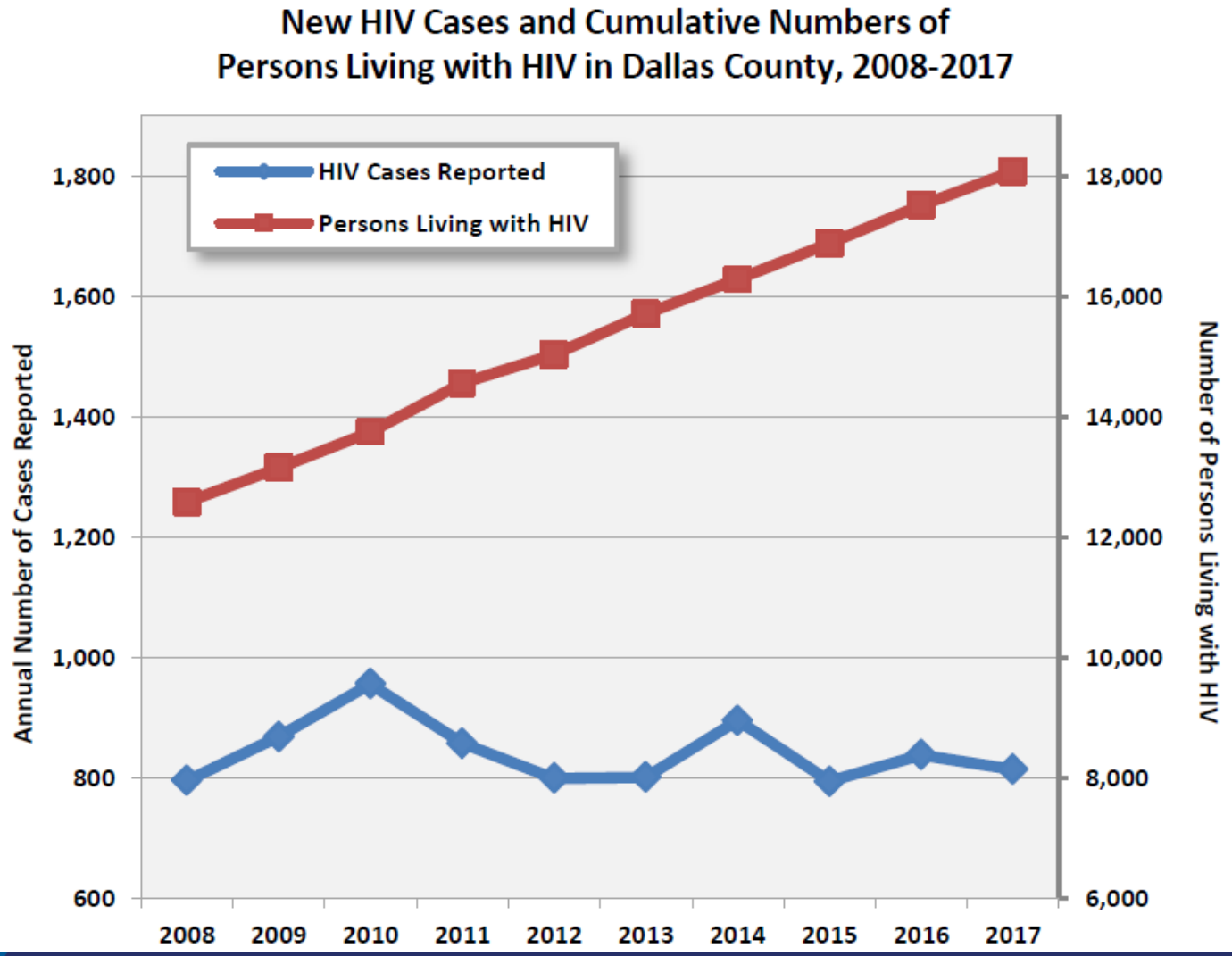
Dallas County had the highest rate of HIV cases of any county in Texas



Geographic locations: The 48 counties, plus Washington, DC, and San Juan, PR, where >50% of HIV diagnoses occurred in 2016 and 2017, and an additional seven states with a substantial number of HIV diagnoses in rural areas. View the list (PDF - 44 kb)

https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview

Dallas HIV Prevalence



https://www.dallascounty.org/Assets/uploads/docs/hhs/epistats/HIVSTIProfiles2017.pdf

Dallas Fast Track Signing

- Dallas County Judge Clay Jenkins signed the *Paris Declaration on Fast-Track Cities* 8/26/2019
- Addison, DeSoto, and Grand Prairie accompanied Dallas County in signing the *Paris Declaration*

Fast Track Targets

UNAIDS

An ambitious treatment targ
to help end the AIDS epidem

Fast-Track Targets

by 2020	by 2030
90-90-90 Treatment	95-95-95 Treatment
500 000 New infections among adults	200 000 New infections among adults
ZERO Discrimination	ZERO Discrimination

https://www.unaids.org/ene

Texas and Dallas Current Status of UN 90-90-90 Goals

Goal	Current Status	Gap
HIV Testing	83% of all Texans living with HIV know their status	**7%**
Linkage & Retention in Care	73% of people living in Dallas diagnosed with HIV are receiving ART	**17%**
Viral Suppression	87% of people living in Dallas diagnosed with HIV and retained in care are virally suppressed	**3%**

UN AIDS

An ambitious treatment target to help end the AIDS epidemic

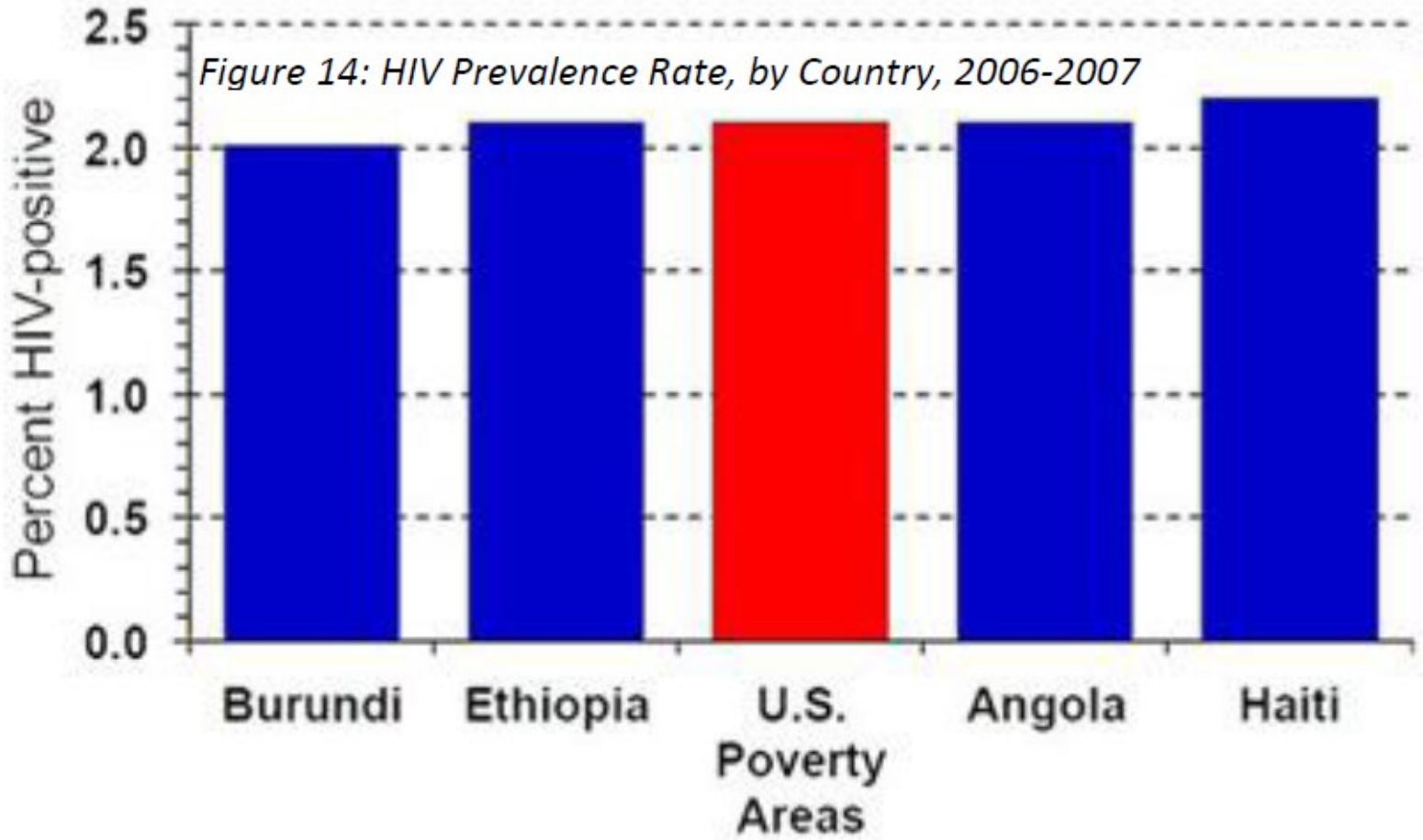
- September 2019 Status of 90-90-90 = 73% all HIV+ virally suppressed reduce transmission and end epidemic
- London, United Kingdom
  - 95% - 98% - 97% = **90%** all HIV+ virally suppressed
- Kigali, Rwanda
  - 84% - 98% - 90% = **74%** of all HIV+ virally suppressed
- Dallas, Texas
  - 83% - 73% - 87% = **53%** of all HIV+ virally suppressed

https://www.unaids.org/en/resources/presscentre/featurestories/2019/september/20190910_300-Fast-Track-cities-come-together https://www.cdc.gov/media/releases/2019/p0925-survey-rwanda-hiv-control.html

Social Determinants of HIV

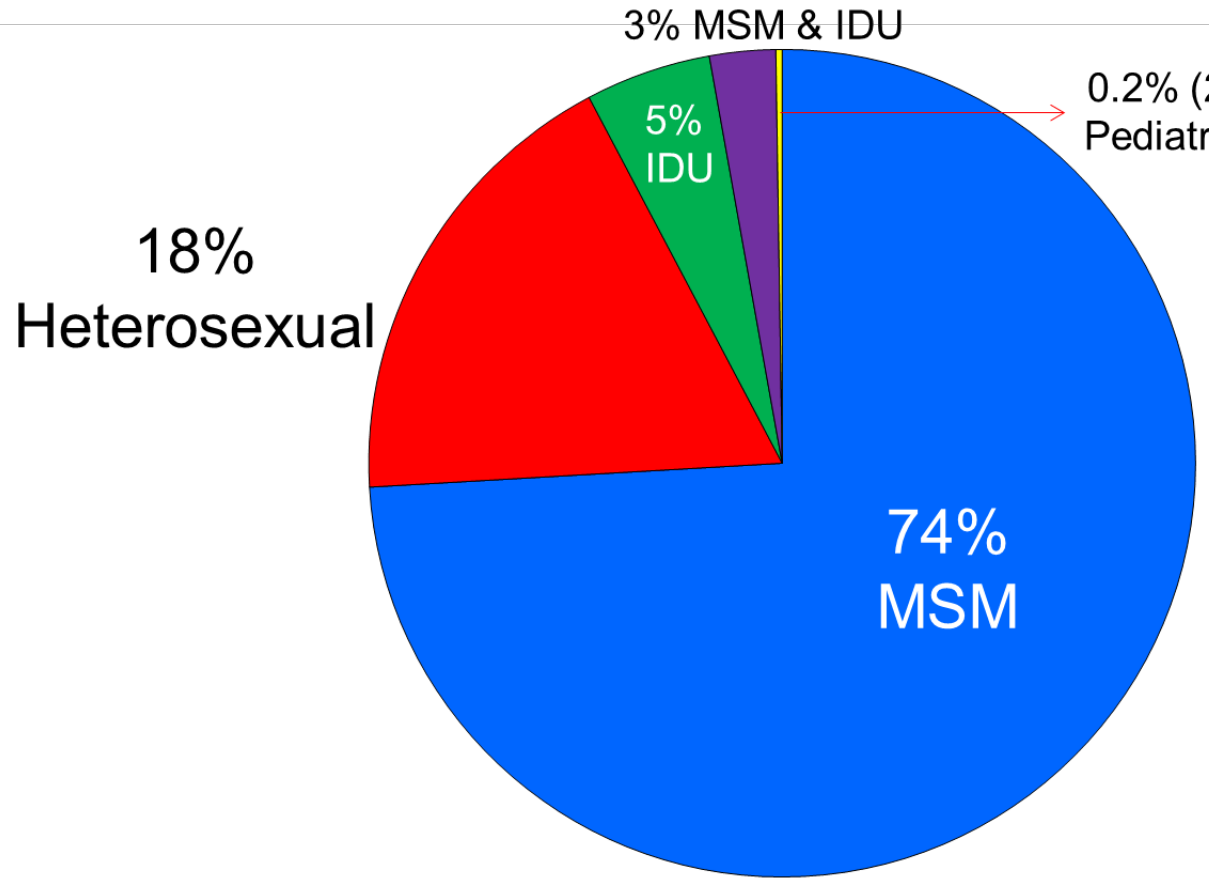
- Insurance
  - Texas is home to the largest number of uninsured individuals of any state in the country at 21.9% (2010-14) did not expand Medicaid low uptake of affordable care act
- Education
  - 16.3% Dallas residents aged ≥25 do not have high school diploma or GED rate >3 times higher for Hispanic Dallas residents 45.5%
  - Rate of death in HIV patients highest in those with lowest levels of education
- Housing
  - 2016 Point-In-Time homeless count, conducted by the Metro Dallas Homeless Alliance found an increase of 21% in the homeless population in Dallas over 2015 numbers
  - homeless have higher rates mental illness, substance abuse, HIV, TB, and chronic medical conditions

US HIV Rate by Income



- CDC study in 25 urban areas including Dallas found HIV prevalence rates in urban poverty areas in the US similar to rates found in low-income countries such as Burundi, Ethiopia, Angola, and Haiti

Dallas HIV - Transmission

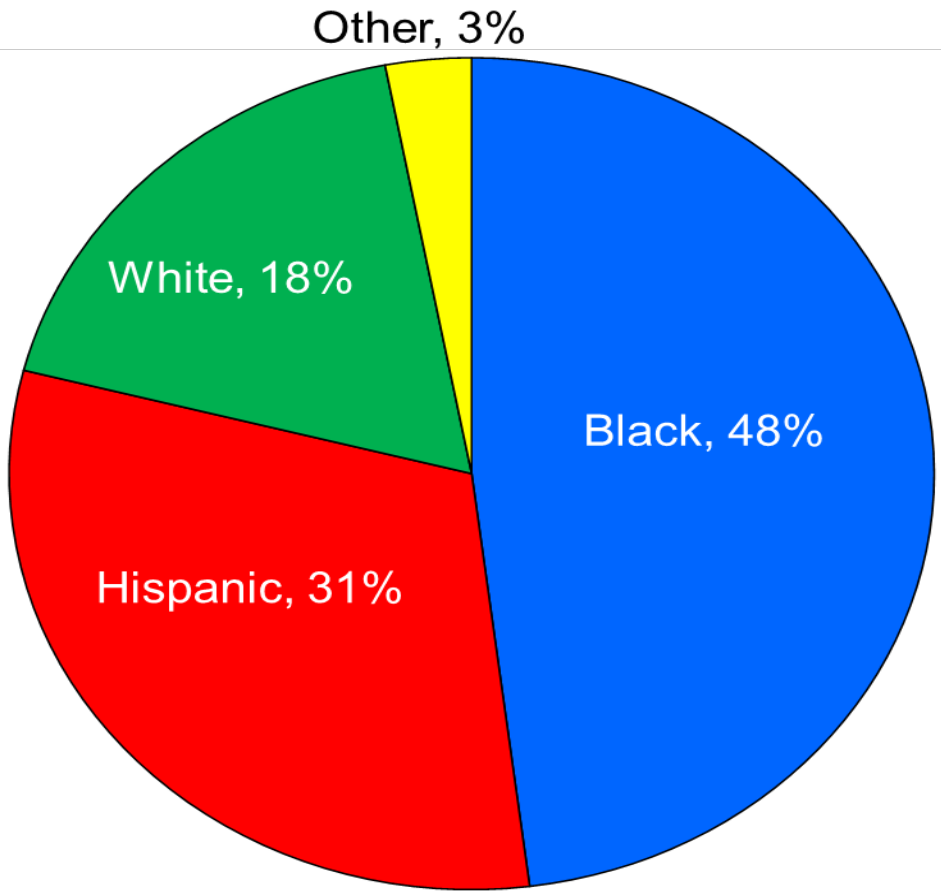


92% Sexual Transmission

814 New HIV Diagnosis 2017

https://www.dallascounty.org/Assets/uploads/docs/hhs/epistats/HIVSTIProfiles2017.pdf

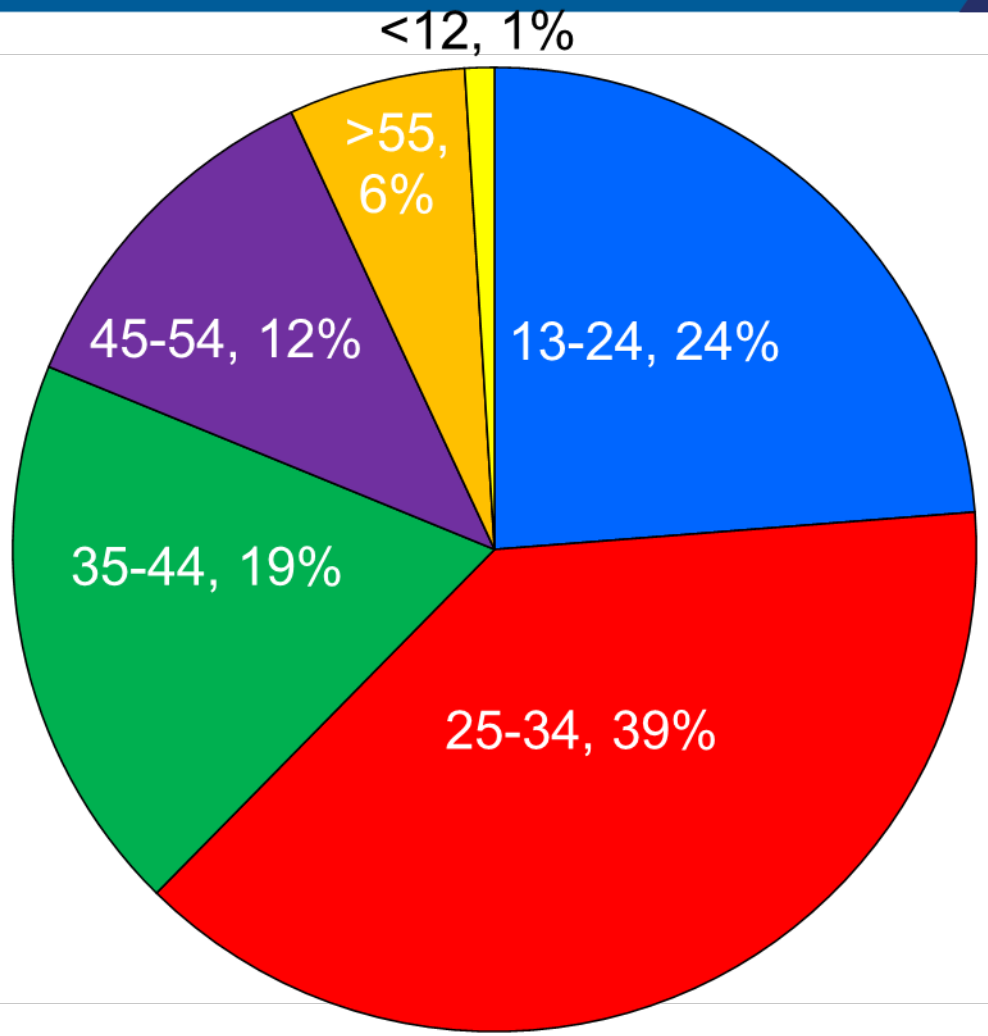
Dallas HIV - Race



79%
AA or Latinx

https://www.dallascounty.org/Assets/uploads/docs/hhs/epistats/HIVSTIProfiles2017.pdf

Dallas HIV - Age



63% Under 35 Years

https://www.dallascounty.org/Assets/uploads/docs/hhs/epistats/HIVSTIProfiles2017.pdf

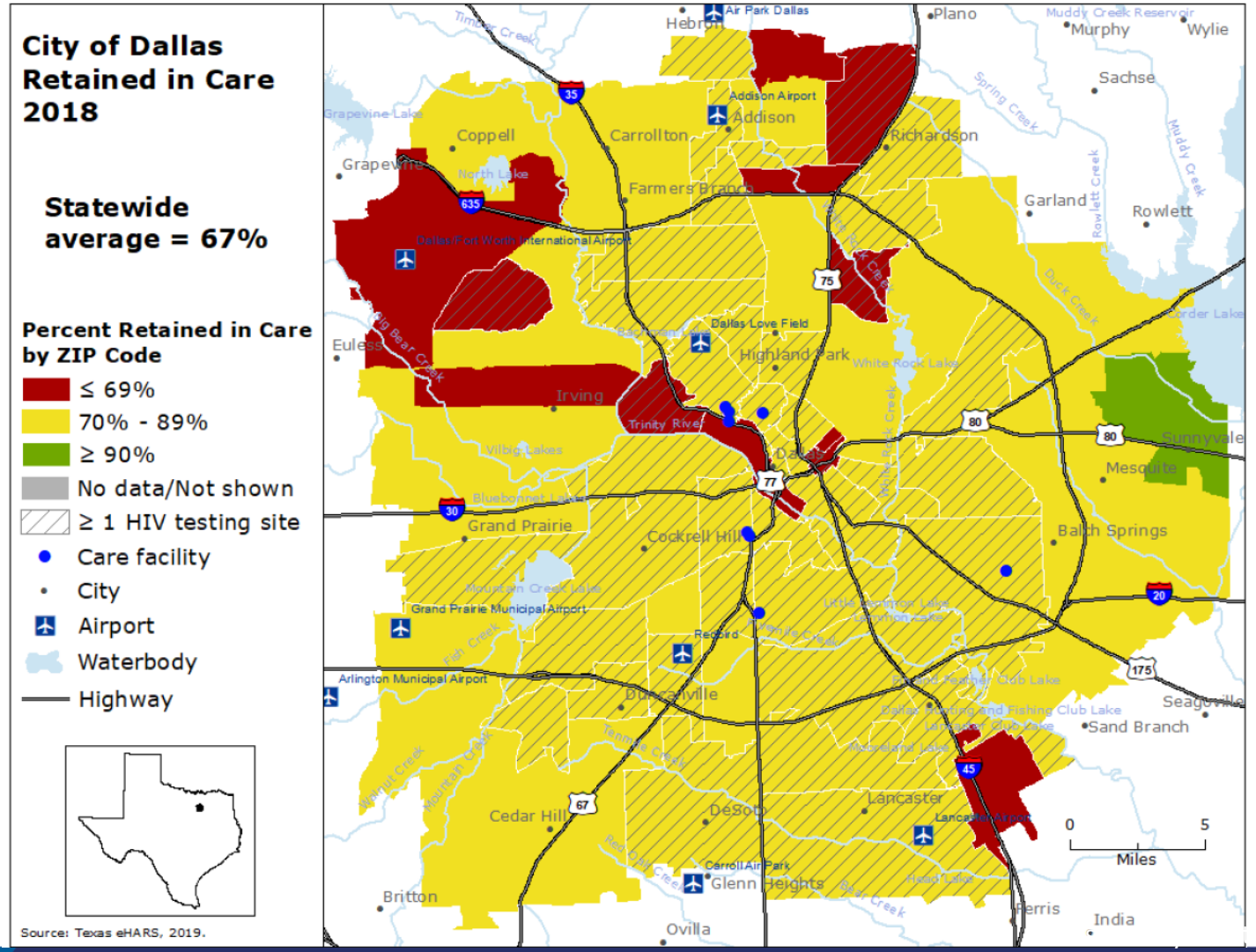
Stage 3 HIV --AIDS at Diagnosis

- 27% of all newly diagnosed persons in Dallas County progressed to a concurrent AIDS diagnosis within 12 months of initial HIV diagnosis from 2013 – 2016

- Representing missed opportunities for testing and early HIV diagnosis

https://www.dallascounty.org/Assets/uploads/docs/hhs/epistats/HIVSTIProfiles2017.pdf

Dallas Retained in Care



Face of HIV in Dallas

- Young
- MSM
- Ethnic or Racial Minority
- Shared Provider Language barriers - English as a second Language
- Low level of education & lack of sexual health education and access to prevention in primary school
- No health insurance| No Medicaid Expansion
- Late Stage 3 HIV- AIDS at entry to care

Our Challenges to Rapid Start

- Little municipal coordination, no centralization
- Difficulty accessing ART
  - Texas AIDS Drugs Assistance Program (ADAP) primary payer with paper enrollment process that can take 2-8 weeks to receive ART
  - Parkland Hospital policy no medication samples / starter packs
  - Reliance on accessory programs to obtain immediate access to ART
  - Pharmaceutical company patient assistance programs and Harbor Path
- No pharmacy on site
  - each of the 4 Parkland HIV clinics utilizes a Parkland Pharmacy location nearest to them with no dedicated staff or priority given for ART initiation

Opportunities to Change the Story of HIV in the South

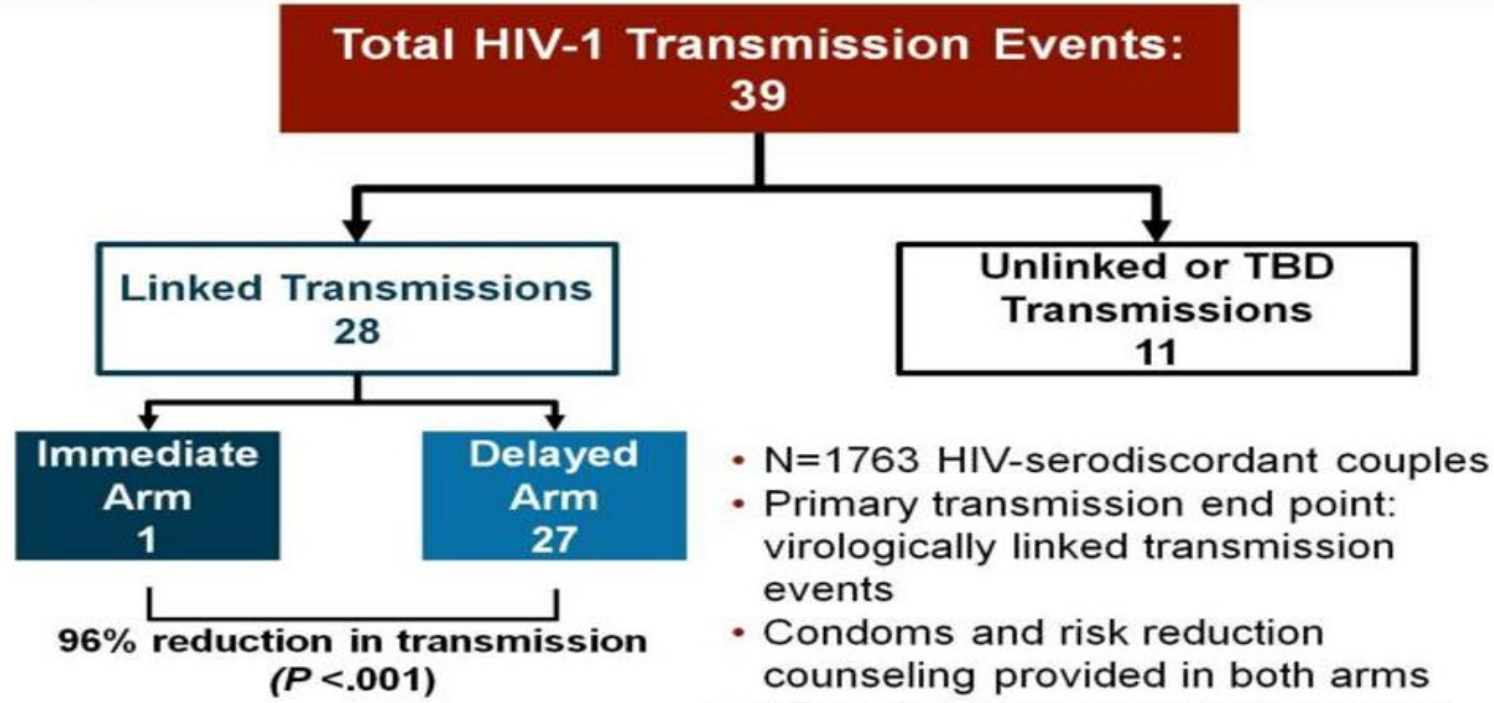
Treatment as Prevention

UNDETECTABLE = UNTRANSMITTABLE

Prevention Access Campaign

Treatment as Prevention 2

HPTN 052: Antiretroviral Therapy as Prevention



- N=1763 HIV-serodiscordant couples
- Primary transmission end point: virologically linked transmission events
- Condoms and risk reduction counseling provided in both arms
- 97% of couples were heterosexual

Cohen MS, et al. *N Engl J Med*. 2011;365:493-505.[3]

HPTN 052
1,763 couples enrolled
13 sites 9 countries
97% heterosexual
Median follow-up 5.5 years
2005-2010

PARTNER 1
888 couples enrolled
75 sites 14 countries
61.7% heterosexual
38.3% MSM
58,000 condom less sex acts
2010-2014

PARTNER 2
782 couples enrolled
100% MSM
76,088 condom less sex acts
2010-2018

=

ZERO

within couple transmissions HIV VL < 200 copies/mL

N Engl J Med 2016; 375:830-839 DOI: 10.1056/NEJMoa1600693 JAMA. 2016;316(2):171-181. doi:10.1001/jama.2016.5148
Lancet. 2019 Jun 15;393(10189):2428-2438. doi: 10.1016/S0140-6736(19)30418-0. Epub 2019 May 2.

Why is Early HIV Diagnosis and ART Important?

- 2016 update to national guidelines for HIV treatment from the Department of Health and Human Services (DHHS) Adult and Adolescent HIV Guidelines recommended starting ART regardless of CD4 count

- ~50% reduction in morbidity and mortality among HIV patients with CD4 >500 randomized to receive ART immediately versus delaying initiation – START & TEMPRANO

- Genuine benefit to the individual patient to offer ART as soon as possible following diagnosis

AIDS at Diagnosis

- 27% of all newly diagnosed persons in Dallas County progressed to a concurrent AIDS diagnosis within 12 months of initial HIV diagnosis from 2013 – 2016

- Representing missed opportunities for engaging and retaining people in care

https://www.dallascounty.org/Assets/uploads/docs/hhs/epistats/HIVSTIProfiles2017.pdf

Rapid initiation of Antiretroviral therapy

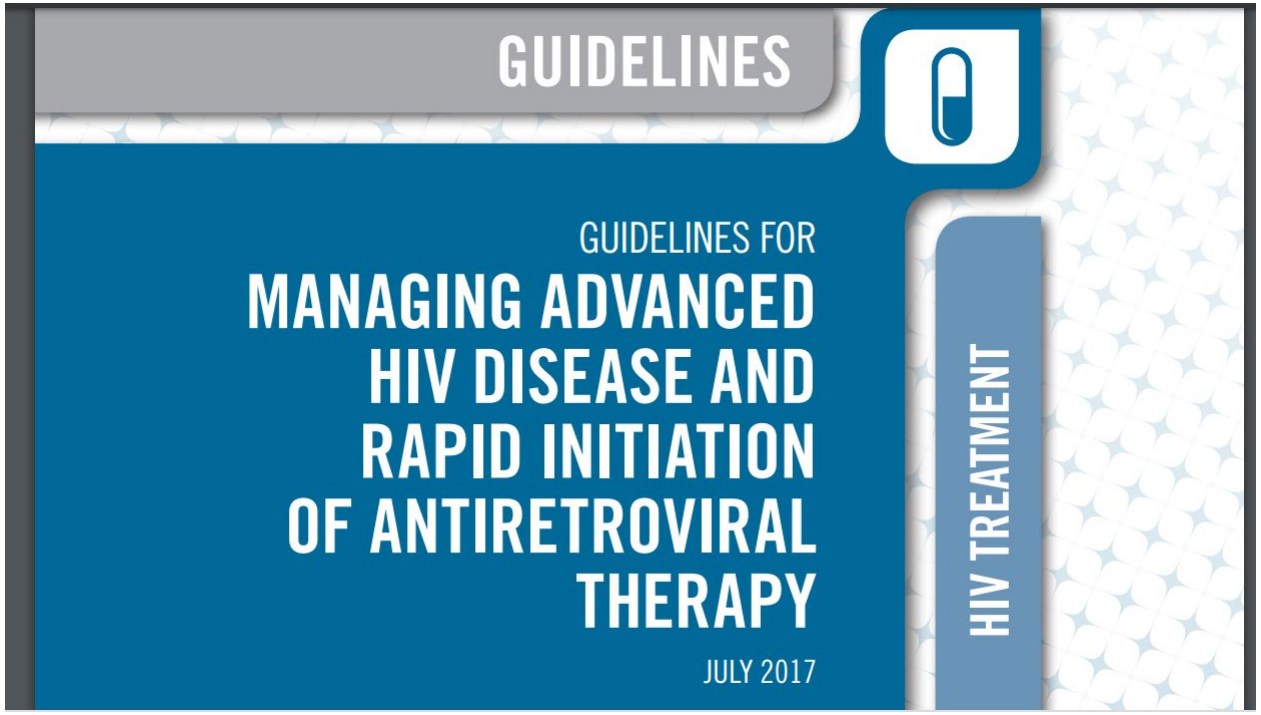
Pioneer efforts in rapid initiation of antiretroviral therapy

Rationale for Rapid ART

- Patients may become lost to care between the time HIV is diagnosed and the time ART is prescribed
- Take advantage of patient momentum, interest, and match urgency
- Enhance linkage and engagement in HIV care by building trust and addressing patient anxiety over new diagnosis
- Reduce time during which people with newly diagnosed HIV can transmit
- For persons with acute infection, immediate ART may limit the HIV viral reservoir

WHO Guidelines

- **Rapid** initiation of ART is **defined** as within seven days of HIV diagnosis.
- WHO further strongly recommends ART initiation on the same day as HIV diagnosis based on the person's willingness and readiness to **start** ART immediately, unless there are clinical reasons to delay treatment.



WHO https://www.who.int/hiv/pub/guidelines/advanced-HIV-disease/en/

Rapid Start Recommendations

DHHS (2019):

The Panel on Antiretroviral Guidelines for Adults and Adolescents recommends **initiating ART immediately (or as soon as possible) after HIV diagnosis** in order to increase the uptake of ART and linkage to care, decrease the time to viral suppression for individual patients, and improve the rate of virologic suppression among persons with HIV **(AII)**.

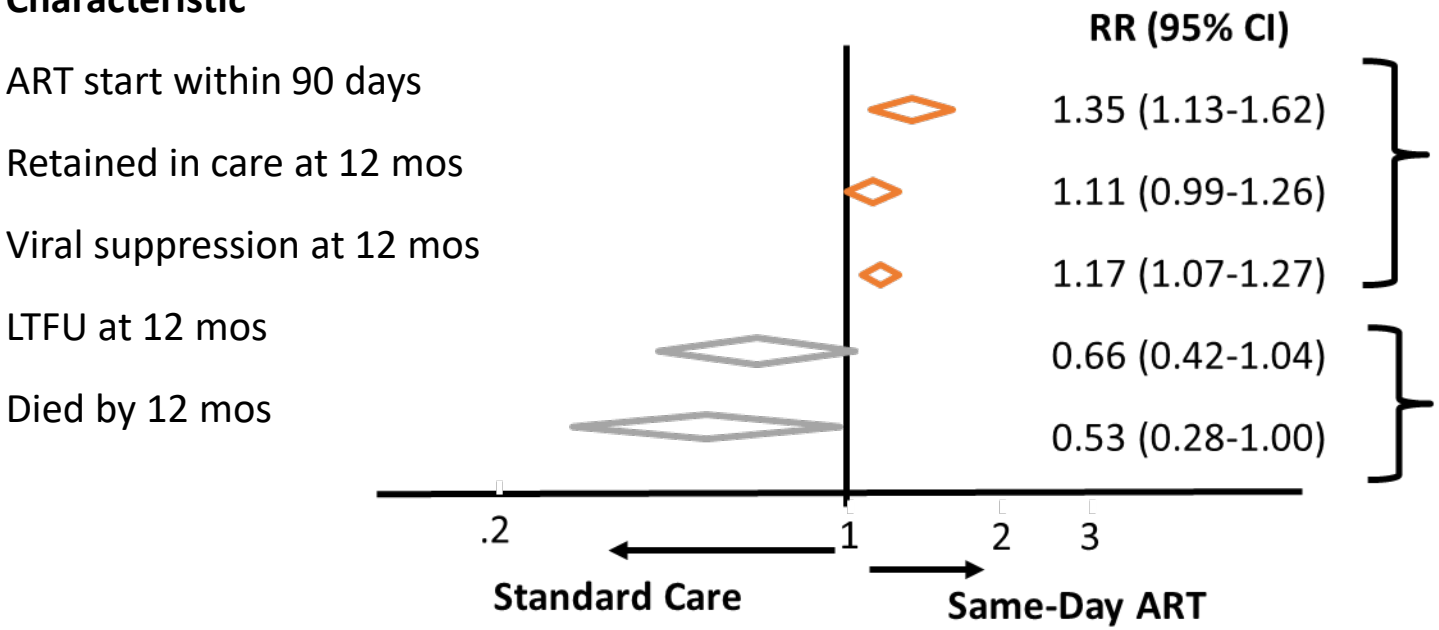
https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/10/initiation-of-antiretroviral-therapy

What is the evidence?

- 2 RCTs done in Haiti and South Africa. 2 Cluster Randomized trials done in Uganda, Lesotho
- All 4 looked at effect of starting ART on the same day that eligibility was established/first clinic visit on various clinical outcomes

Improved Clinical Outcomes With Rapid ART Initiation

- Systematic review of rapid ART initiation (including 4 RCTs)[1]



Same-day ART associated with:

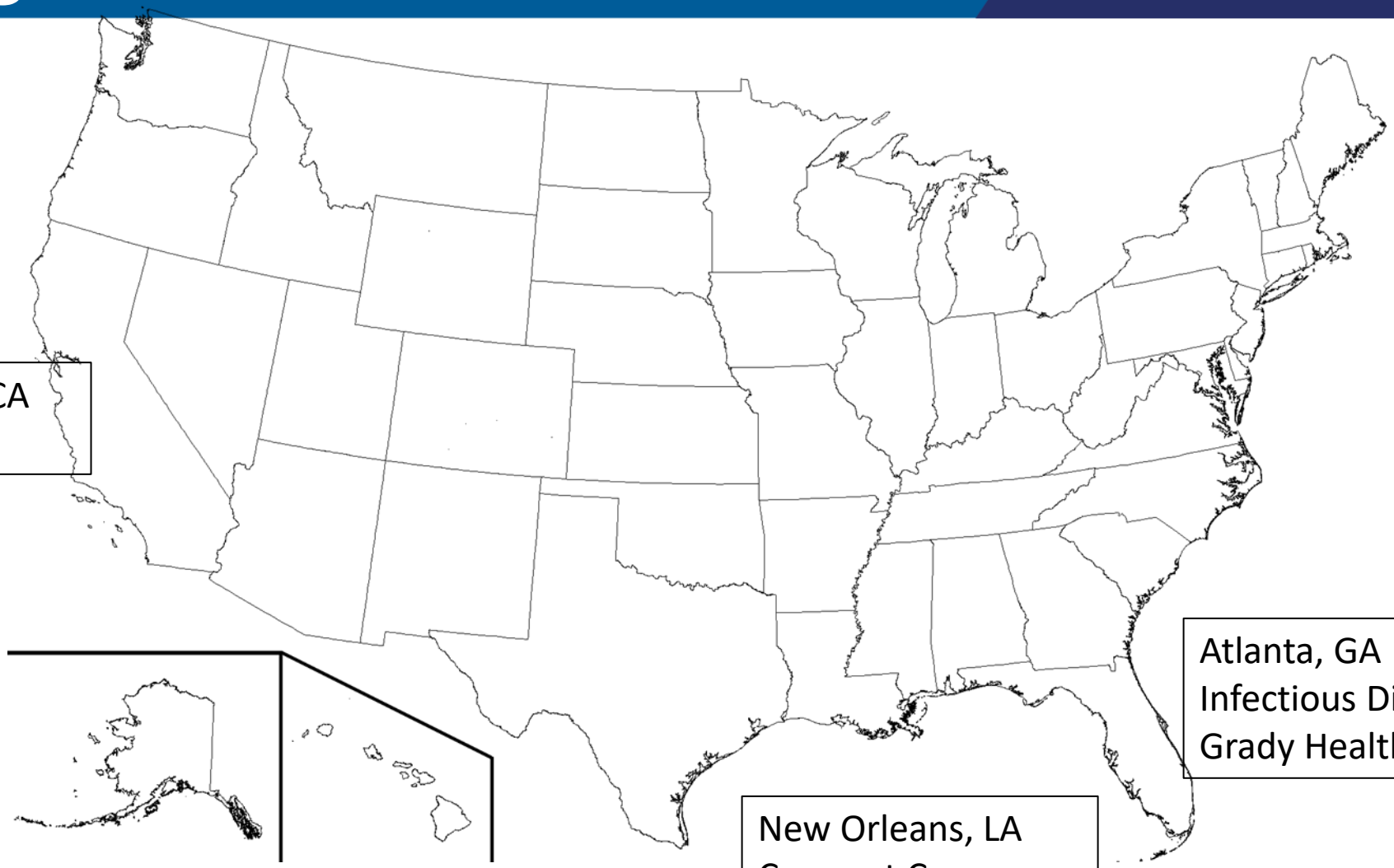
- **Increased** likelihood of ART initiation, retention in care, viral suppression
- **Decreased** likelihood of loss to follow-up and death

- In addition, earlier ART initiation reduces the viral reservoir in the individual[2-5]

1. Ford. AIDS. 2018;32:17. 2. Tagarro. JAIDS. 2018;79:269. 3. Luo. BMC Infect Dis. 2019;19:257.
4. Jain. J Infect Dis. 2013;208:1202. 5. Buzon. J Virol. 2014;88:10056.

What about the US?

Evidence from real-world clinic settings:



San Francisco, CA
Ward 86

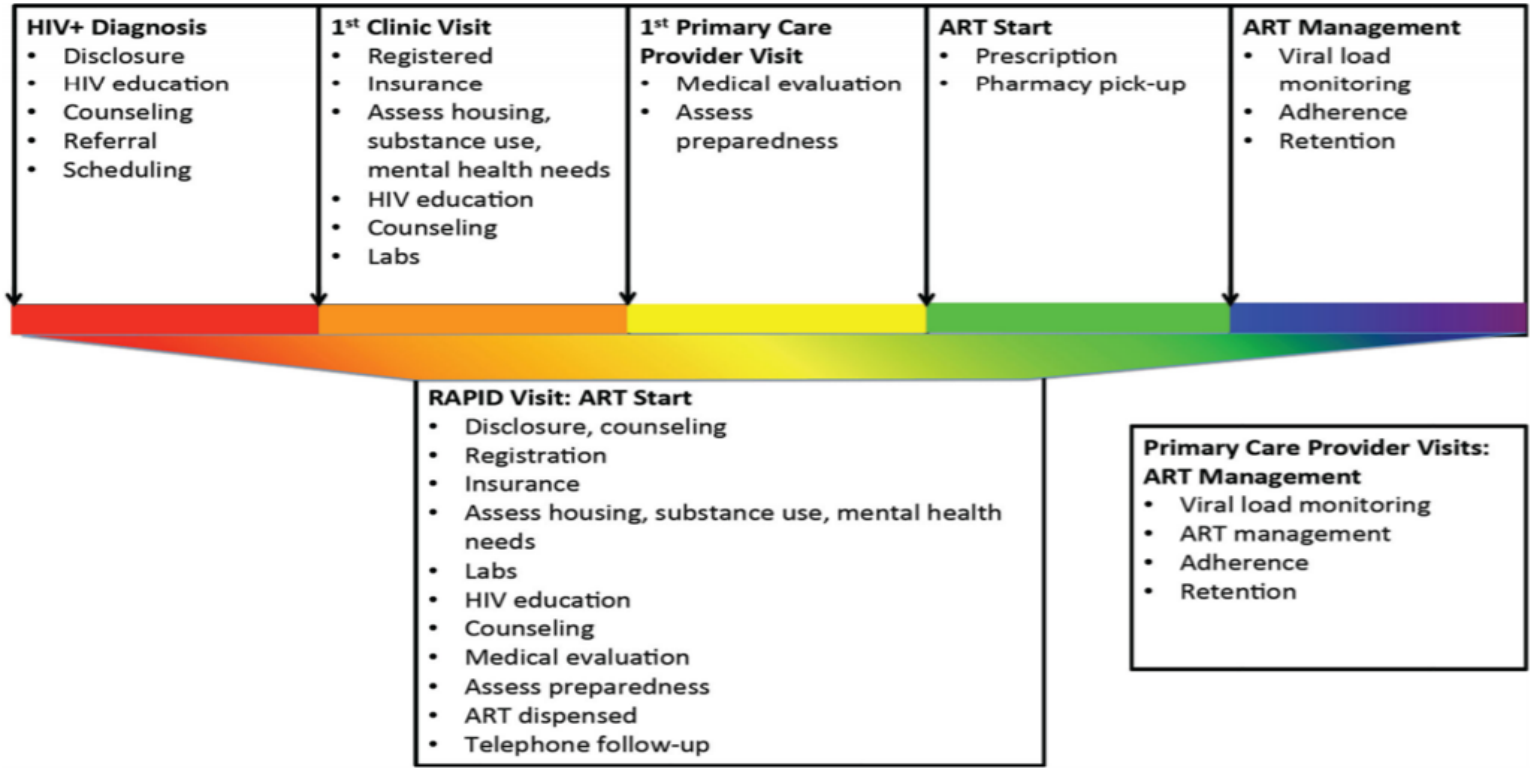
Atlanta, GA
Infectious Diseases Program,
Grady Health system

New Orleans, LA
Crescent Care

San Francisco

SFGH Ward 86 RAPID Program

Rapid ART Program Initiative for HIV Diagnoses (RAPID)



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

San Francisco: Ward 86 RAPID Protocol

- Positive test within SF triggers referral to RAPID program
- Scheduled for same-day or next-day clinic appointment, transportation provided
- Multidisciplinary evaluation, support, and insurance enrollment/optimization
- Evaluation by medical provider
- Offered ART (unless deemed inappropriate), Provide 3-5 day ART starter pack, Rx sent to pharmacy
- Most pts received DTG+FTC/TDF
- F/u: SW calls within 1-2 days, clinic appt within 1-2 weeks

Coffey. *AIDS*. 2019; 33(5):825-832.

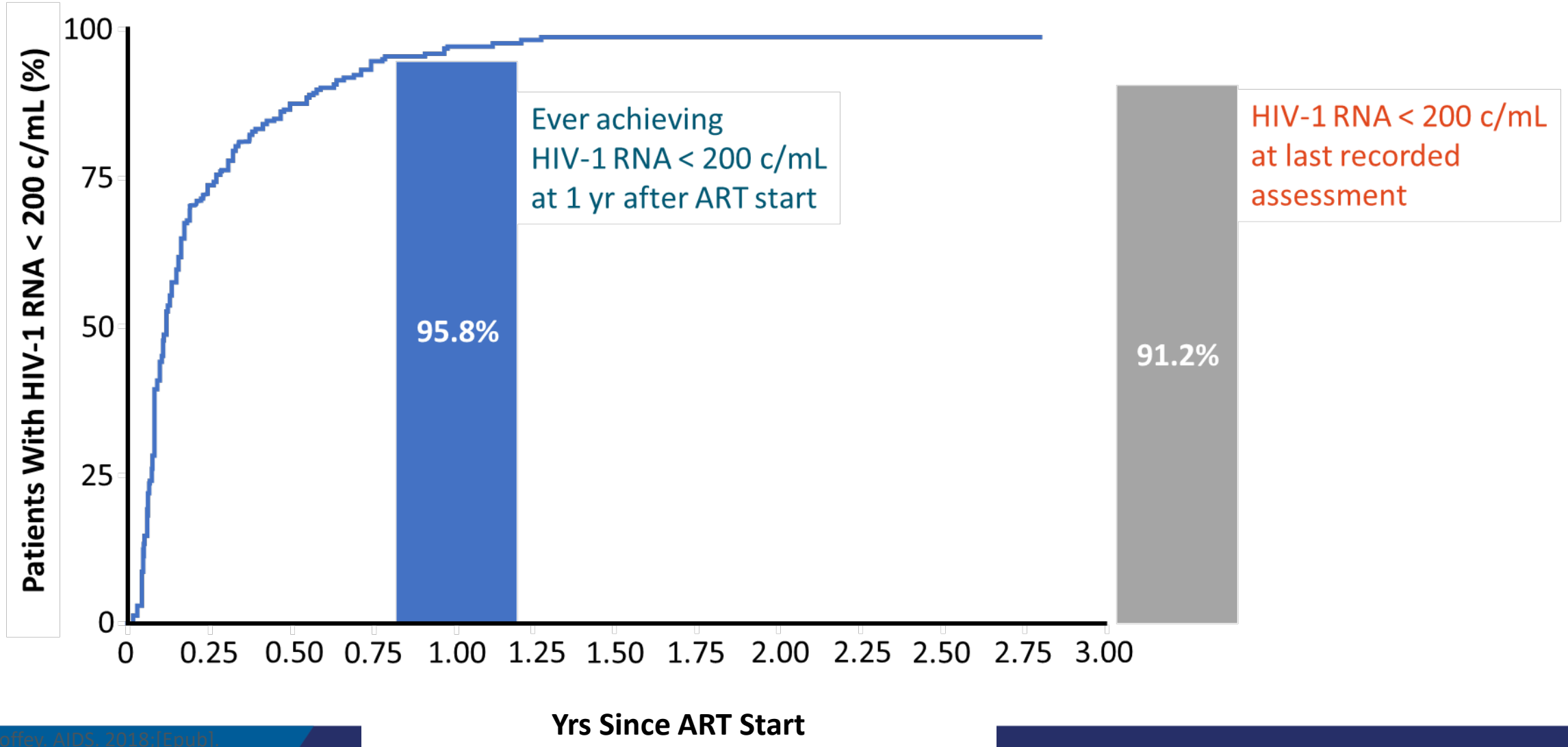
Ward 86 RAPID Analysis

- Retrospective analysis on 216 out of 225 patients (96%) referred to RAPID program from 2013-2017
  - Reasons for not starting rapid ART: declined, 4; not started by clinician, 3; excluded from analysis, 2*

Baseline Characteristic	Retrospective Cohort (N = 216)
Median age at HIV diagnosis, yrs (range)	30 (16-61)
Female/transgender female, n (%)	17 (7.9)/1 (0.5)
Race/ethnicity, n (%)	
▪ Black	25 (11.6)
▪ Latinx/Hispanic	58 (26.9)
▪ White	79 (36.6)
Health challenges, %	
▪ Substance use disorder	51.4
▪ Major mental health disorder	48.1
▪ Homeless/unstable housing	30.6
Median CD4+ cell count, cells/mm^3	441 (3-1905)
Median HIV-1 RNA, copies/mL	37,011 (0 to > 10 million)

*Excluded because no HIV-1 RNA measurements performed after initiating ART.

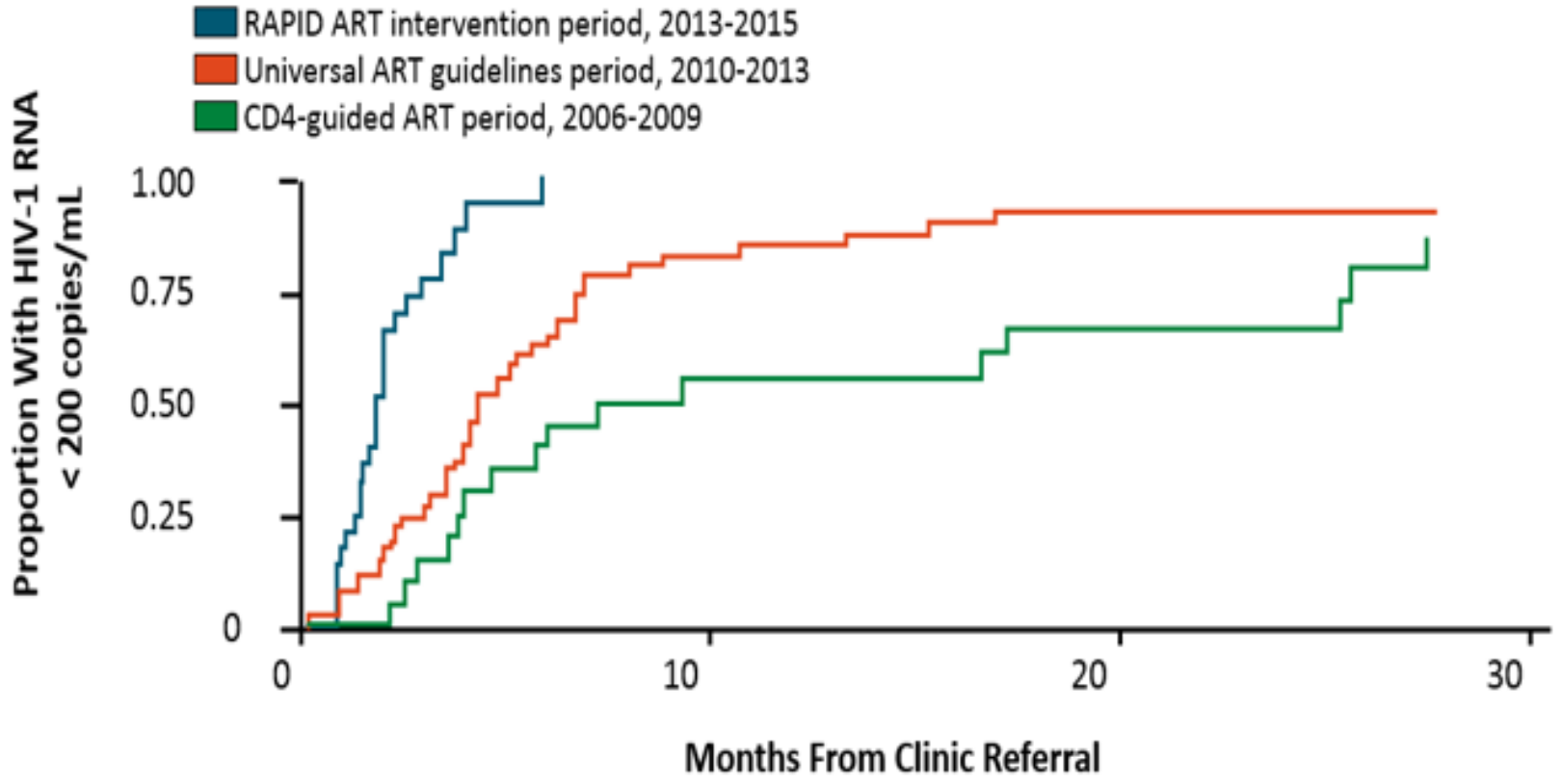
Ward 86 RAPID ART Program: Time to Virologic Suppression, 2013-2017



Coffey. AIDS. 2018;[Epub].

UCSF SFGH Rapid Program

Time to Viral Suppression in Patients Newly Diagnosed HIV+ at UCSF With RAPID vs Prior Periods



Pilcher. JAIDS 2017; 74:44

New Orleans

New Orleans: Crescent Care Start Initiative (CCSI)

- Federally Qualified Health Center
- Linkage coordinator available 24h/day to assist linkage of new dx
- New pts mostly referred from their own testing centers
- Link pts to start ART within 72 hrs of dx
- Paperwork filled out
- Initial visit with provider: 30 min
- Labs, and enrollment in insurance after
- Directly observed therapy, DTG + FTC/TAF 30-day dose pack given
- Follow up within 4 weeks

Halperin. *AIDS Patient Care STDS.* 2018;32(2):39-41.

CrescentCare Start Initiative: ART Within 72 Hrs of Diagnosis vs ART Within 72 Hrs of Clinic Contact

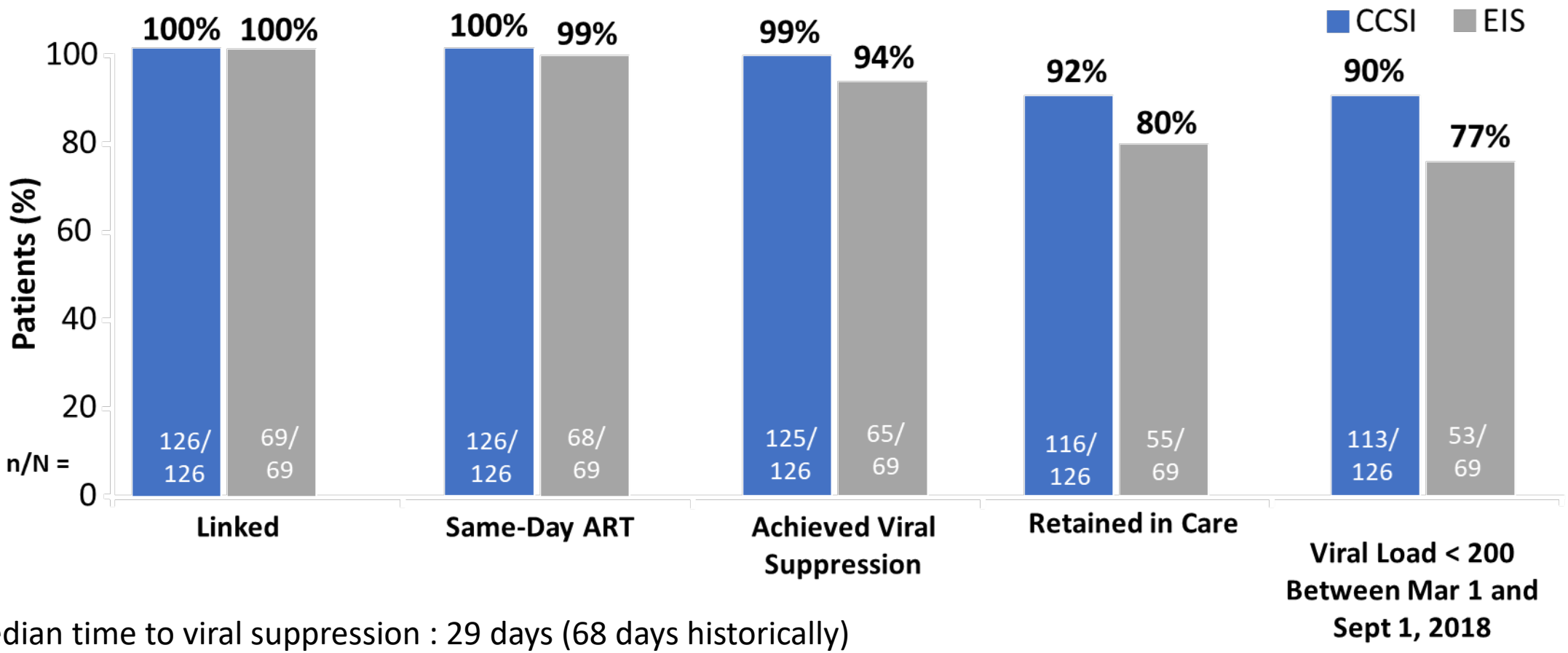
- All patients started on TAF/FTC + DTG (December 2016 - February 2018):
  - CCSI patients (n = 126): linked and same-day ART within 72 hrs of diagnosis
  - EIS patients (n = 69): ART naive and started same-day ART within 72 hrs of contact with clinic

Characteristic, n (%)	CCSI	EIS	*P* Value
Sex			
▪ Male	94 (74.6)	57 (82.6)	
▪ Female	27 (21.4)	10 (14.5)	
▪ Transgender female	5 (4.0)	2 (2.9)	.4533
Race			
▪ Black	81 (64.3)	48 (69.6)	.7576
▪ White	30 (23.8)	14 (20.3)	
▪ Latino/other	15 (11.9)	7 (10.1)	
HIV risk factor			
▪ MSM	73 (57.9)	42 (60.9)	.4775
▪ Heterosexual	48 (38.1)	22 (31.9)	
▪ IDU	5 (4.0)	5 (7.2)	

Characteristic	CCSI	EIS	*P* Value
Age < 25 yrs, n (%)	35 (27.8)	23 (33.3)	.4171
Age, yrs + IR	29 ± 13	29 ± 13	.9280
Syphilis/GC/CT, n (%)	48 (38.1)	32 (46.4)	.2609
Mental health diagnosis, n (%)	25 (20.0)	23 (33.3)	.0394
Baseline CD4+ cell count, cells/mm^3 + IR	444 ± 375	271 ± 335	.0003
Baseline CD4+ % + IR	25.7 ± 16.6	18 ± 16	.0022
Baseline HIV-1 RNA, copies/mL + IR	42,600 ± 147,000	70,150 ± 187,7000	.2260

Halperin. Open Forum Infect Dis. 2019;6:ofz161.

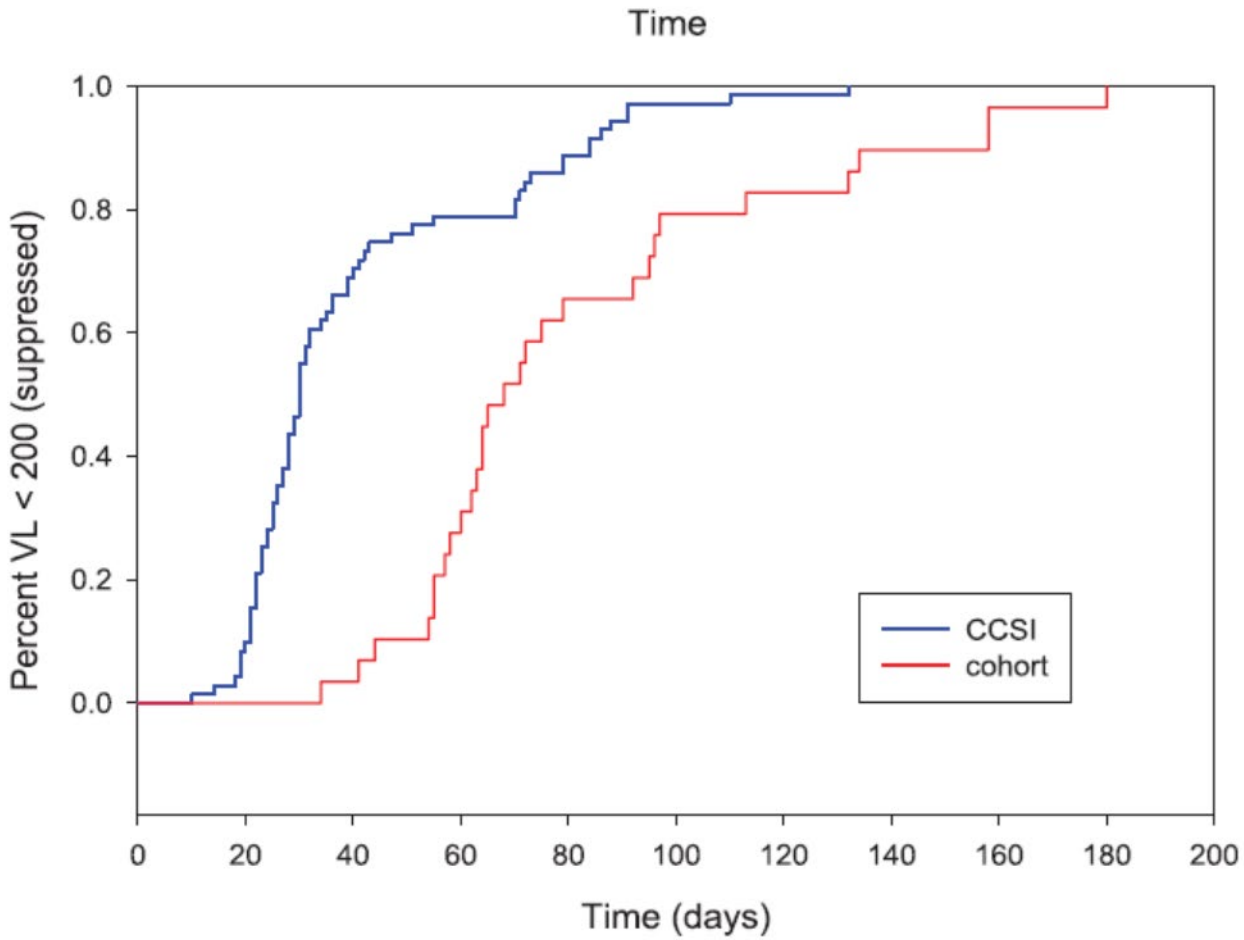
More CCSI Than EIS Patients Achieved Viral Suppression



Median time to viral suppression : 29 days (68 days historically)

All patients with transmitted resistance achieved viral suppression, including 5 patients with M184V/I (3/5 had previously been on PrEP); no change in ART due to hepatic or renal toxicities

New Orleans CCSI: Time to Virologic Suppression



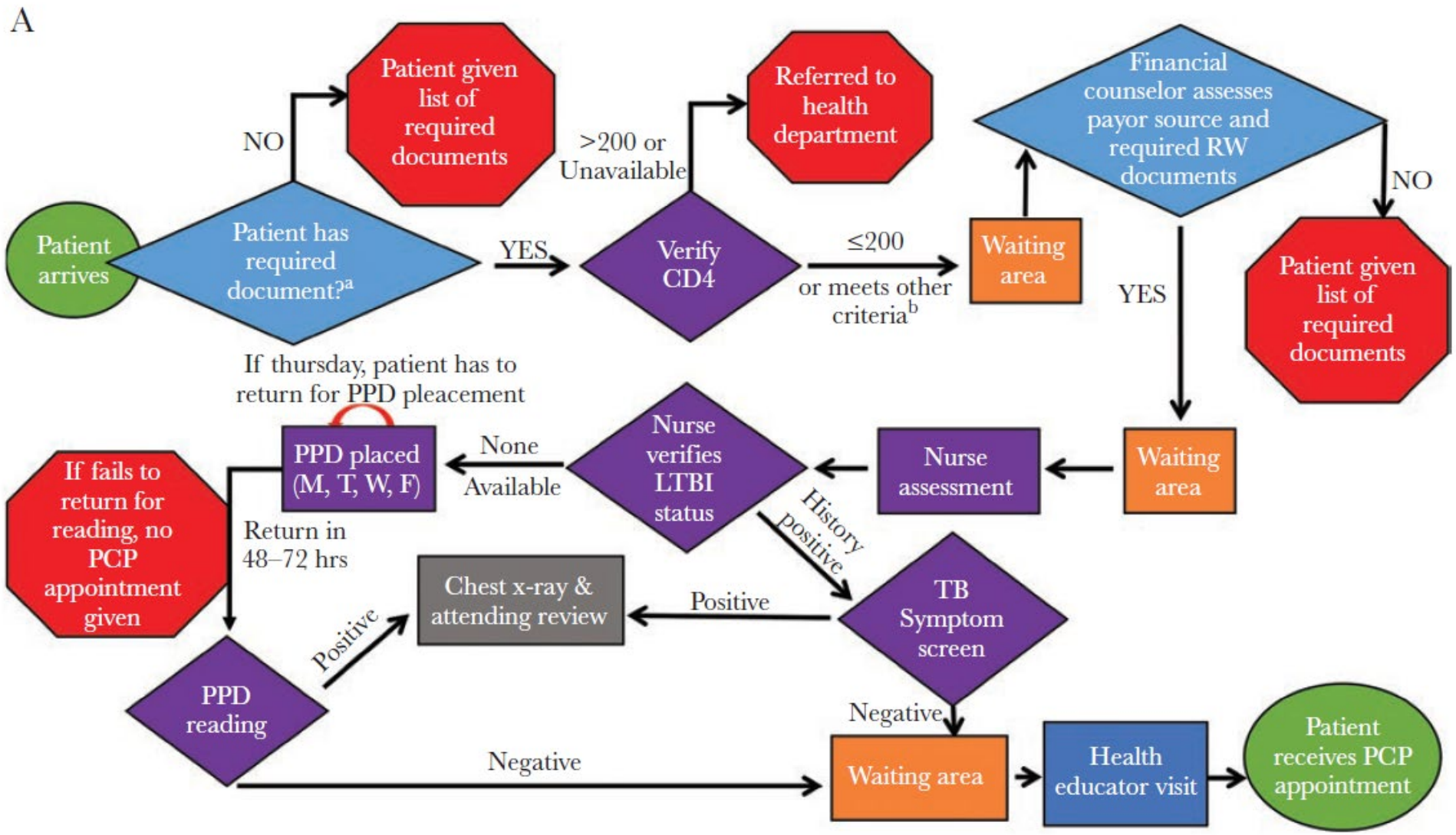
Halperin. *AIDS Patient Care STDS.* 2018;32(2):39-41.

Atlanta

Atlanta: Infectious Diseases Program, Grady Health System

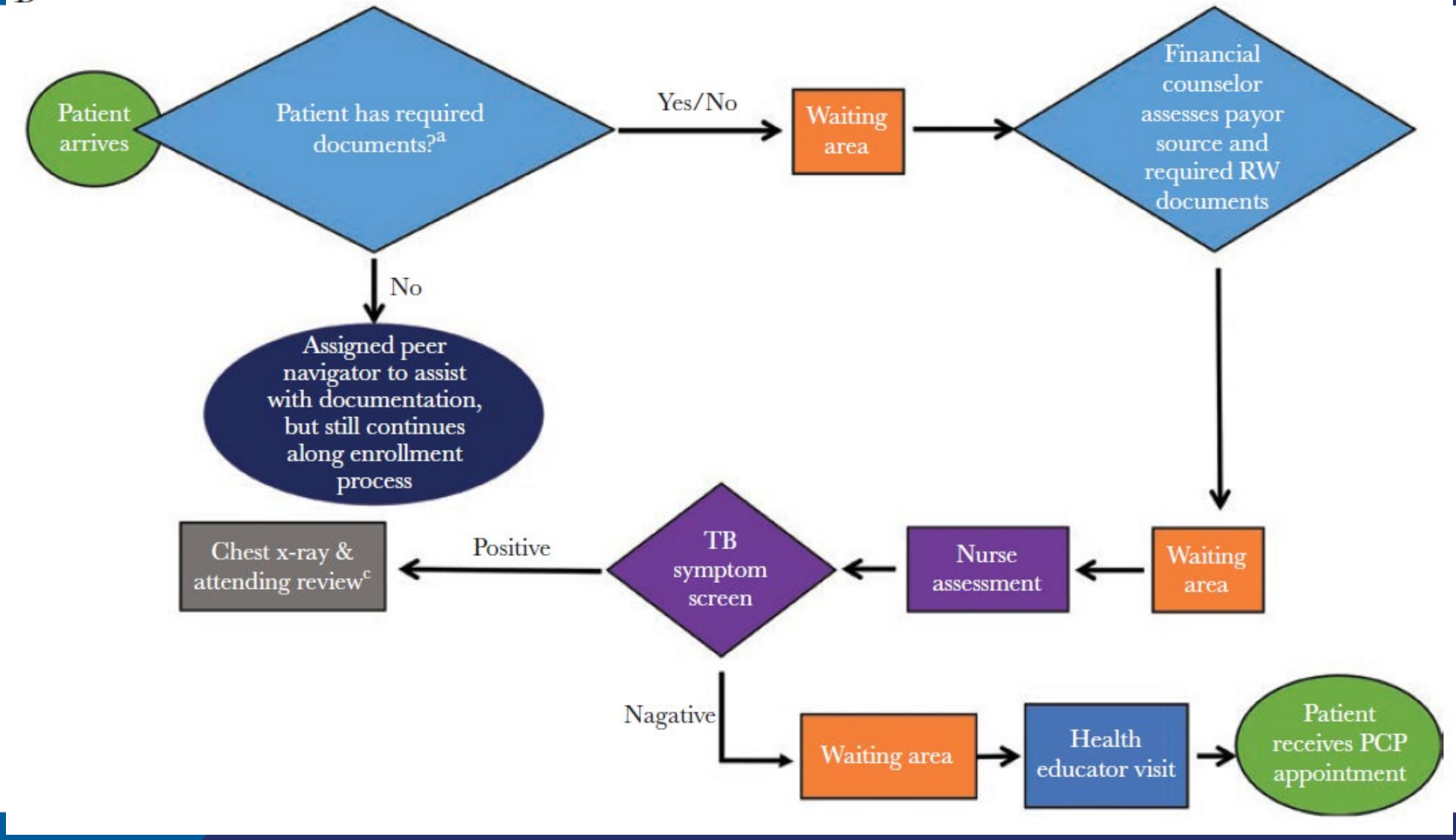
- Rapid Entry and ART in Clinic for HIV (REACH)
- Started May 2016
- Provider visit and option to initiate ART within 72 hours of ***establishing care*** at the clinic
- New dx and re-entering care
- Pts given initial provider appt even if missing required documents at first visit
- Dispense 30 day supply of ART

Pre-REACH


A
Patient arrives
Patient has required document?[a]
NO
Patient given list of required documents
YES
Verify CD4
>200 or Unavailable
Referred to health department
≤200 or meets other criteria[b]
Waiting area
Financial counselor assesses payor source and required RW documents
NO
Patient given list of required documents
YES
Waiting area
Nurse assessment
Nurse verifies LTBI status
None Available
PPD placed (M, T, W, F)
If thursday, patient has to return for PPD pleacement
Return in 48–72 hrs
If fails to return for reading, no PCP appointment given
History positive
TB Symptom screen
Positive
Chest x-ray & attending review
Positive
PPD reading
Negative
Negative
Waiting area
Health educator visit
Patient receives PCP appointment

REACH

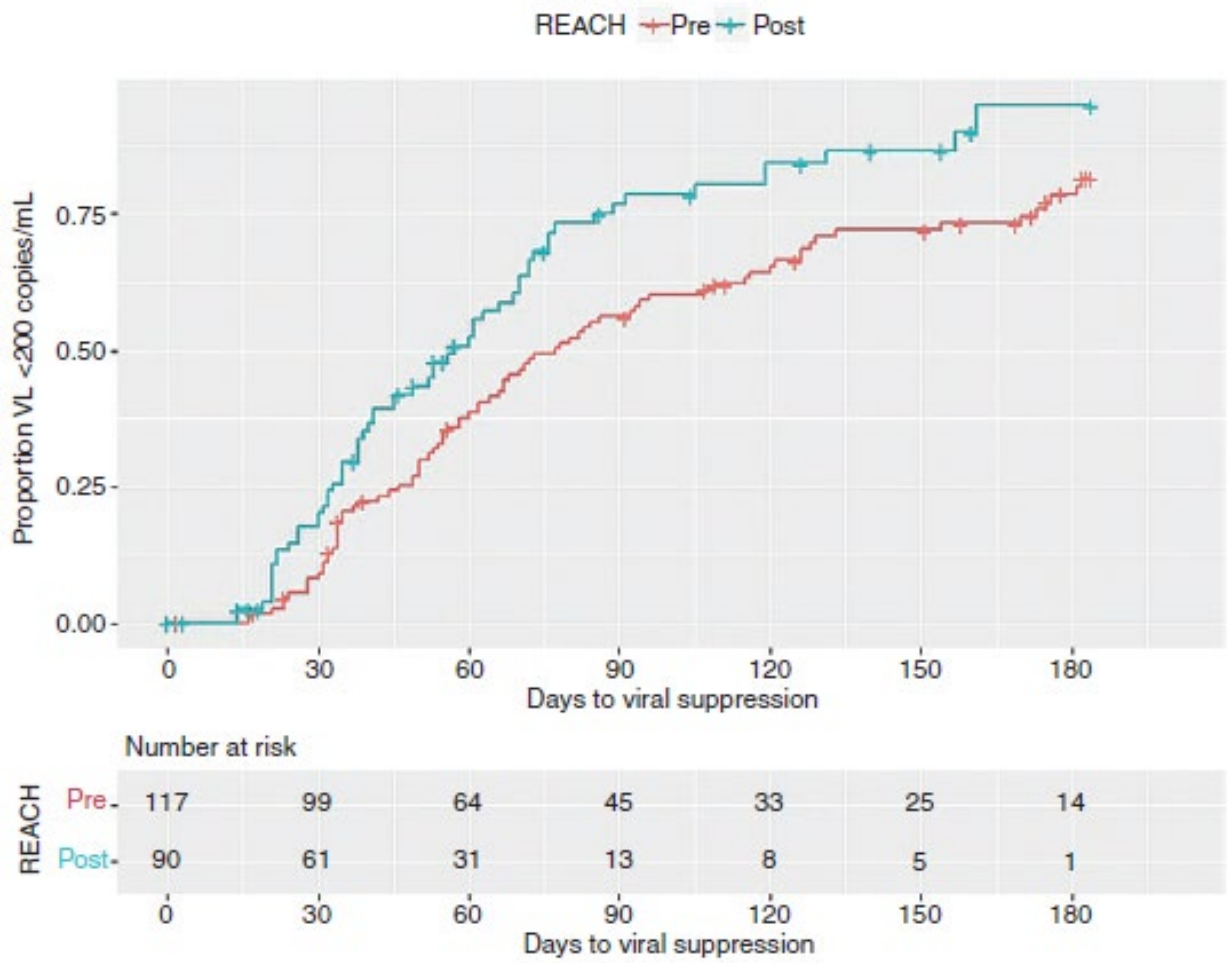
B


Patient arrives
Patient has required documents?[a]
Yes/No
Waiting area
Financial counselor assesses payor source and required RW documents
No
Assigned peer navigator to assist with documentation, but still continues along enrollment process
Waiting area
Nurse assessment
TB symptom screen
Positive
Chest x-ray & attending review[c]
Nagative
Waiting area
Health educator visit
Patient receives PCP appointment

Demographics and Clinical Characteristics

- 79.7% male
- 90.8% African American/Black
- 59.9% MSM
- 57.0% Ryan White , 4.3% Medicare. 26.6% Medicaid
- 60.9% Unstable housing
- 44% Active substance use
- 26.1% with Mental health diagnosis
- Median CD4: 146 (45-302)
- 59.9% ART Naïve
- Median time from diagnosis to clinic presentation: 18 mo (1-93)

Outcomes: Time to Virologic Suppression



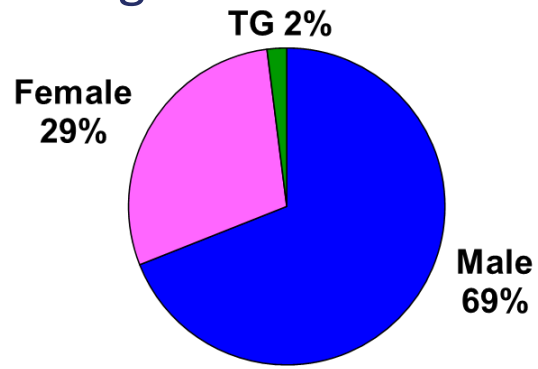
Our Rapid Start Story
iSTAT Clinic
Parkland HIV Services
Dallas Texas

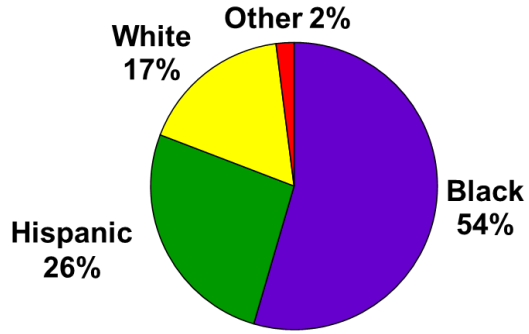
- Share processes and plan to meet the need of newly diagnosed and vulnerable return-to-care populations

Parkland HIV Services

- Majority of patients are uninsured and seen under Ryan White Program
- 5,837 patients seen by an HIV medical provider
- 258 newly diagnosed with HIV
- Gender
  - Male 4,051 (69%)
  - Female 1,691 (29%)
  - Transgender 95 (2%)
- Race
  - Black 3,179 (54%)
  - Hispanic 1,521 (26%)
  - White 996 (17%)
  - Other 141 (2%)

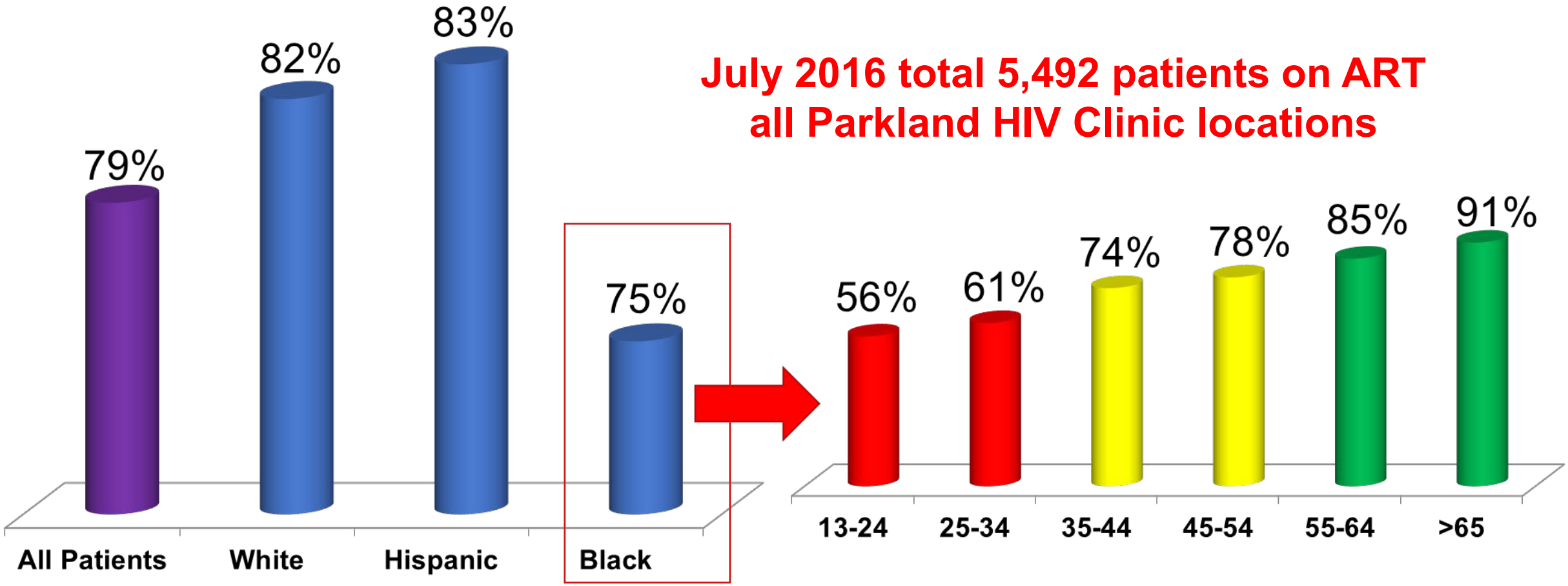
  (includes Asian and Pacific Islander)



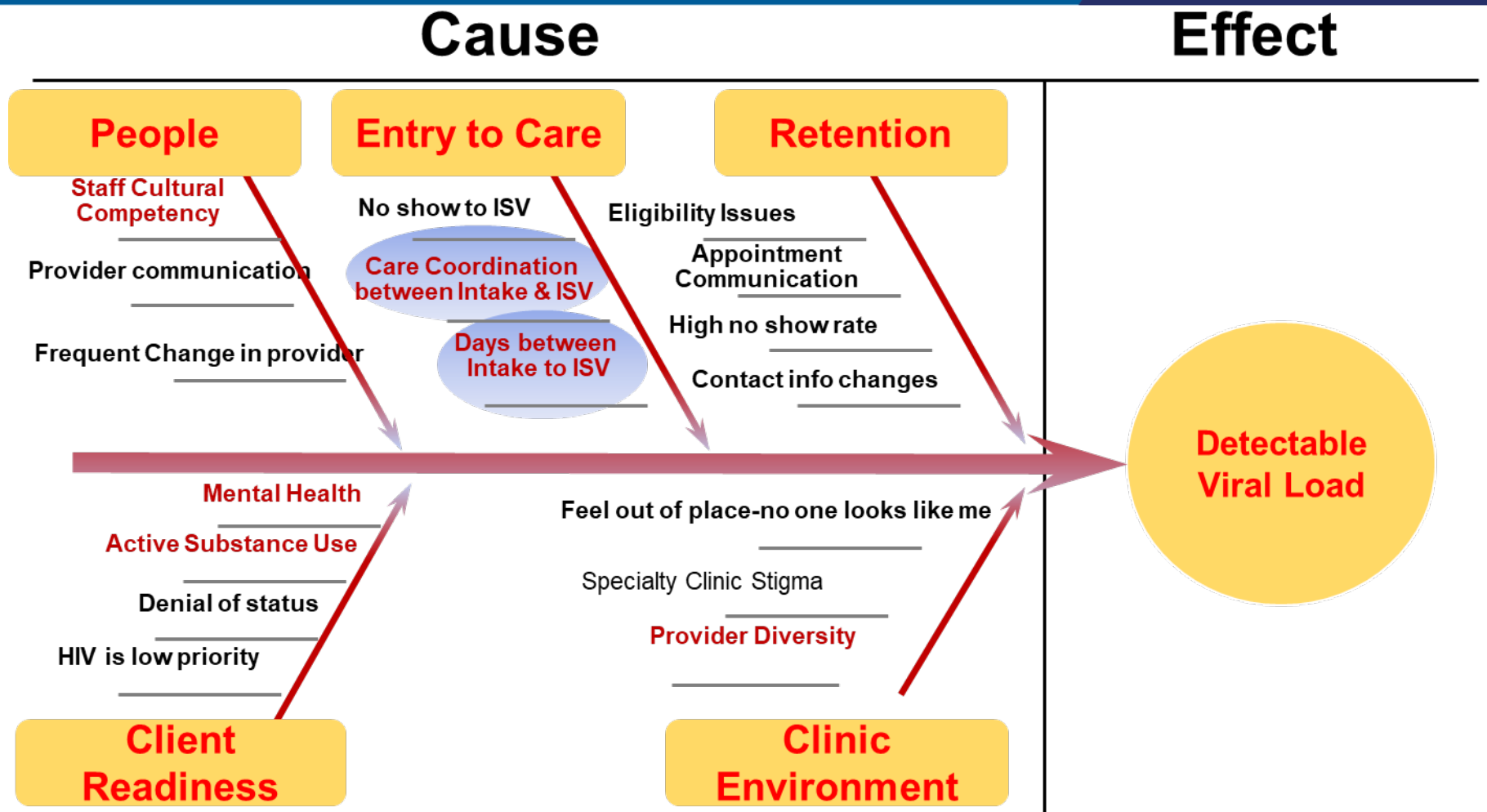


Parkland Viral Suppression

July 2016 total 5,492 patients on ART all Parkland HIV Clinic locations



Parkland Detectable HIV VL



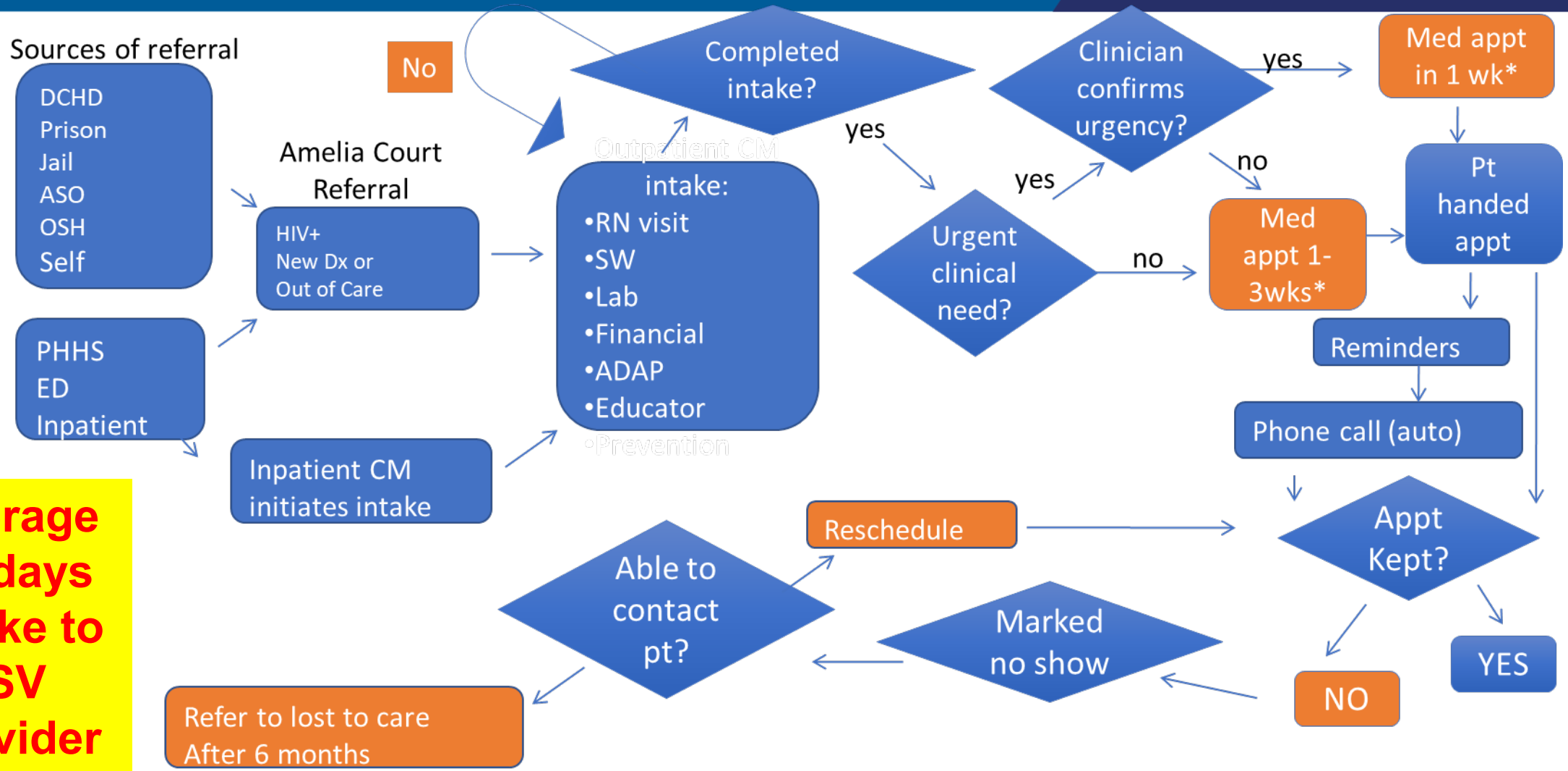
Parkland Baseline

- Reviewed 200 cases of HIV patients presenting for care in Dallas and San Antonio, Texas
- 28% new diagnosis of HIV
- >70% minority race/ethnicity
- Shorter time to initial medical service visit (ISV) completion associated with
  - CD4 <200 cells/uL
  - Dallas study site vs San Antonio
  - Recent hospitalization
- ISV attendance associated with higher proportion of visits attended in the future and fewer gaps in care

Parkland Baseline 1

AIDS Patient Care and STDs. 2017 May;31(5):213-221. doi: 10.1089/apc.2017.0030.

Parkland Baseline Process



Average 37 days intake to ISV provider

2017 Nijhawan AE, Liang Y, Vysyaraju K, et al. Missed Initial Medical Visits: Predictors, Timing, and Implications for Retention in HIV Care. *AIDS Patient Care STDS*. 2017;31(5):213-221. doi:10.1089/apc.2017.0030

Parkland Baseline 2

- Complex entry into care process with long delays between steps created a high no-show rate for ISV
  - New Patient Show rate: 63%
  - Intake to ISV <30 days: 61%
- Appointments for an individual patient would be scheduled and rescheduled multiple times filling up the schedule for a provider
- Often took 2-3 provider visit slots to complete a new patient visit
- Needed increased flexibility for providers to see patients in clinic vs sitting waiting between patients who did not show for scheduled visit

Parkland Rapid Start = iSTAT

Aims and Change Ideas:
iSTAT can address both ACCESS and VIRAL LOAD SUPPRESSION

Aim	Drivers	Change Ideas (PDSAs)
Increase Viral Load Suppression among priority populations from 64% to 80% by September 2019	Improve Care Coordination	1. Integrate Behavioral health to address co-occurring issues with substance use/mental health 2. Case Management Flowsheets now available in EPIC 3. Champion efforts in Clinic Review & Provider meetings
	Reduce days from Intake to Initial Service Visit (ISV)	**1. STAT visit (new) that will offer same day Intake/ISV** **2. Develop STAT protocol for rapid intake- initiation of ART** **3. Hire Advance Practice Providers to improve next available appointments**
	Improve Client Readiness & Engagement	1. Partner with support agencies to co-locate for Intake to receive food/mental health/housing (currently 2 agencies, expanding to 3 in August) 2. Train staff on 'on the fly' text; secure messaging; Request automation of missed lab visits & clinic visits. 3. Validate contact information with every contact 4. Partner with existing support agencies in the community offering Youth services

Rapid Start Plan

- Designate advanced practice providers (APPs) to assist with new patient visit availability
- UTSW HIV/ID Faculty expertise to develop strong protocols for an Immediate Start of Antiretroviral Treatment (iSTAT) visit for APPs to follow
- Empower case managers to drive process to ensure priority given to
    - new HIV diagnosis
    - return to care patients with focus on
        - high viral load/low CD4
        - recently released from the hospital
        - previously incarcerated

Changing the Schedule

- Changed new provider visit slots to an appointment that cannot be filled until the same day
- Hospital discharge slots changed for patients with high no show rates to also wait until patient arrives in clinic to be scheduled and seen
- Crucial role of advance practice providers (APPs) nurse practitioners and physician assistants
- Need for flexibility and acceptance of imperfection
- Cannot cover every single medical and psychosocial issue during the first provider appointment

iSTAT Streamlined

Follow Up Visit in
7-14 Days

iSTAT In Action

- Instant Messaging on PCs for Communication across teams (Jabber)
- Warm handoff to each role in the Intake
- Orange Card 'Fast Track' for Financial Determination
- Flexibility of CM/Clinic in handling late arrivals/complications
- Texas ADAP and Patient Assistance Program Enrollment for clients

Eligible Patients

1. Include those with newly-diagnosed HIV patients, including those with acute and chronic infections:
    A. Acute HIV: Patients with positive 4th generation HIV-testing, negative antibody differentiation assay, and positive HIV-1 RNA or TMA testing
    B. Chronic HIV: Patients with positive 4th generation HIV testing, positive antibody differentiation assay

Eligible Patients: What About Unconfirmed HIV?

A. Patients with positive 4th generation HIV-testing, pending confirmatory HIV assay results
    1) Specificity of 4th generation testing is approximately 99.6%→false positive results are very rare
    2) Benefit of starting ART early may outweigh the negligible risk of taking ART for a few days and then stopping if confirmed HIV negative.
    3) Patients started on therapy on the day of diagnosis rather than multiple visits may have improved adherence and retention in care.
    4) Clinicians should discuss risk factors and pre-test probability of a positive result with patients in deciding to start therapy without a confirmatory result.

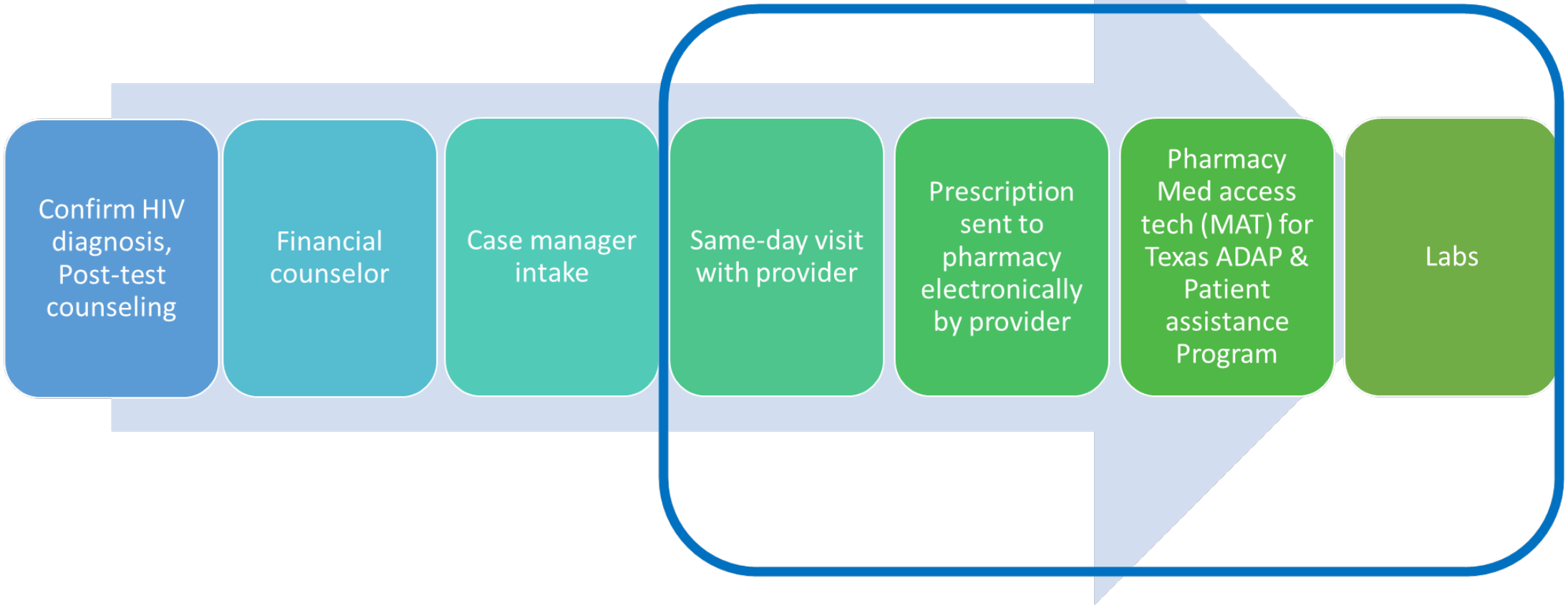
Unconfirmed HIV

1) For patients with a reactive HIV screening test pending confirmation, it is discussed that screening test results are not diagnostic, and false-positive results are possible
    a) That a confirmatory HIV test will be performed
    b) That ART will be discontinued if confirmatory test is negative and continued if it is positive
    c) Confirmatory HIV test results will be provided as soon as possible. HAART will be discontinued if results are negative. If results are positive, adherence will be reinforced.

Prioritization of Patients

- First priority to patients with no history of HIV diagnosis
- If available, patients with prior history also seen in these slots; priority of patients who are lost to care, recently hospitalized, incarcerated
- Lower priority to patients who are currently taking medications and have no urgent medical needs

iSTAT Streamlined Cont..



Follow Up Visit in 7-14 Days

iSTAT Protocol

- Targeted medical history and physical examination, including evaluation for possible opportunistic infections

- In patients with symptoms of suspected opportunistic infections, a diagnostic evaluation will be performed and antiretroviral therapy initiation will be deferred

Parkland

Procedure Title	Number	Published: MM/DD/YY
Name of Manual		Page 1 of 7

SCOPE:

Parkland Health & Hospital System ("Parkland") HIV care facilities, including outpatient care areas and clinics.

PRACTICE STATEMENT:

The Rapid ART Initiative or iSTAT (Immediate STart of Antiretroviral Therapy) is a clinical program intended to further the goals of the Parkland 2020 strategy, to reduce new HIV diagnoses, improve linkage to and retention in primary care services, and improve virologic suppression. Based on recently published data demonstrating the benefits of immediate linkage and treatment of HIV, we propose to provide initiation of antiretroviral therapy at the time of confirmed HIV diagnosis. The potential benefits include: improving individuals' health by decreasing time to virologic suppression, improving rates of early engagement in care and long-term retention in care, and reduction of new HIV infections through viral suppression of known HIV+ patients. The goal of the program is for newly-diagnosed patients to meet with case management to receive counseling and be connected to community services, see a medical provider who is expert in HIV care, and be offered antiretroviral therapy on the day of their diagnosis.

Lab Tests

- Baseline labs ordered by provider, allowing freedom to adjust lab orders based on clinical need rather than “one-size-fits all”
- We include cryptococcal antigen screening for most patients since 27% of patients in Dallas County who are newly diagnosed with HIV have AIDS at the time of diagnosis
- We have diagnosed multiple patients with minimal or no symptoms and cryptococcal meningitis in this way

Antiretroviral Initiation

- Patient-centered discussion regarding risks and benefits
- Discuss the possibility of immune reconstitution syndrome
- Selection of regimen depends on patient preference, co-morbidities, potential drug interactions, side effects, allergies
- Preferred regimens include:
  - Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide)
  - Symtuza (darunavir/cobicistat/tenofovir alafenamide/emtricitabine)
  - Dolutegravir (Tivicay) + Descovy (emtricitabine/tenofovir alafenamide)
  - Raltegravir (Isentress) + Descovy (emtricitabine/tenofovir alafenamide)

Preferred Antiretroviral Regimens

- If patients have access to funding (private insurance, Medicare/Medicaid), prescription sent to patient's pharmacy
- If patients do not have access to immediate funding, patients meet with Medication Access Specialists
- Patient assistance programs available: certain medications can be sent to our hospital pharmacy and 30 day prescription provided which patient can pick up the day of the appointment
- Alternatively application for Harbor Path completed, patient receives medication through the mail within 2-5 days
- Patient completes paperwork for ADAP, which typically takes 4-6 weeks to complete in Texas

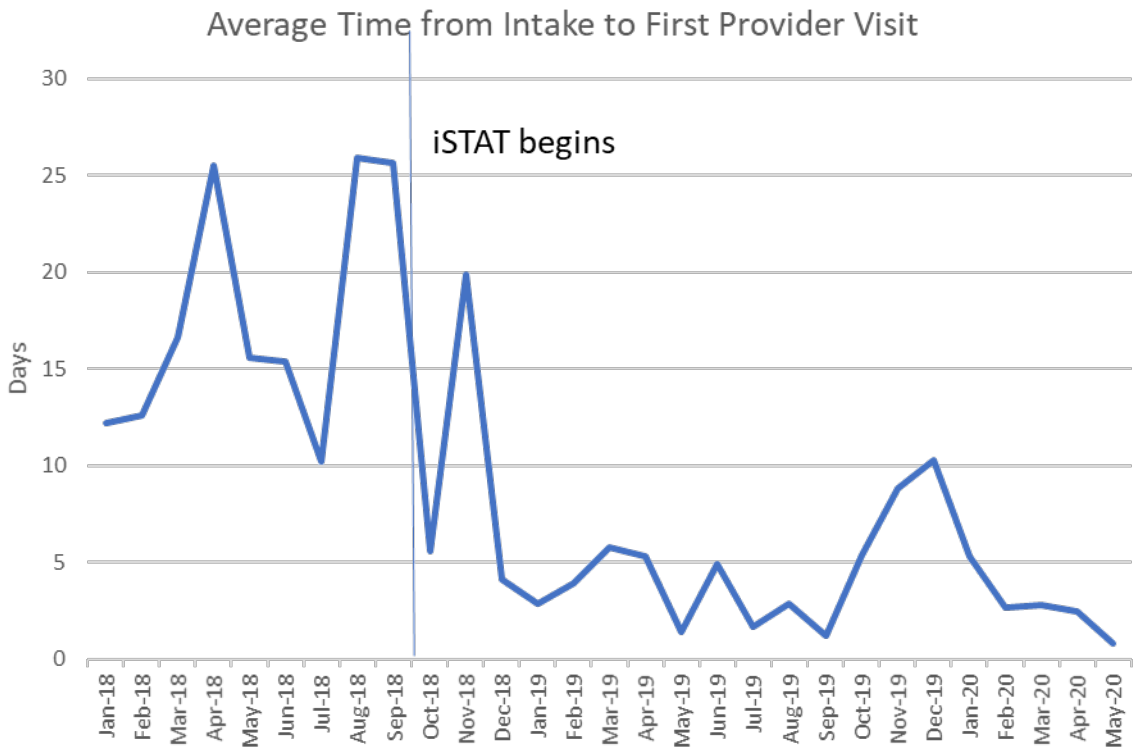
Follow Up

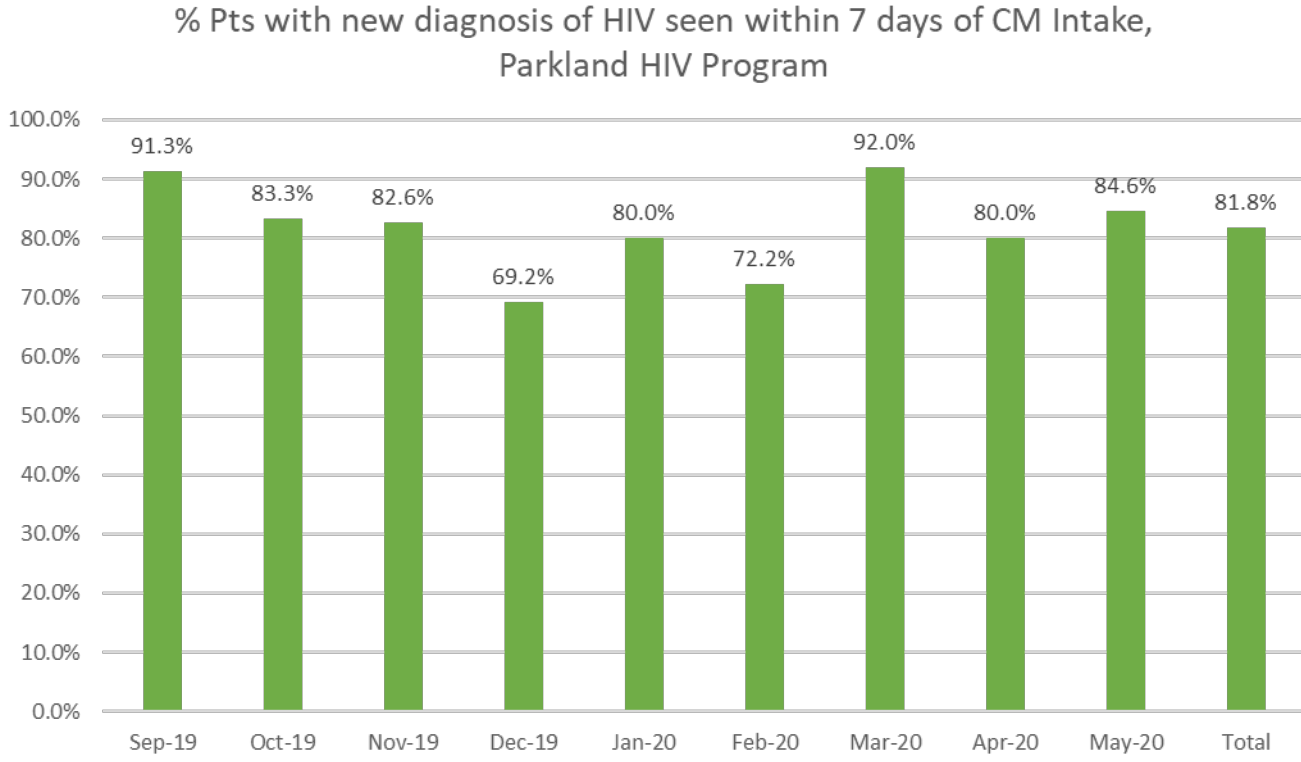
- Ordered labs return to provider's inbox
- Patient contacted with any immediately actionable labs
- Virtual visit in 14 days to discuss lab results and to discuss the medication

iSTAT – Initial Outcomes, Achievements & Next Steps

- Discuss outcomes that can support replication and expansion of Rapid Entry Programs beyond new diagnosis

iSTAT: Improving Access





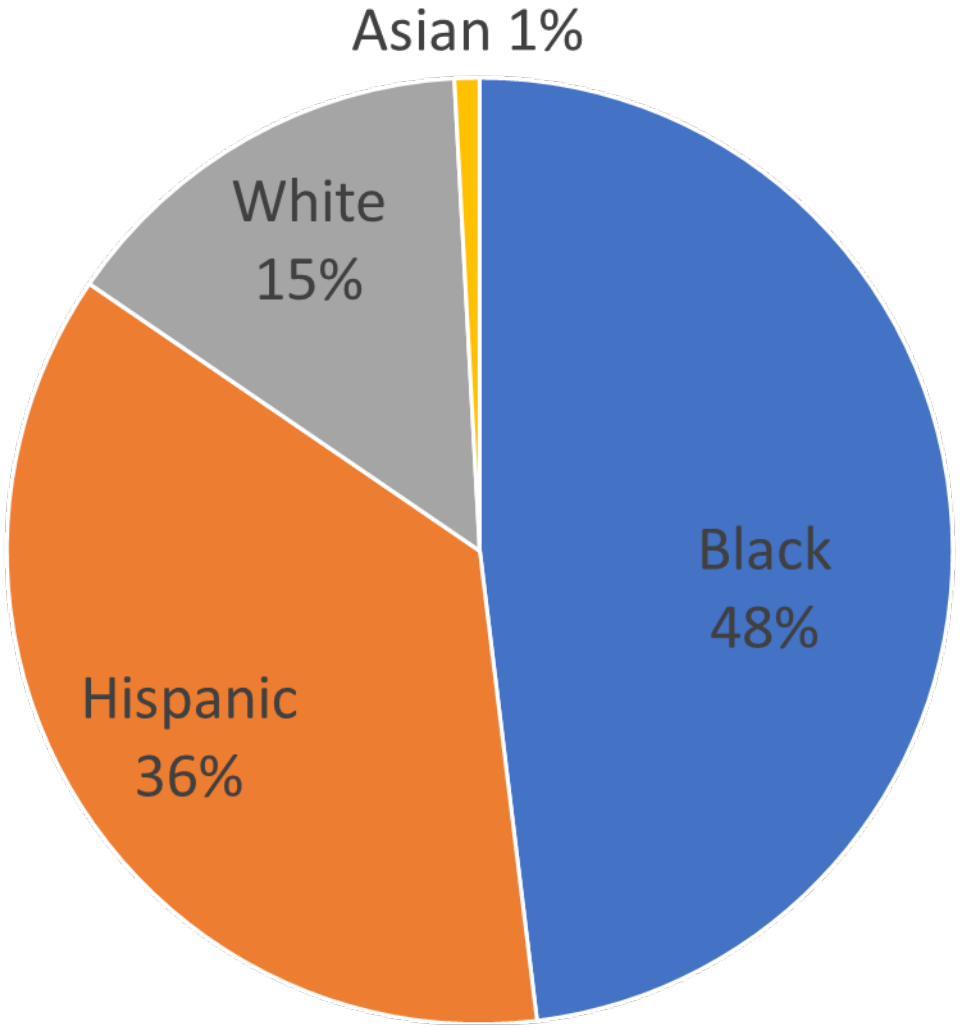
iSTAT: Initial outcomes

- Review of clients with completed iSTAT visits
- October 2018 – December 2019
- 770 total HIV patients seen in rapid start iSTAT clinic
- Majority of patients were previously diagnosed with HIV and returning to care

…SO LET US SHARE SOME OF OUR iSTAT DEMOGRAPHICS AND CLINICAL CHARACTERISTICS

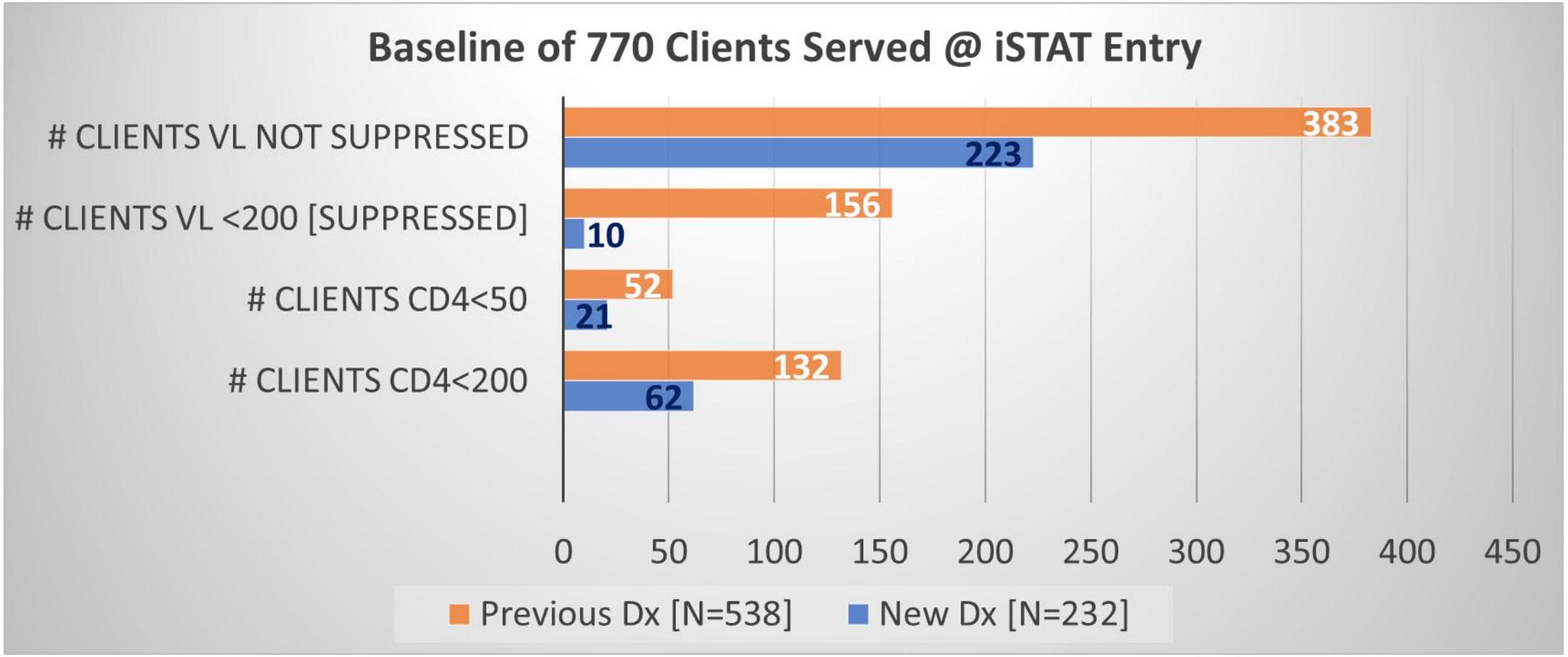
iSTAT: New HIV Diagnosis

232 newly diagnosed HIV patients 10/18-12/19



84%
AA or Latinx

iSTAT: Snapshot of Clients at Entry



- Case Management 'triages' Intake clients to ensure priority is given to
  - new diagnoses, previously incarcerated, high viral load/low CD4 , recently released from the Hospital, & return to care

ACUITY needs:

Questions span the following Life Areas:

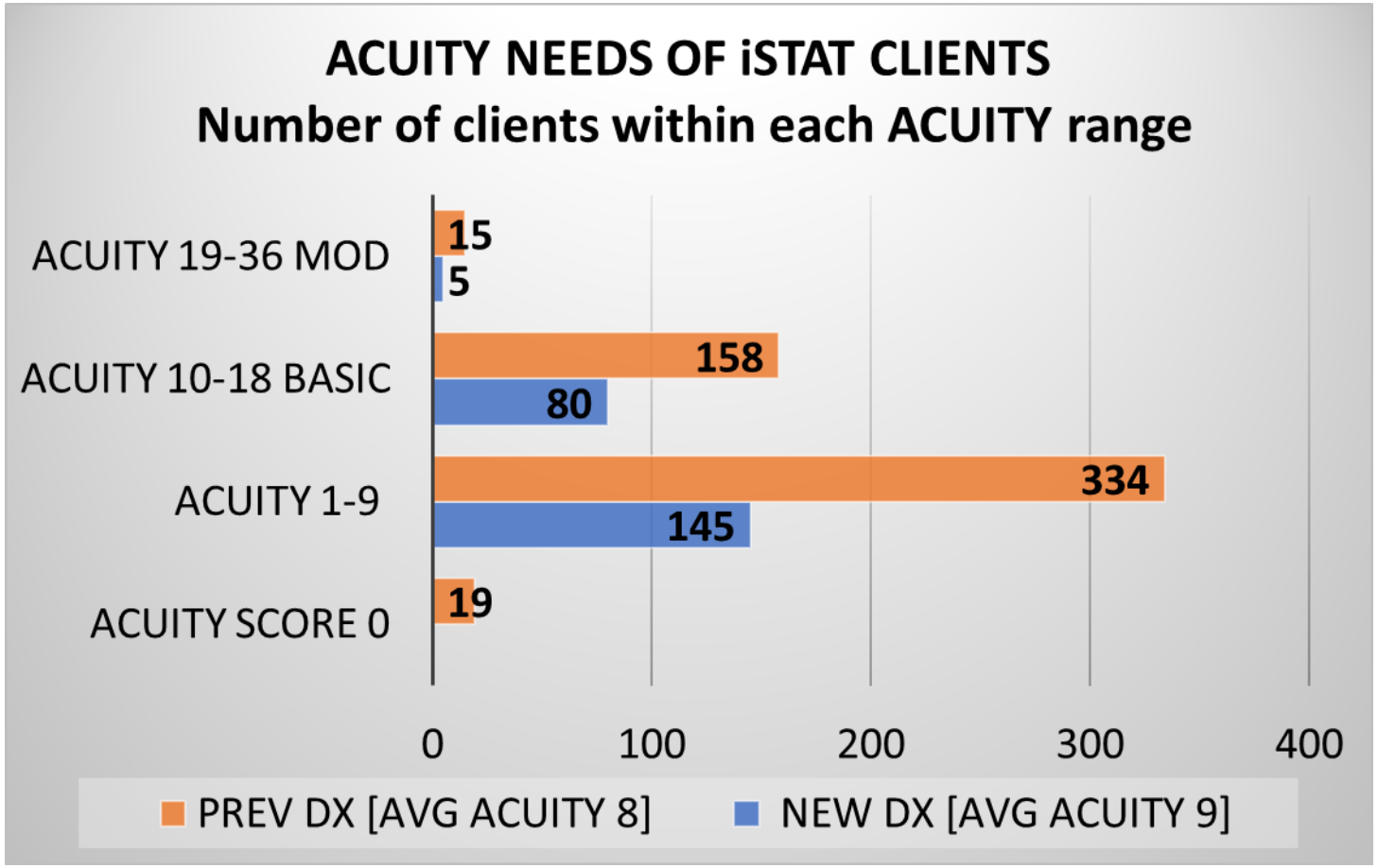
- *HIV Knowledge; Mental Health; Domestic Abuse/IPV; Substance us; Living Situation; Transportation; Cultural/Linguistic in navigating Health Care system; Support system; Utilities/Financial needs*

Responses to each Life Area are scaled **0-3**

0 (Self Management) to **3** (Intensive CM Need)

TOTALED SCORE

- 0-9 POINTS: no ongoing cm needed
- 10-18: potentially 3-6 months & reassess ACUITY @ 90 days
- 19+: Moderate to intense cm needed & reassess ACUITY between 45-60 days.



ACUITY needs (cont'd)

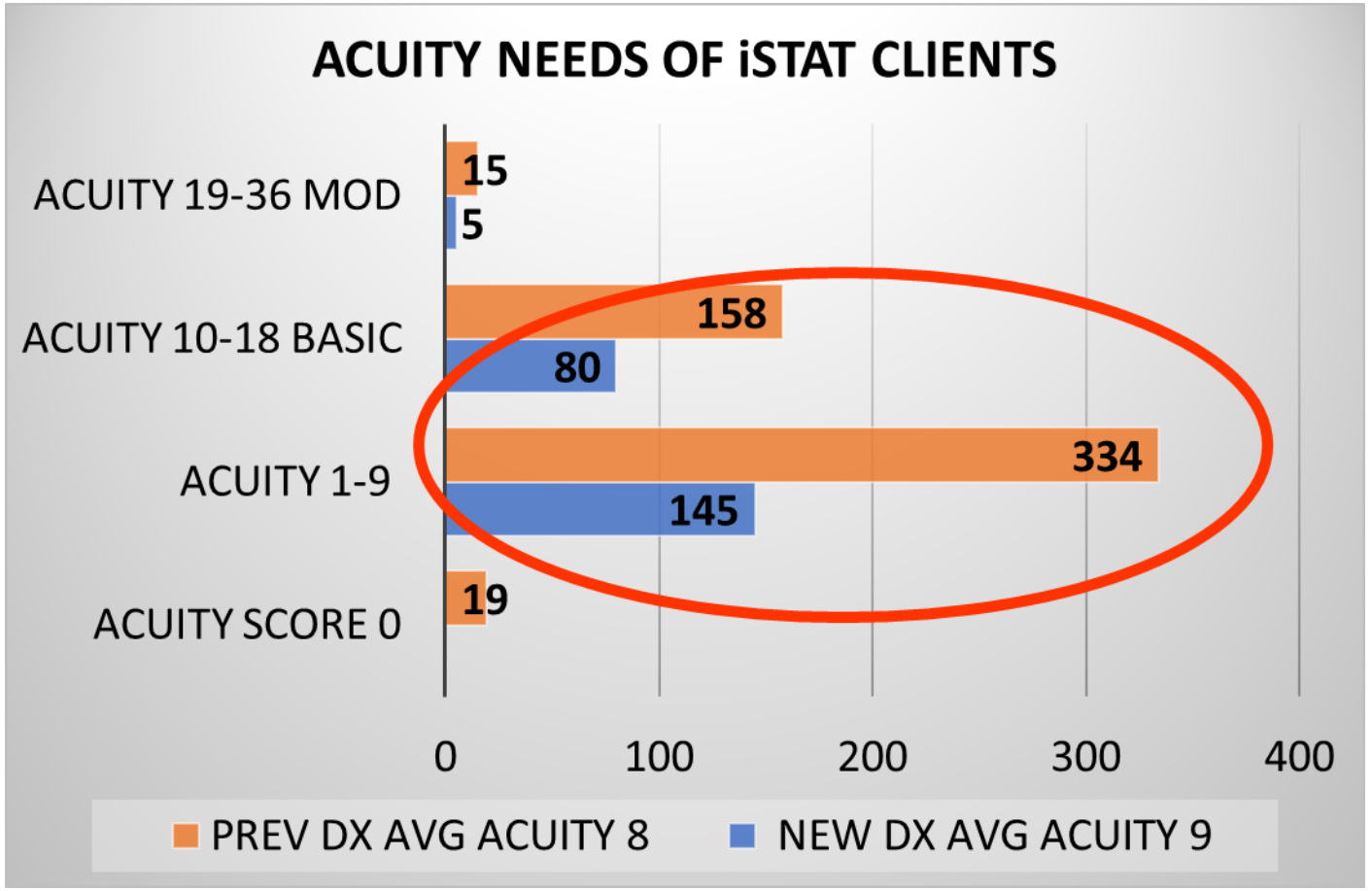
Texas Dept of Health and Human Service Standard of Care guides Case Management.

Though responses to each Life Area are scaled 0-3

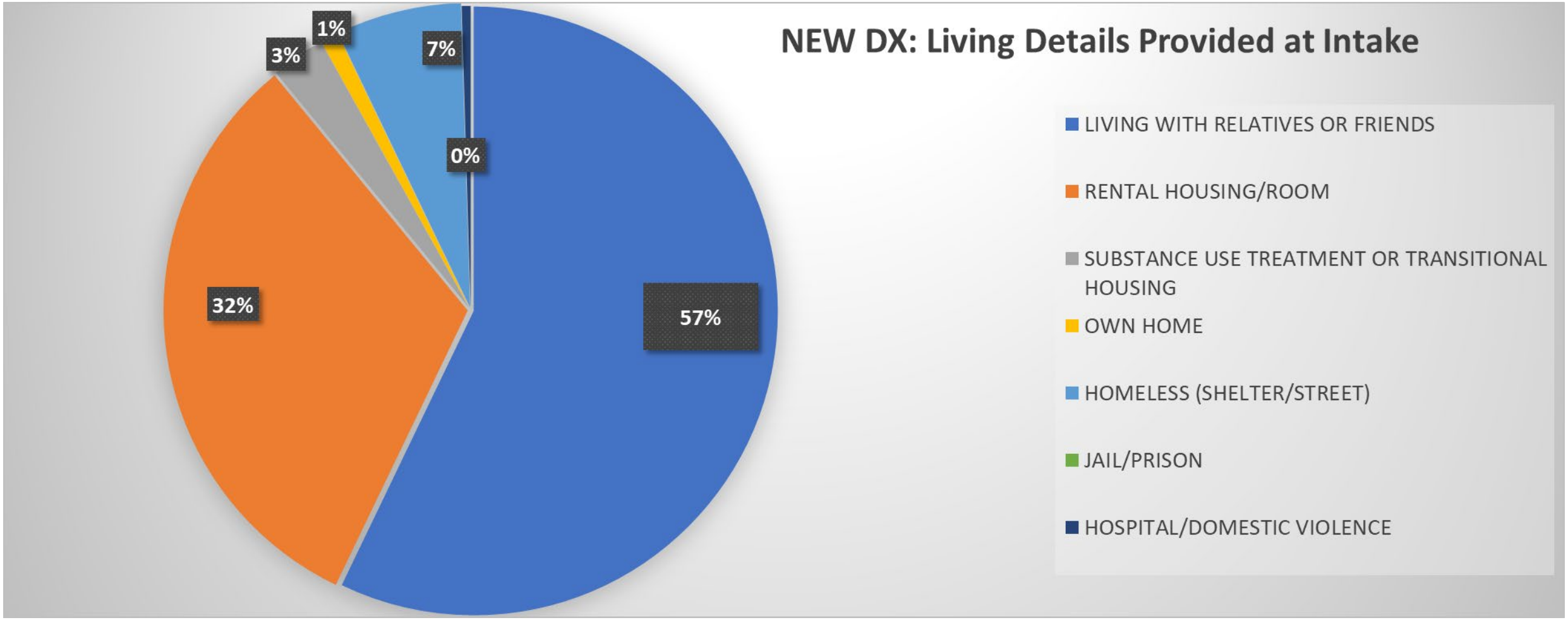
0 (Self Management) to 3 (Intensive CM Need)

- 145 New Dx still identified several areas at a possible Intensive Need Score and
- 80 New Dx had combined needs that ranged from 10-18.

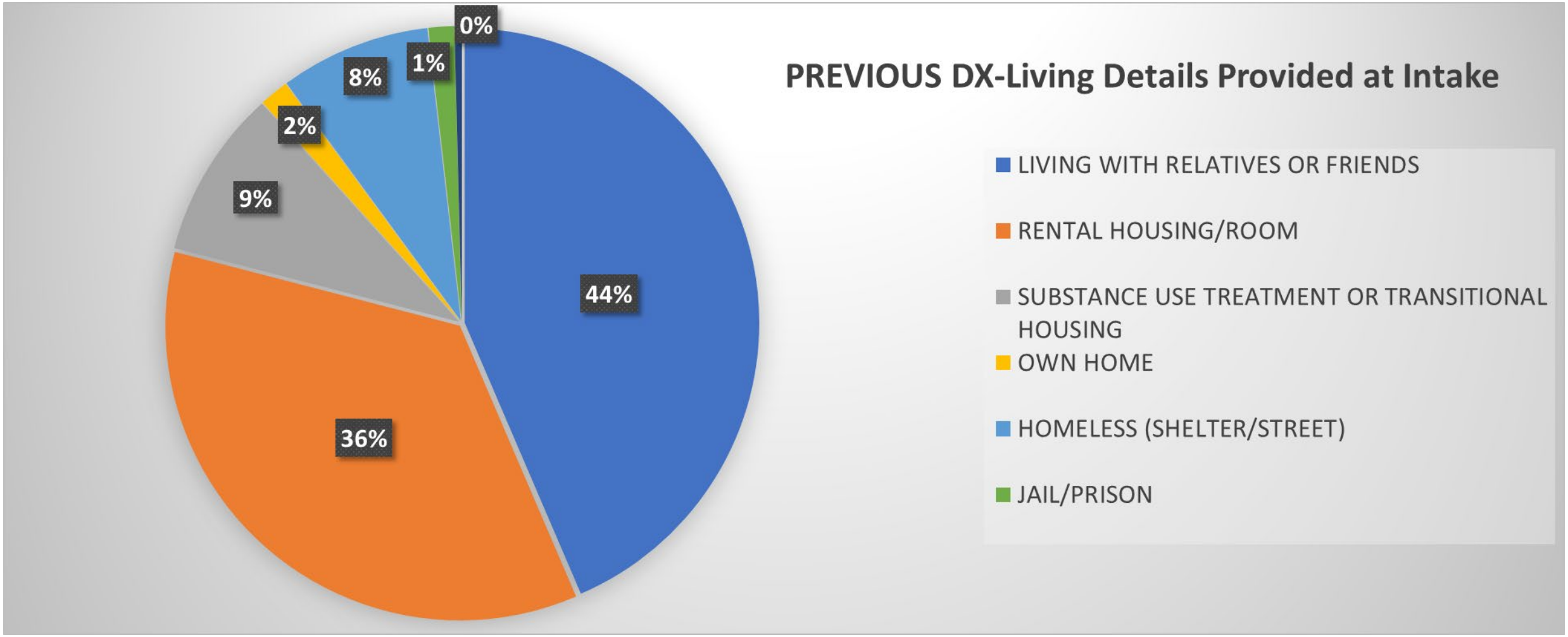
These scores and the underlying response within categories have created conversations in our Dept to better triage these needs and possibly shift response to match individual intraACUITY scoring. Several pilots in priority groups are ongoing.



Knowing who we serve: Housing at entry- New Diagnosis



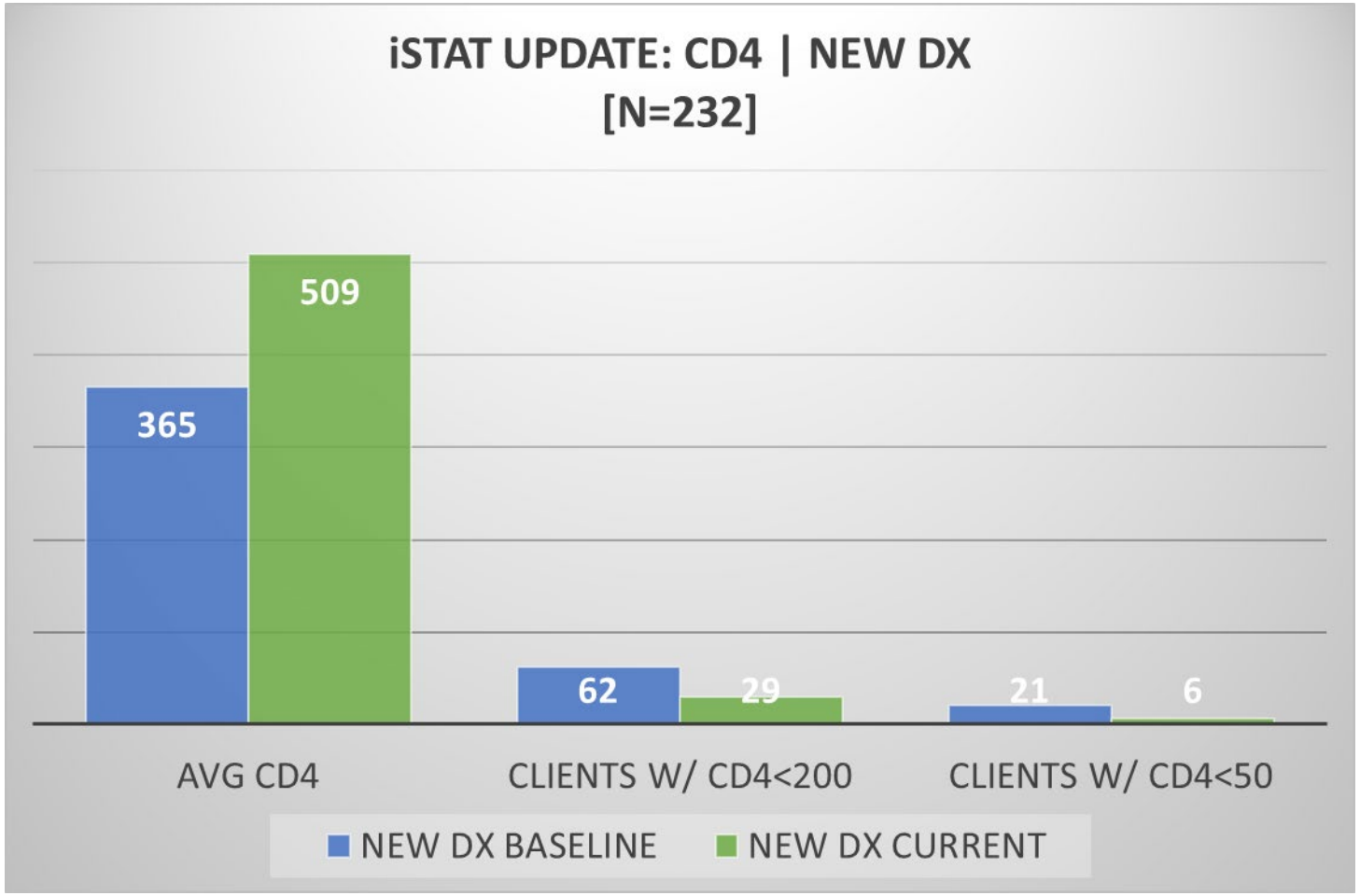
Knowing who we serve: Housing at entry- Previous Diagnosis



iSTAT initial Outcomes: New Diagnosis CD4

For our New Dx we noted the following:

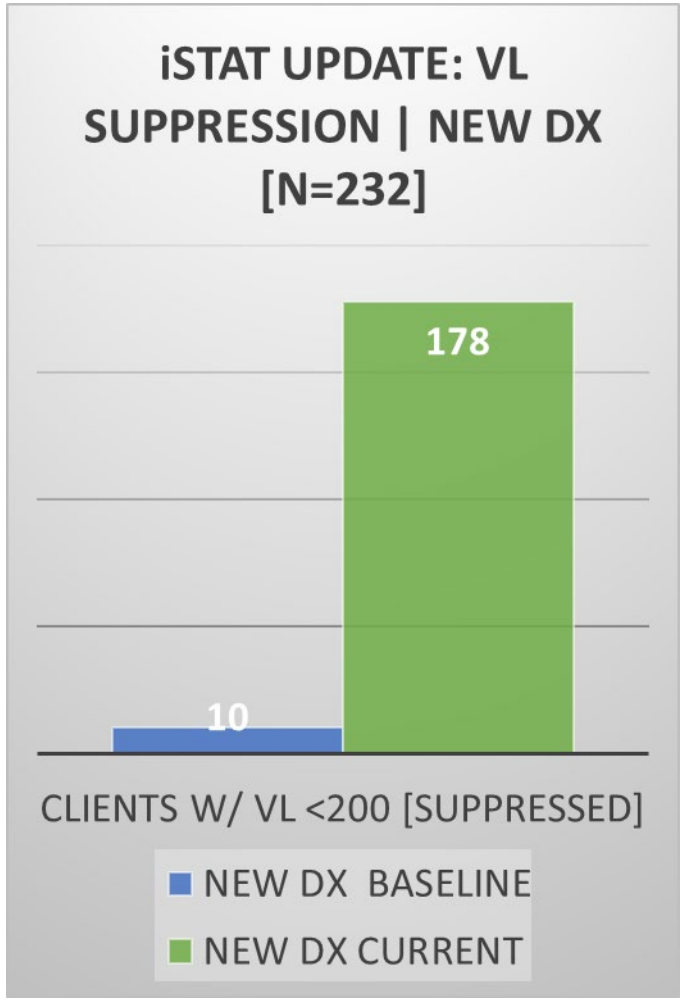
- ❑ Increased CD4
- ❑ Dramatically improved clients with previous CD4 @ critical values
- ❑ Lab collection and engagement has been impacted by COVID-19

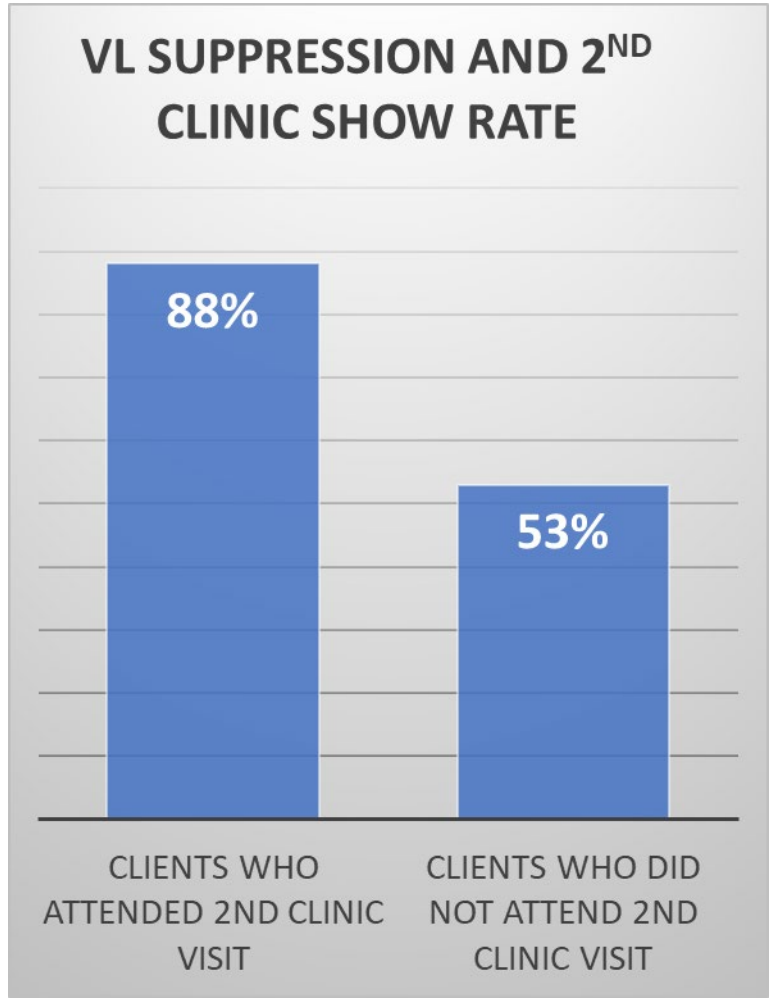


iSTAT initial Outcomes: New Diagnosis Viral Suppression

For our New Dx we noted the following:

- Overall 77% achieved Viral Suppression
- *94% achieved suppression of those who have had labs/continued in our care after 6 months
- Lab collection and engagement has been impacted by COVID-19
- iSTAT '2.0' will gauge staff capacity to better follow client to sustained viral suppression (through behavioral health, peer navigation and/or more intensive case management)

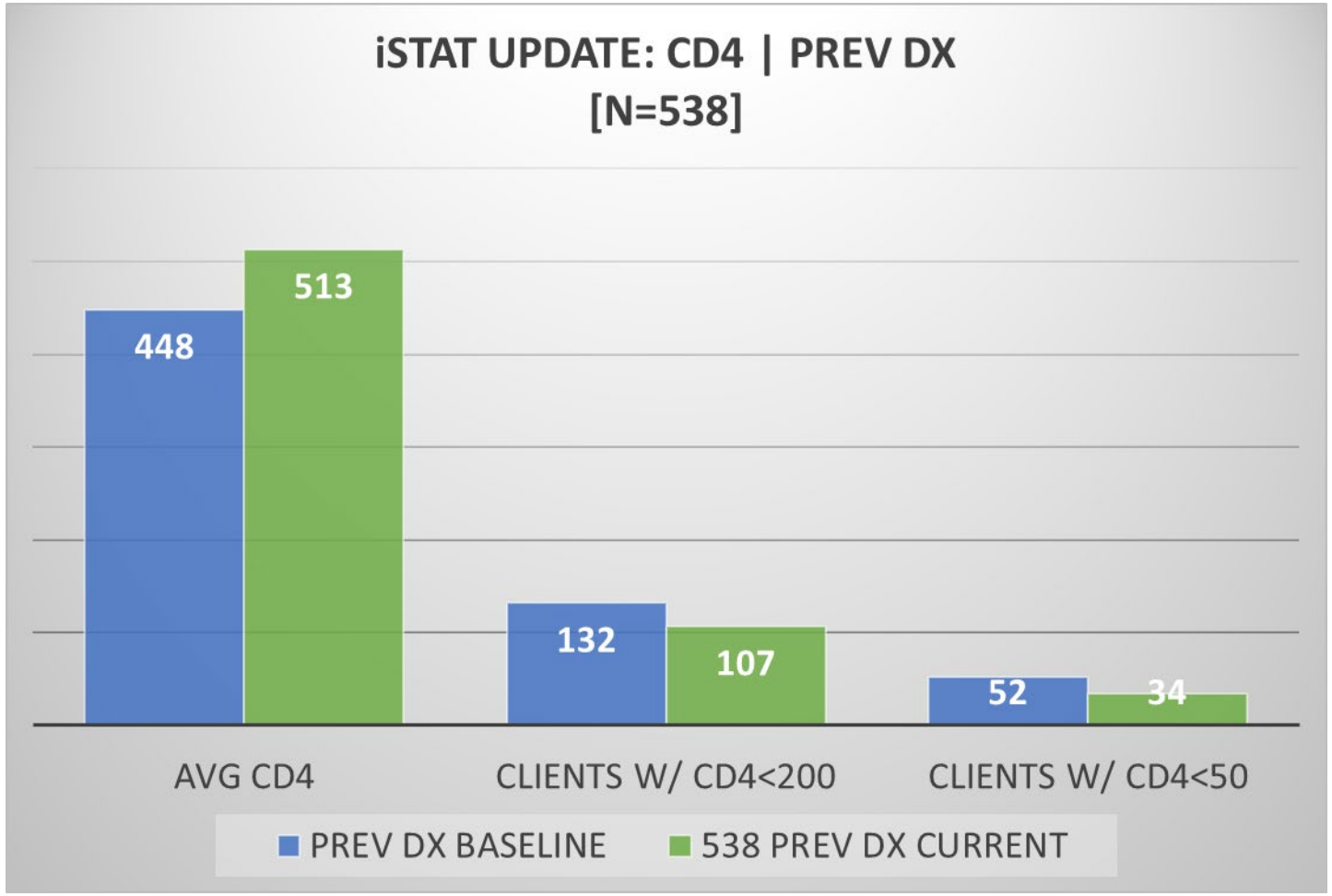




iSTAT initial Outcomes: Vulnerable Previous Diagnosis CD4

For our Previous Dx, some observations

- Overall, average CD4 improved across the clients seen through the iSTAT clinic
- Particular improvement among those who re-entered care with critically low CD4
- iSTAT re-entry capacity would be best supported by an EMA-wide collaboration to better 'see' our clients who receive care at various organizations along their care continuum



iSTAT initial Outcomes: Vulnerable Previous Dx Viral Load Suppression

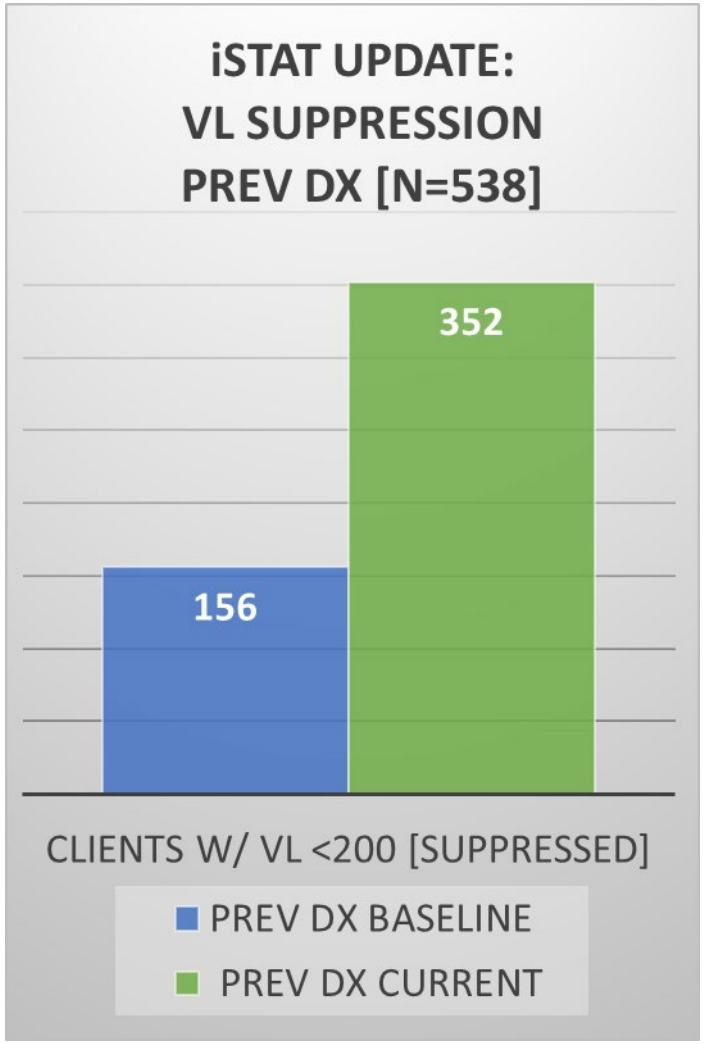
For Previous Dx (cont'd):

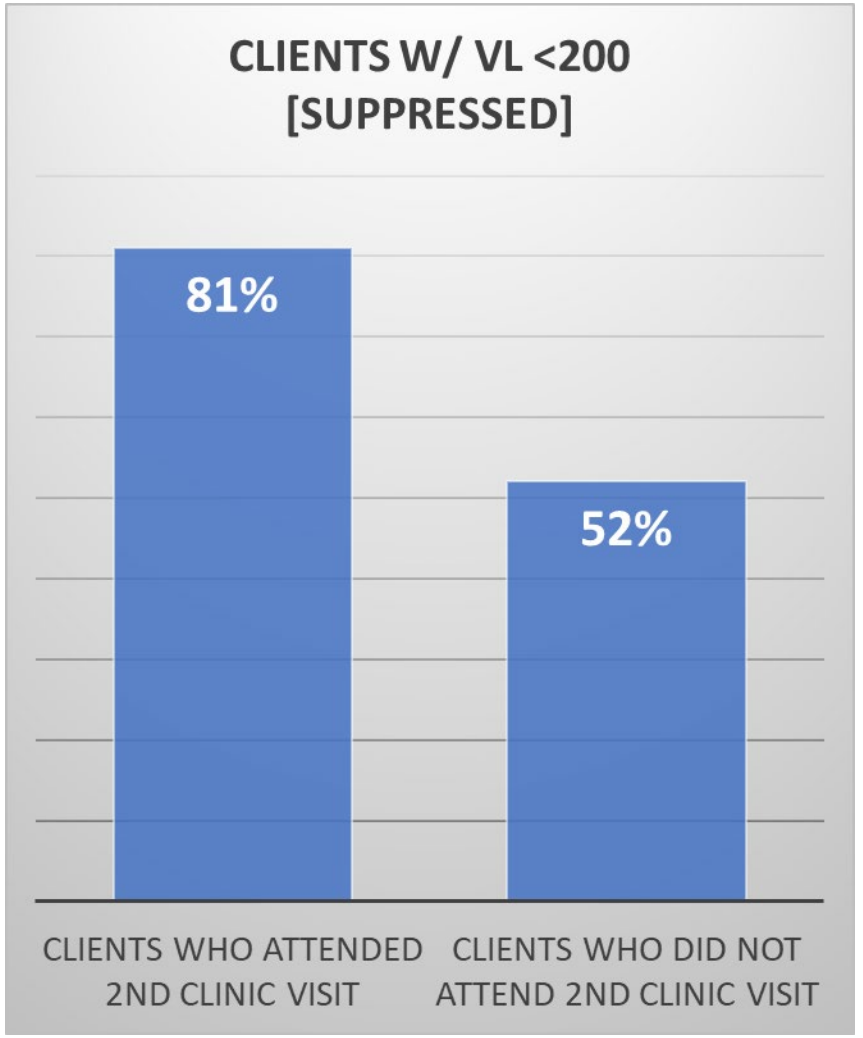
Of clients 'not suppressed' or 'unknown'

- 78 clients did not have a viral load more current than their iSTAT labs-

Possible drivers:

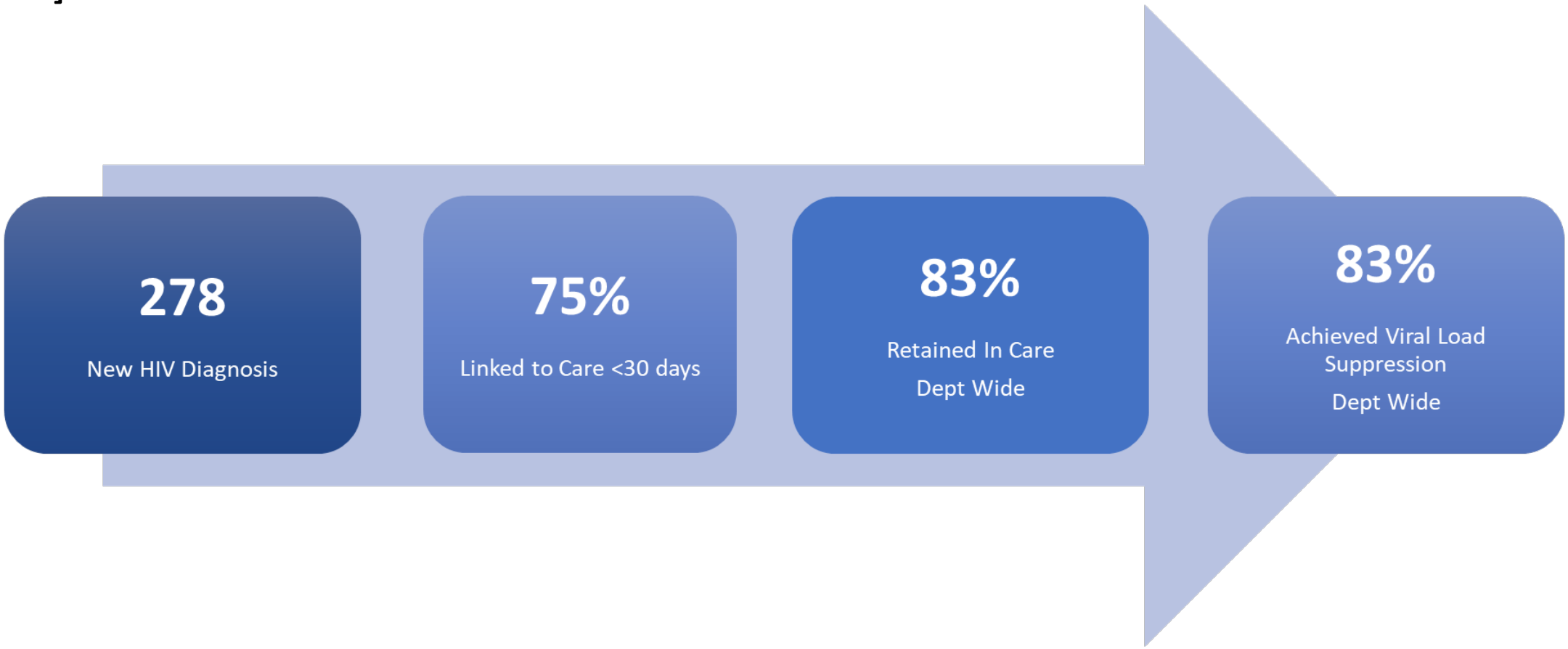
- Clients experiencing more intense need & complications (seen through ACUITY scoring), transitional status (seen through Living Situation detailed)
- Labs impacted by COVID for more current follow up (as of 3/2020)
- Again, iSTAT re-entry capacity would be best supported by an EMA-wide collaboration to better 'see' our clients who receive care at various organizations along their care continuum



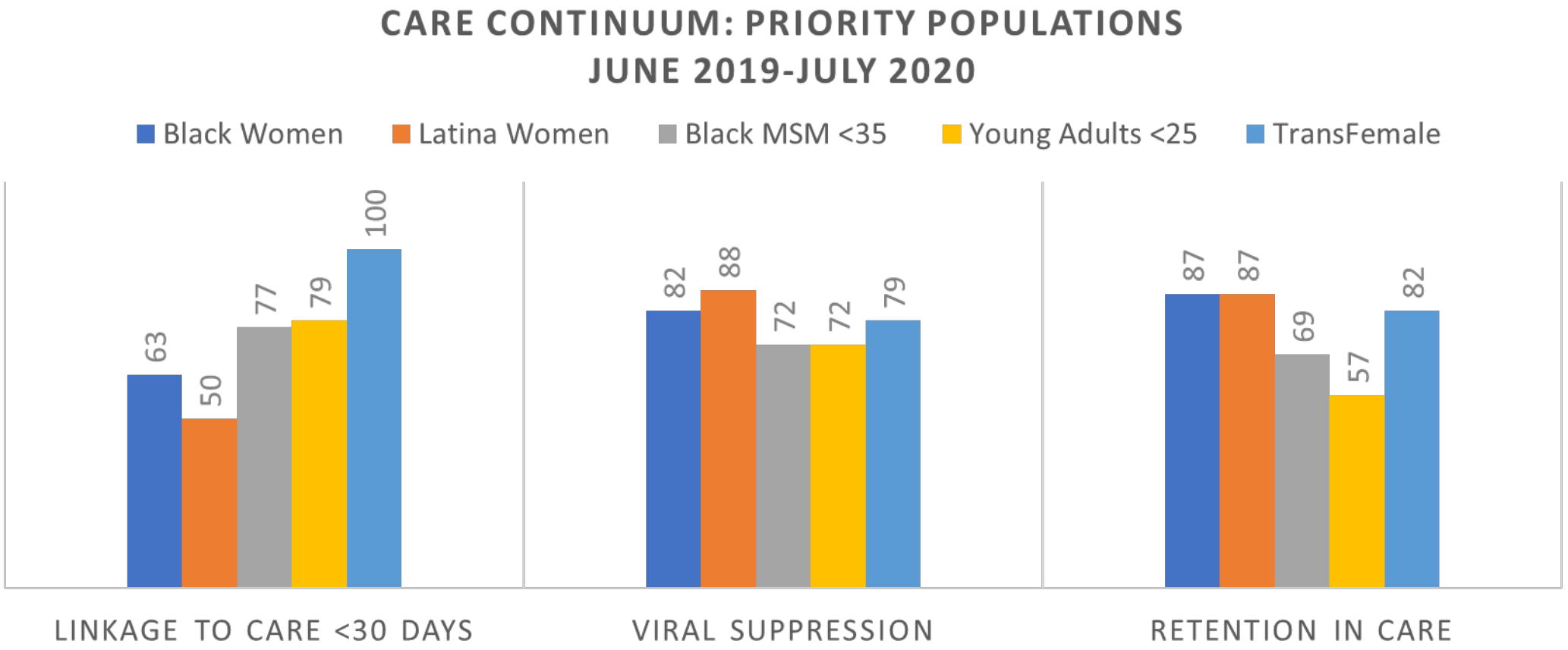


iSTAT: Impact on Access

Parkland HIV Services July 2019- June 2020 Dept Care Continuum [N=5914]



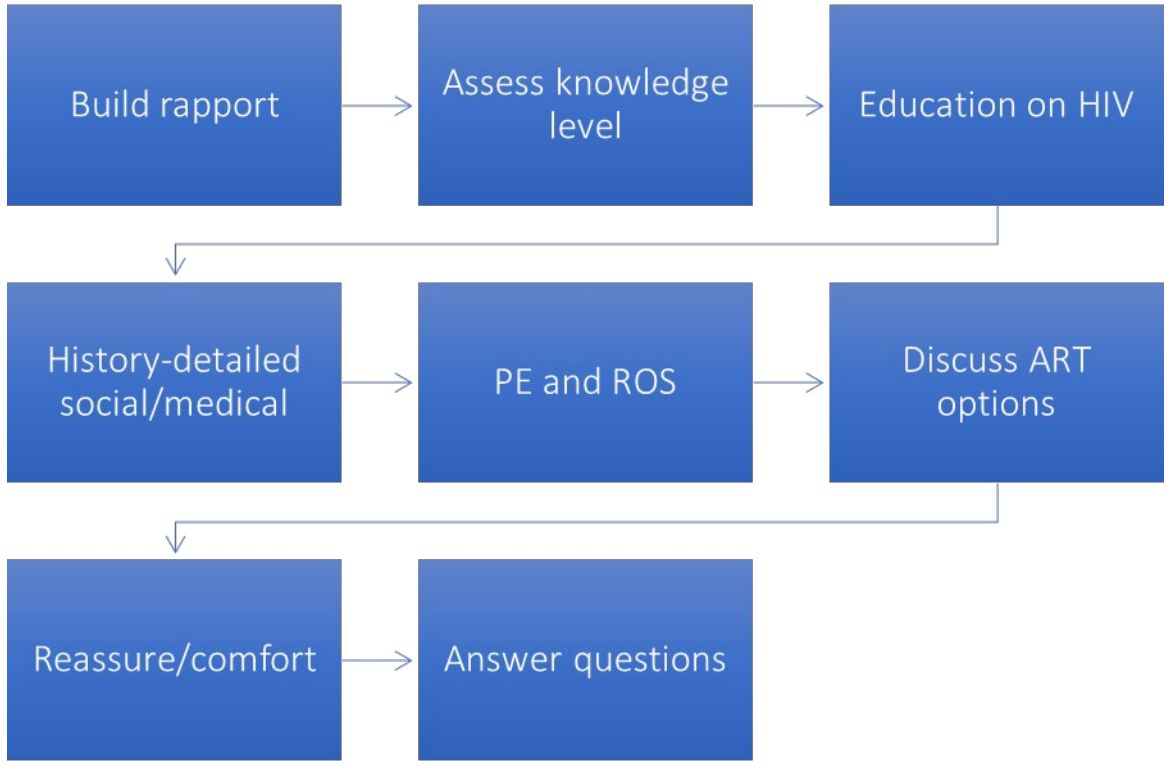
iSTAT: Impact on Priority Populations



Our Patients – Case Examples
Parkland HIV Services

iSTAT: Provider visit

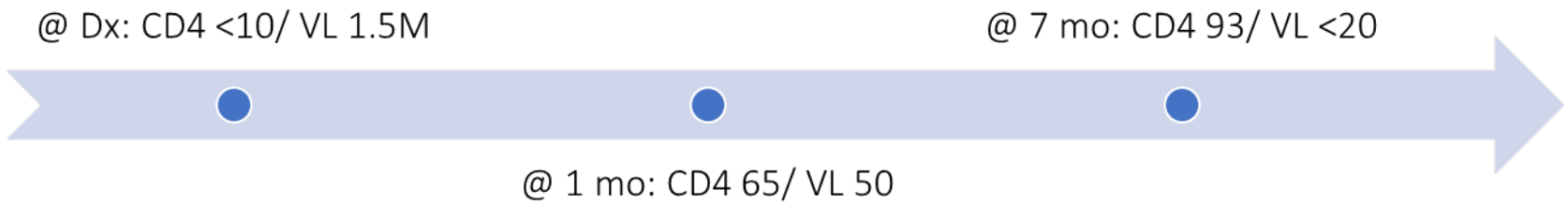
- Education on living with HIV
  - U=U, having children, life expectancy, etc.
- Discussing ART choices and importance of adherence
  - PMH, home medications, lifestyle, etc.
- Dispelling myths
  - Transmission modes, safety of people in home, etc..
- Therapeutic communication
  - Grappling with "new normal," what to tell family/friends, etc..



iSTAT: Case Examples

26 year old African American Female. Presented to our ED with c/o vaginal discharge and LAP (Nov 2019)

- DOD (day of diagnosis): + HIV test (Universal Screening in all our EDs)
- DOD+6: returned to UCED for notification of positive test
- DOD+8: iSTAT visit in clinic
  - ROS: blurred vision, weight loss, 2 months of headaches, hair falling out
  - PE: diffuse rash, no thrush, no wasting
  - Started on BIC/TAF/FTC, sent for baseline labs
  - CD4 <10 and HIV VL 1.5M, started pjp ppx
  - CryptoAg Neg, serum CMV 1470, referred to optometry
- DOD+10: presented to ED for fever, chills, tachycardia
  - Negative OI workup including CMV retinitis, treated for cystitis
- DOD+36: clinic f/u visit
  - Doing well with no s/s of IRIS
  - Repeat labs done. CD4 65/8.9% and VL 508
- DOD+69: clinic f/u visit
  - Doing well with no s/s of IRIS
  - Repeat HIV VL 50
- DOD+7mo: clinic f/u visit
  - ✓ Doing well with no s/s of IRIS
  - ✓ Repeat HIV VL <20, CD4 93/12.8%



iSTAT: Case Examples

- History—
  - Dx with HIV Nov 2019. Heterosexual female, no IVDU. 5 lifetime partners.
  - G2P0A2. Hx chlamydia and trichomoniasis infections. Last neg HIV test Dec 2017
  - Was seen in the ED/UCs 5x from Dec 2017-Nov 2019
    - 5 missed chances for an HIV dx|notification

Lessons learned

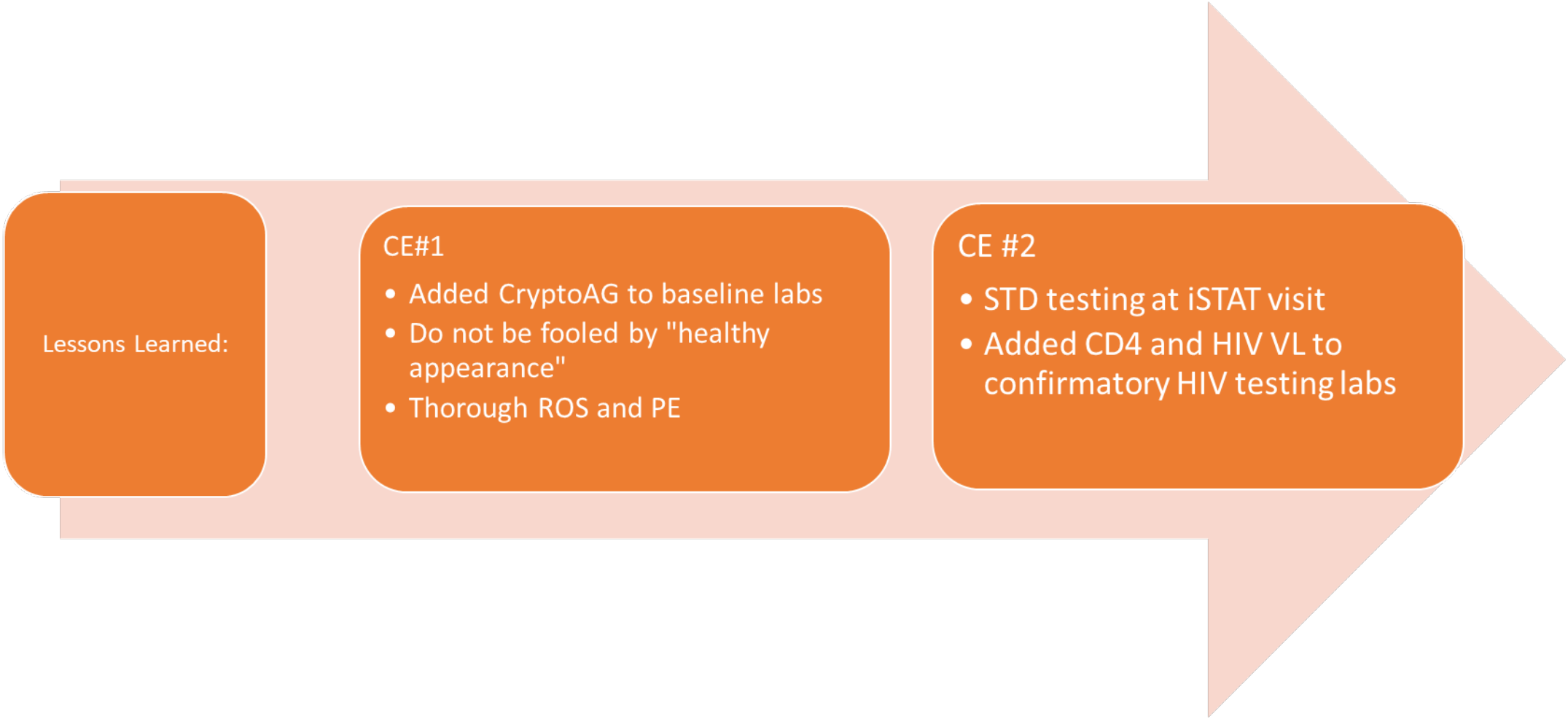
- Added CryptoAg to baseline labs
- Do not be fooled by "healthy appearance"
- Thorough ROS and PE

iSTAT: Case Examples (cont..)

32 year old Hispanic Transgender Female. Presented to our clinic as walk-in requesting HIV test (May 2019)

- DOD: + HIV POC, confirmatory labs done
  - CD4 163/14.4% and HIV VL 688K
- DOD+3: returned to clinic for result notification appointment
- DOD+5: iSTAT visit in clinic
  - Hx: last neg HIV POC (per pt.) 6-8 months prior
  - ROS: night sweats
  - PE: no abnormals
  - Started on BIC/TAF/FTC and Bactrim, sent for baseline labs
  - CryptoAg and AFB blood cx both NEG
  - Oral, rectal and urine GC/CT done > oral GC+
- DOD+7: in clinic for GC treatment
- DOD+25: clinic for f/u visit
  - ROS: diarrhea (2-3/day), abd bloating and worsening night sweats
  - small concern for IRIS/unmasking > urine histo Ag, serum CMV, stool cx, shiga, O&P, microsporidia, Cyclospora, cryptosporidium, giardia, c.diff, bacterial blood cx, fungal blood cx
  - All Negative
- DOD+42: clinic f/u visit
  - ROS: all symptoms resolved. OI work up negative
  - CD4 377/23% and **HIV VL 236**
  - Started hormone therapy
- DOD+4mo: clinic f/u visit
  - ✓ Doing well with no s/s of IRIS
  - ✓ CD4 463/29.3% and **HIV VL 144**,
- DOD+7mo: clinic f/u visit
  - ✓ CD4 533/32.5% and **HIV VL 83**
- DOD+12mo: clinic f/u visit
  - ✓ CD4 457/34.6 and **HIV VL 62**

iSTAT: Case Examples-



iSTAT: Case Examples (cont.)

42 year old Hispanic Male. Presented to Health Dept for HIV test. (Dec 2019)

- DOD: + HIV POC, confirmatory labs done @ Health Department
- DOD+1: iSTAT visit in clinic
  - Hx: last neg HIV POC (per pt.) 6-8 months prior
  - ROS: night sweats, weight loss, cough, diarrhea
  - PE: temporal wasting, tachycardia
  - CD4 <10 and HIV VL 1.5M
  - Concern for TB, so ART delayed
  - AFB blood cx, CryptoAg, LD, fungitell, fungal cx, urine histo, fungal blood cx, STAT CT chest/abd/pelvis
  - Outpatient workup showed +GGO on CT, +fungitell and giardiasis
- DOD+5: hospital admission for PJP PNA
  - Tx pjp pna (Bactrim), elevated LFTs 2/2 CMV viremia (Valganciclovir)
  - ART continued delay until ophthalmology eval
- DOD+17: hospital admission for hyponatremia
  - Continue plan, still holding ART
- DOD+26: clinic for f/u visit
  - Previous AFB blood cx now positive for MAC
  - Hold ART, continue PJP and CMV treatment, start MAC treatment
- DOD+27: ophthalmology clinic
  - Concern for CMV retinitis- continue treatment dosing Valganciclovir
- DOD+32: hospital admission for AMS
  - required intubation d/t low GCS, infectious work up negative, new HFrEF (LVEF 28%), started on DTG +TDF/FTC, continue MAC and CMV treatment
- DOD+39: clinic f/u visit
  - Improving continue POC
- DOD+2 mo: clinic f/u visit
  - CD4 <10 and HIV VL 38
  - Completed valganciclovir induction, continue MAC treatment
- DOD+4mo: clinic f/u visit
  - ✓ CD4 31/5.9% and HIV VL <20
  - ✓ Pt doing well, overall health improving

iSTAT: Case Examples—
Learned Lessons to adapt iSTAT protocol

Lessons Learned:

CE#1

- Added CryptoAG to baseline labs
- Do not be fooled by "healthy appearance"
- Thorough ROS and PE

CE #2

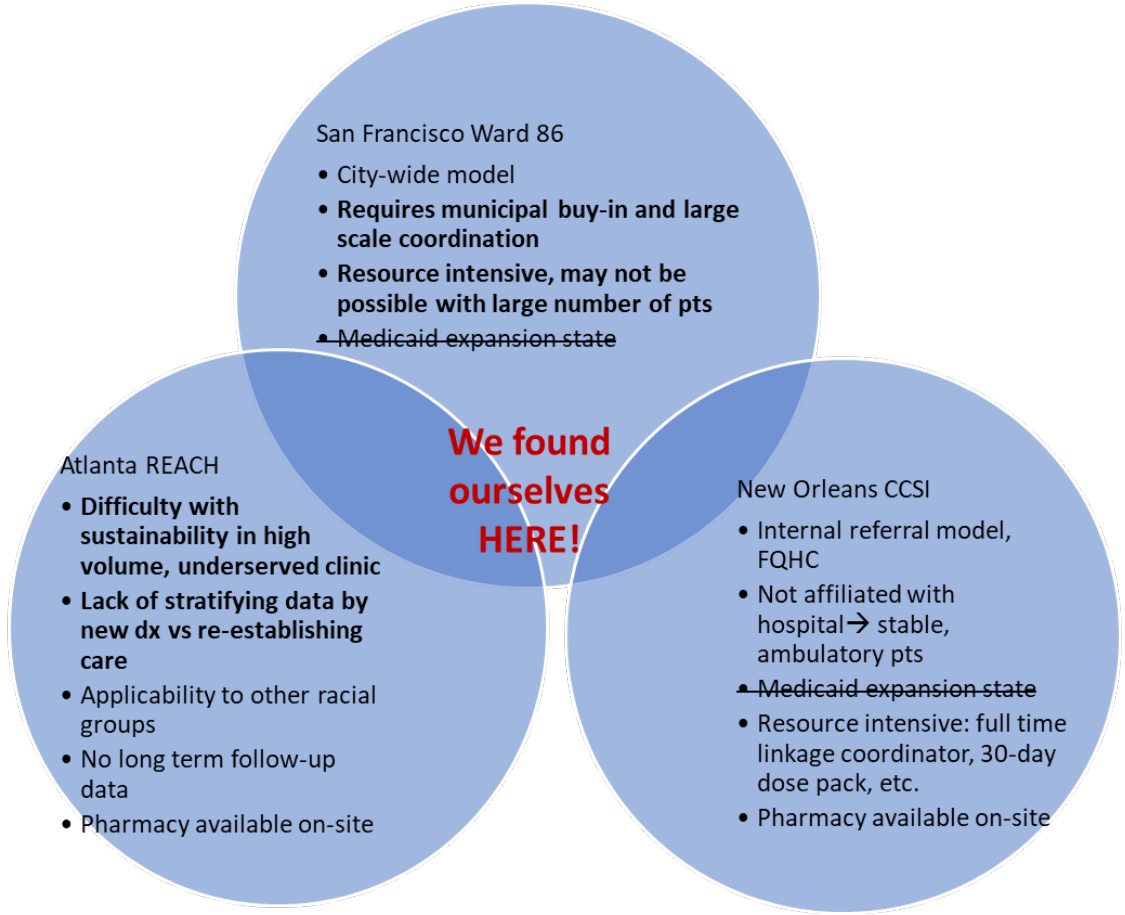
- STD testing at iSTAT visit
- Added CD4 and HIV VL to confirmatory HIV testing labs

CE #3

- OK to delay ART for OI work up
- Teamwork!

Is Rapid Start Right for You?

Rapid Start Limitations- Shared barriers



Rapid Start to ART: It can be done

- RAPID Start is not a matter of 'if'; it is a matter of 'how'
- Adapting protocol and policies IS a necessary step- CQM is continuous
- As we explore our data, including clients who have possibly continued care elsewhere, we recognize that Data to Care initiatives have shown tremendous improvements in real time client level data that could improve EMA outcomes (Alabama*, Louisiana** to name two)
- Volume and capacity can seem daunting, but clinic wide teamwork can make it a reality
- We now have an average of 4 iSTAT visit slots per day.

- https://www.thirdcoastcfar.org/wp-content/uploads/2018/10/Retention-in-Care-Example-D4C-UABCFAR-MMugavero.pdf ALABAMA
- https://pubmed.ncbi.nlm.nih.gov/30457958/ LOUISIANA

Thank YOU for joining us.
A moment to thank our bigger team

Our work would not be possible without the support from the following:

- ❑ Crystal Curtis, Director HIV Grants Program
- ❑ Kellie A Norcott HIV Program Manager
- ❑ Jane Fitzpatrick, BSN, RN, Ambulatory Services OPC
- ❑ Gwendolyn Martin, LMSW- HIV Case Management Manager
- ❑ Traneika Turner-Wentt, DSW, LCSW Program Manager, HIV Prevention & Testing
- ❑ Ank Nijhawan, MD-UTSW ID Faculty
- ❑ Loretta Hendrix, Manager of Practice Operations
- ❑ HIV Analytics Team- Narcis Demeter, Claudia Ferrari, Yvette Chino & Will Powers

*And to **All of the AMAZING dedicated employees** of:*

Parkland HIV Services &
UTSW ID Division

<u>You</u> make Ending the HIV Epidemic in Dallas possible!!!