TEST & TREAT IN A RURAL STATE

Madhuri J. Lad, DO, FACOI, AAHIVS

Assistant Medical Director of Oklahoma State University Internal Medicine Specialty Services Ryan White Clinic

Contributions by Randolph Hubach, PhD, MPH, Director of OSU Rural Health

DISCLOSURES

- Madhuri J. Lad, DO, FACOI, AAHIVS
  - Is a member of the Speaker's Bureau for ViiV Pharmaceuticals
  - Has served on the Advisory Board for Gilead Pharmaceuticals
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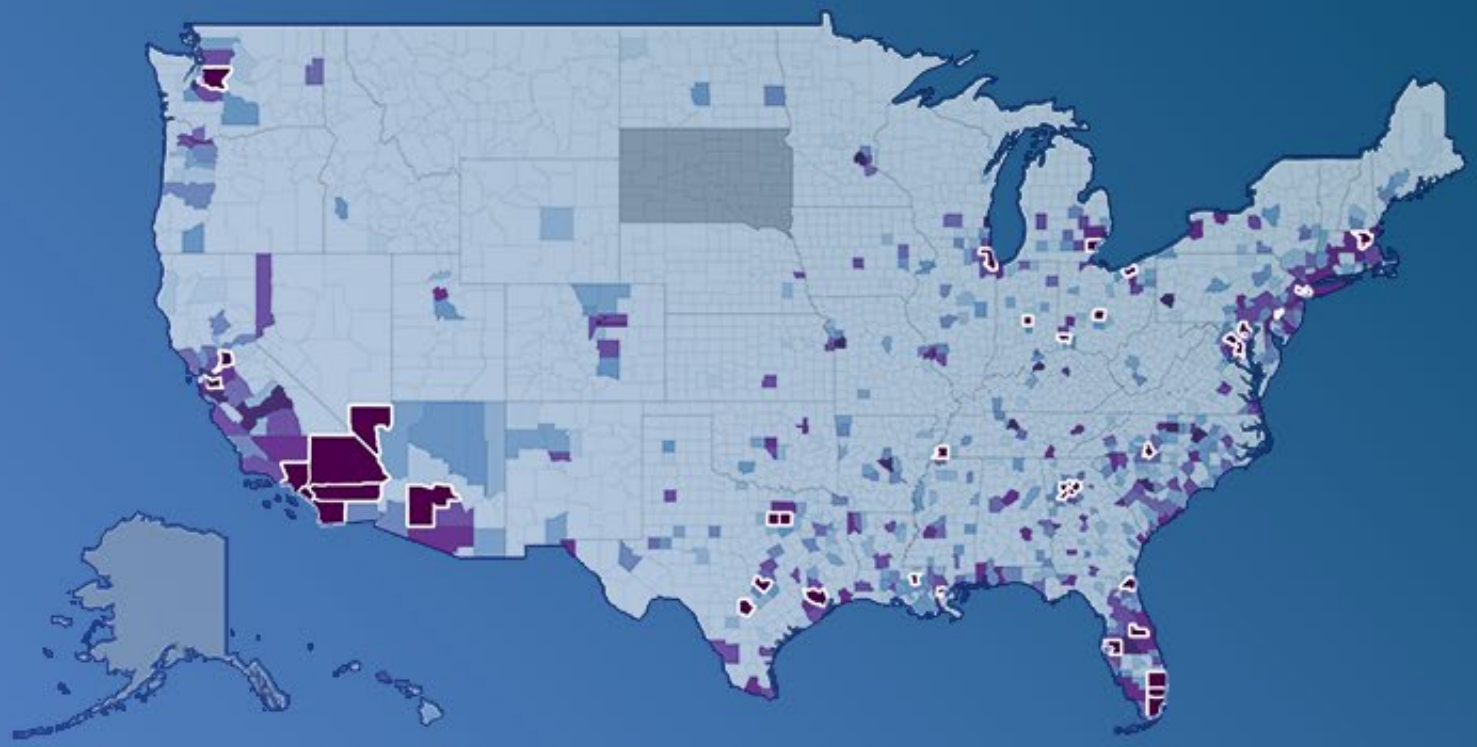
- Commercial support was not received for this activity.

LEARNING OUTCOMES

- At the conclusion of this activity, the participant will be able to:
  - 1. Discuss a test and treat protocol
  - 2. Describe the implementation process of a test and treat protocol in a clinical setting
  - 3. Discuss outcomes of time to viral load suppression when test and treat protocols are implemented

Ending the HIV Epidemic: A Plan for America

48 Highest Burden Counties + DC + San Juan + 7 States with Substantial Rural HIV Burden



ALABAMA

ARKANSAS

KENTUCKY

MISSISSIPPI

MISSOURI

OKLAHOMA

SOUTH CAROLINA

NUMBER OF PERSONS NEWLY DIAGNOSED WITH HIV, 2016

5 - 5	6 - 6	7 - 8	9 - 10	11 - 13	14 - 19	20 - 28	29 - 49	50 - 111	112+

SAN JUAN - NUMBER OF PERSONS NEWLY DIAGNOSED WITH HIV, 2012-2016

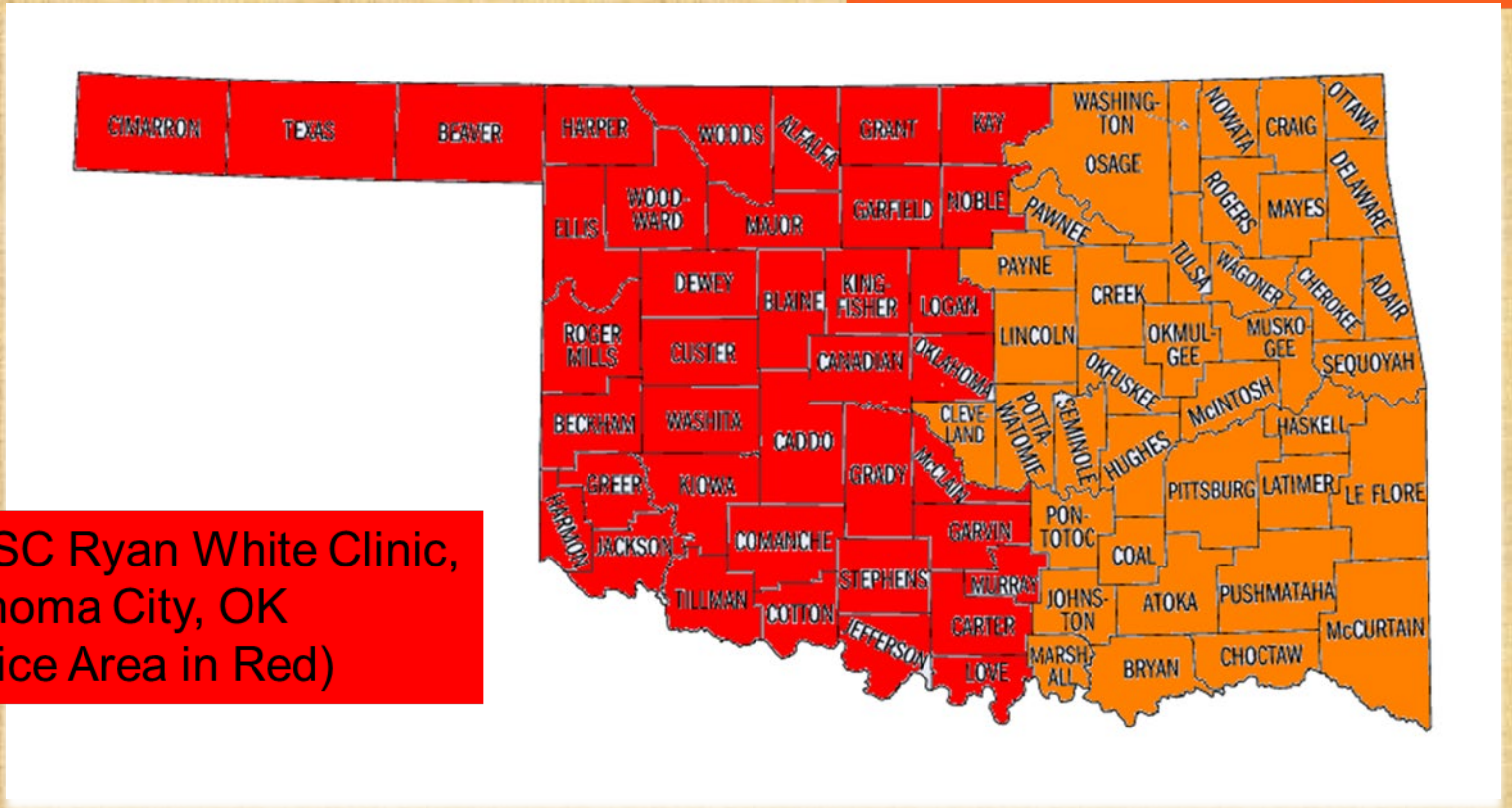
5 - 8	9 - 11	12 - 16	17 - 21	22 - 29	30 - 40	41 - 53	54 - 72	73 - 113	114+

NUMBER OF PERSONS NEWLY DIAGNOSED WITH HIV, 2016

0 - 25	26 - 75	76 - 125	126 - 300	301 - 400
401 - 600	601 - 850	851 - 1,200	1,201 - 2,175	2,176+

Oklahoma Service Areas

OSU-CHS Ryan White Clinic, Tulsa, OK
(Service Area in Orange)



OUHSC Ryan White Clinic,
Oklahoma City, OK
(Service Area in Red)

Key Strategies from *Ending the HIV Epidemic: A Plan for America*

DIAGNOSE

all individuals with HIV as early as possible after infection.

TREAT

the infection rapidly and effectively after diagnosis, achieving sustained viral suppression.

PREVENT

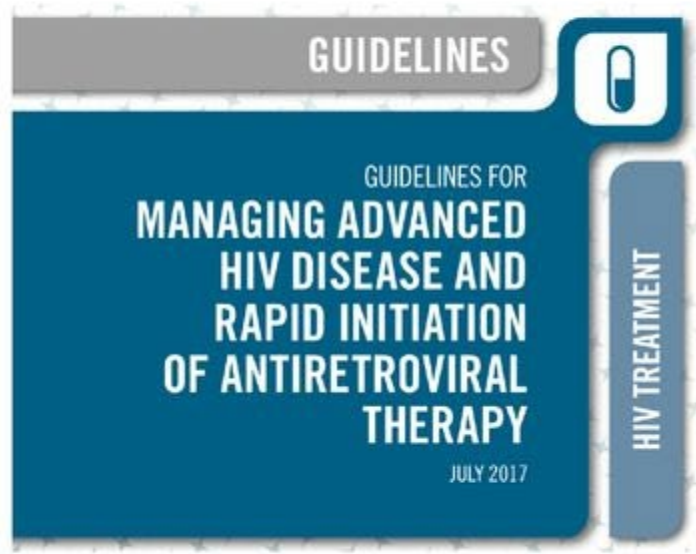
new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).

RESPOND

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

WHO Guidelines July 2017

- "Rapid ART initiation should be offered to all people living with HIV following a confirmed HIV diagnosis and clinical assessment."
  - ➢ *"Rapid" defined as within 7 days*
- "ART initiation should be offered on the same day to people who are ready to start."
- Goal: To improve linkage to care and reduce LTFU



IAS-USA Guidelines

The International AIDS Society (IAS)-USA recently released its 2018 HIV treatment and prevention recommendations. The document is particularly notable for its discussion of "When to Start ART."

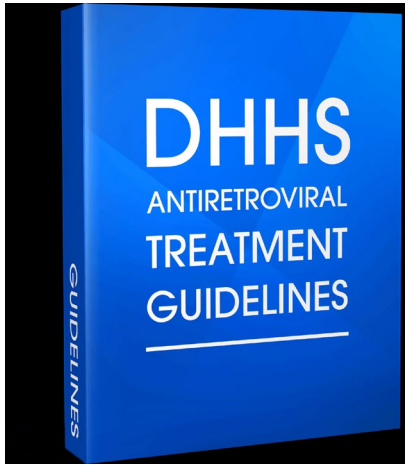
The IAS-USA **recommends "rapid" or immediate start of ART upon diagnosis of HIV**, stating that treatment "should be initiated as soon as possible after diagnosis, including immediately after diagnosis, unless [the] patient is not ready to commit to starting therapy (evidence rating A1a)." IAS-USA recognizes that structural and other barriers may hinder immediate linkage, patient evaluation, and provision of ART, but recommends that testing sites and treatment sites work to resolve any impediments to same-day initiation of ART.

DHHS Guidelines

United States. The Panel on Antiretroviral Guidelines for Adults and Adolescents (the Panel) recommends initiating ART at the time of diagnosis (when possible) or soon afterwards to increase the uptake of ART, decrease the time required to achieve linkage to care and virologic suppression, and improve the rate of virologic suppression among individuals who have recently received HIV diagnoses **(AII)**. This rating for this recommendation reflects the fact that only observational trials have been conducted in the United States or other highly resourced countries, where health systems and socioeconomic contexts differ substantially from those in the countries where randomized trials were conducted.

AIDSinfo

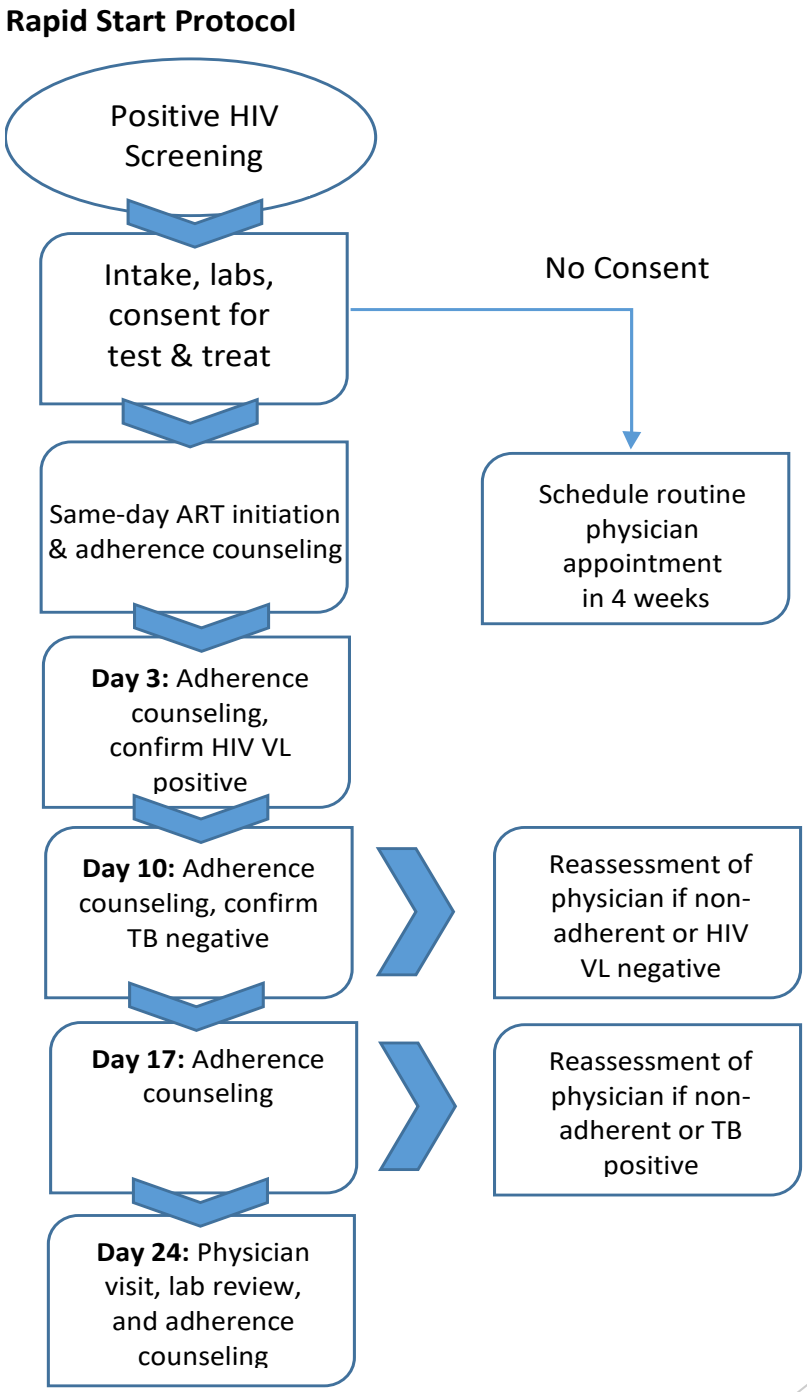
OFFERING INFORMATION ON HIV/AIDS TREATMENT, PREVENTION, AND RESEARCH



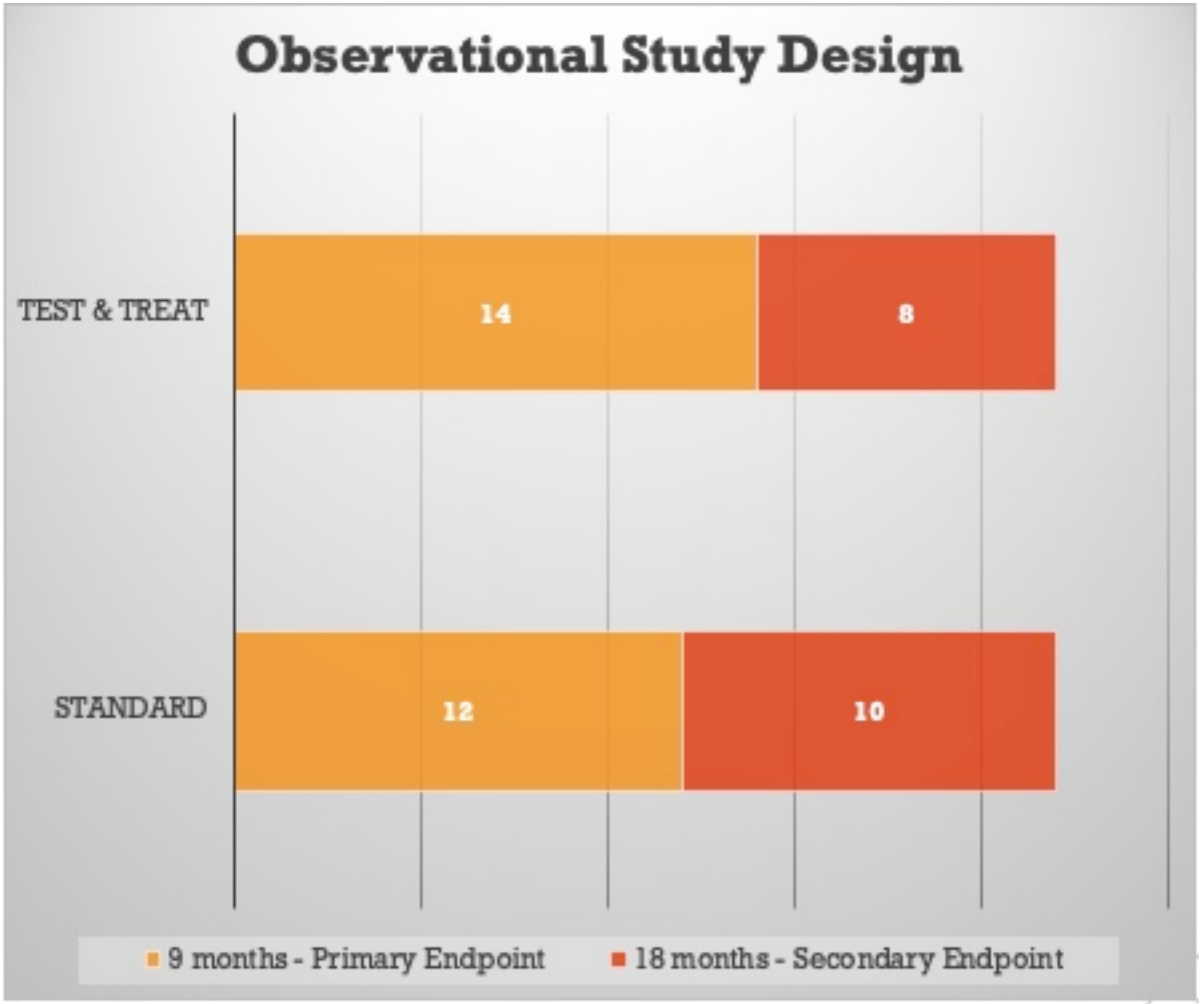
BENEFITS

- Better clinical outcomes
- Earlier engagement in care to prevent lost to follow up
- Less anxiety with waiting
- Earlier viral suppression
- Treatment as prevention

TEST & TREAT PROTOCOL

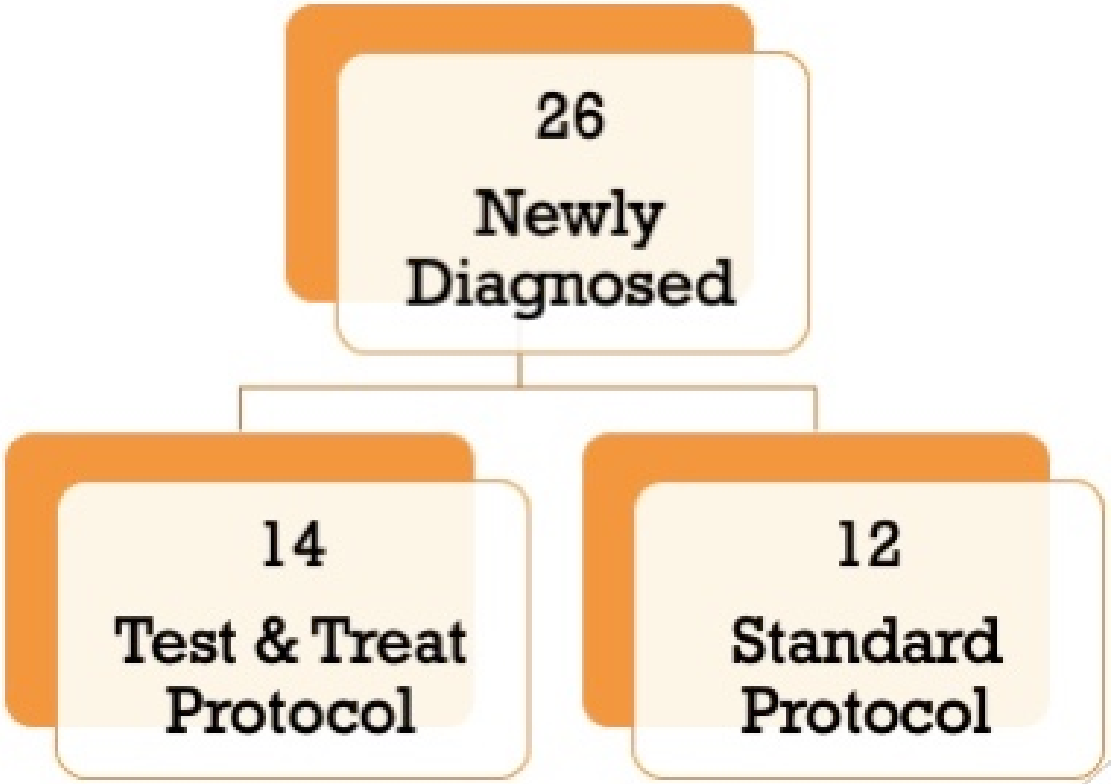


TRIAL DESIGN



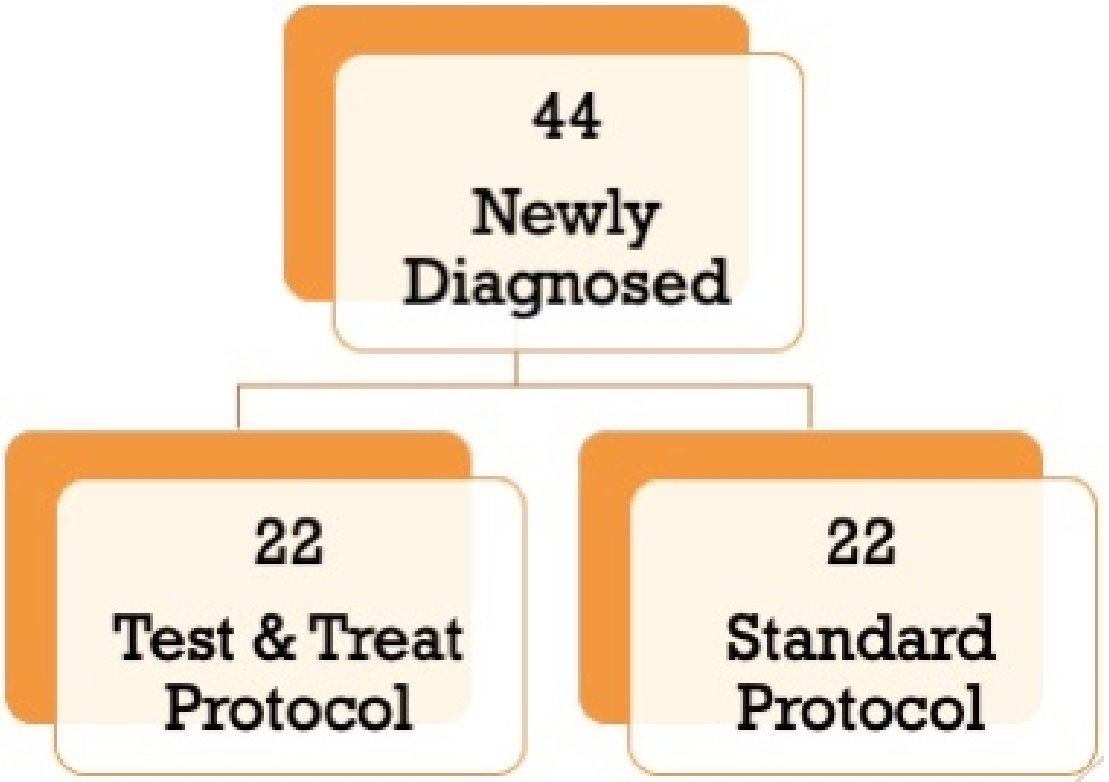
METHODS: 9 MONTHS

- Observational Study Design
- August 2018 to June 2019
- Primary endpoint: HIV-1 RNA < 50 copies at 9 months



METHODS: 18 MONTHS

- August 2018 to June 2019: 26 enrolled
- July 2019 to February 2020: 18 more enrolled
- Secondary endpoint: HIV-1 RNA < 50 copies at 18 months



INCLUSION CRITERIA
(for test and treat)

- Newly diagnosed (within 14 days of new HIV positive test) with proof of positivity
- Willing to start medications (HIV Med Readiness Scale)
- Verbal consent
- Willing to bring all information for HDAP to initial appointment

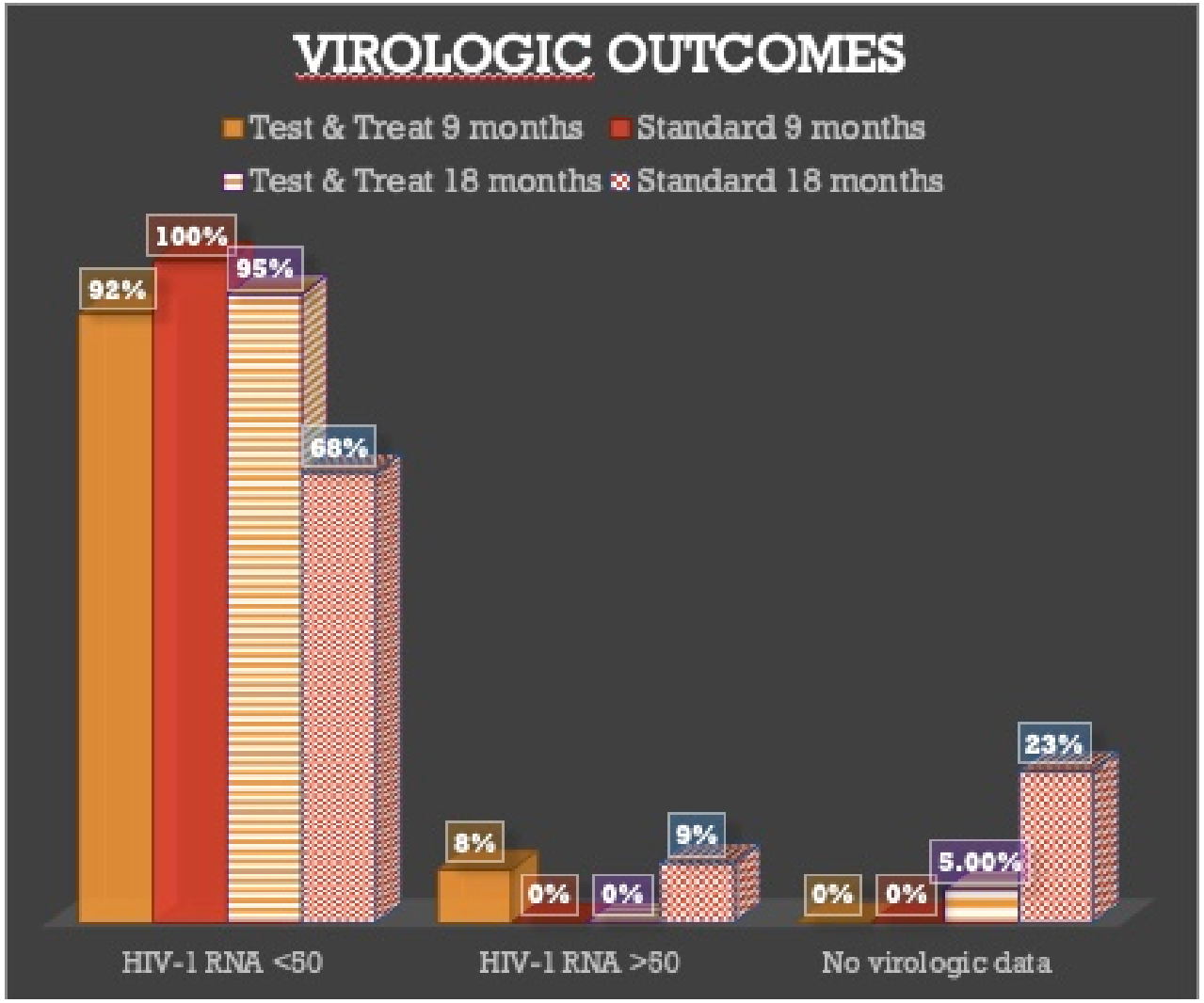
EXCLUSION CRITERIA
(for test and treat)

- Newly diagnosed > 14 days ago
- Unwilling to start meds immediately or low scoring HIV Med Readiness Scale
- No consent
- Active tuberculosis
- Cryptococcal meningitis
- Acutely ill (alarming signs of fever, cough, night sweats, weight loss, or persistent headache) or need for immediate hospitalization

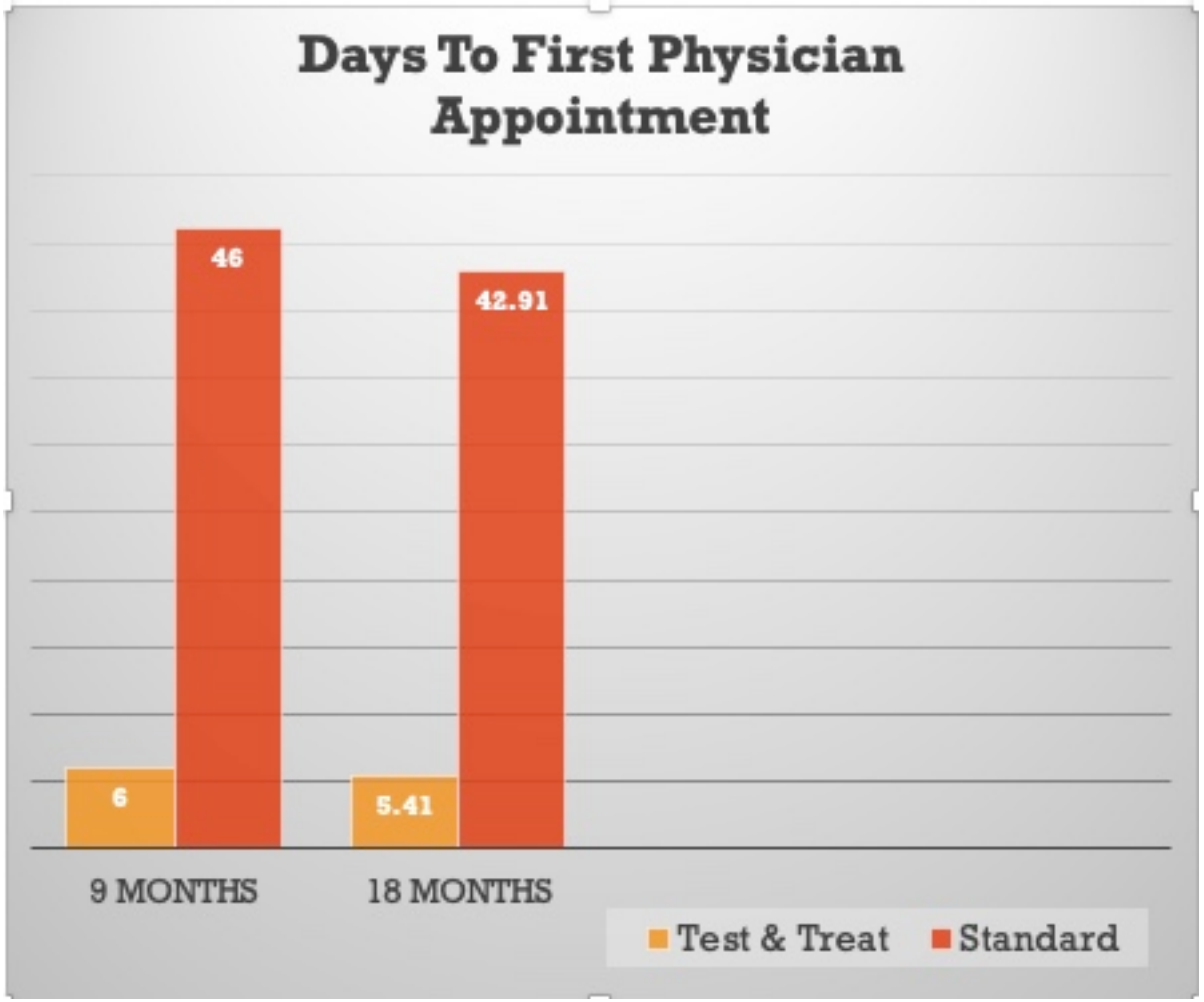
Baseline Characteristics

Baseline Characteristics	Test & Treat n=22	Standard n=22
Age	33.57	33.45
Race		
White	59.1%	63.6%
African American	18.2%	13.6%
Hispanic	18.2%	18.2%
Asian	4.5%	4.5%
Sex		
Male	81.8%	72.7%
Female	9.1%	27.3%
Transgender	9.1%	0%
Mean initial CD4	504	461
CD4 < 200	13.6%	18.2%
Mean initial HIV-1 RNA	203,712	74,258
HIV-1 RNA > 100,000	27.3%	22.7%

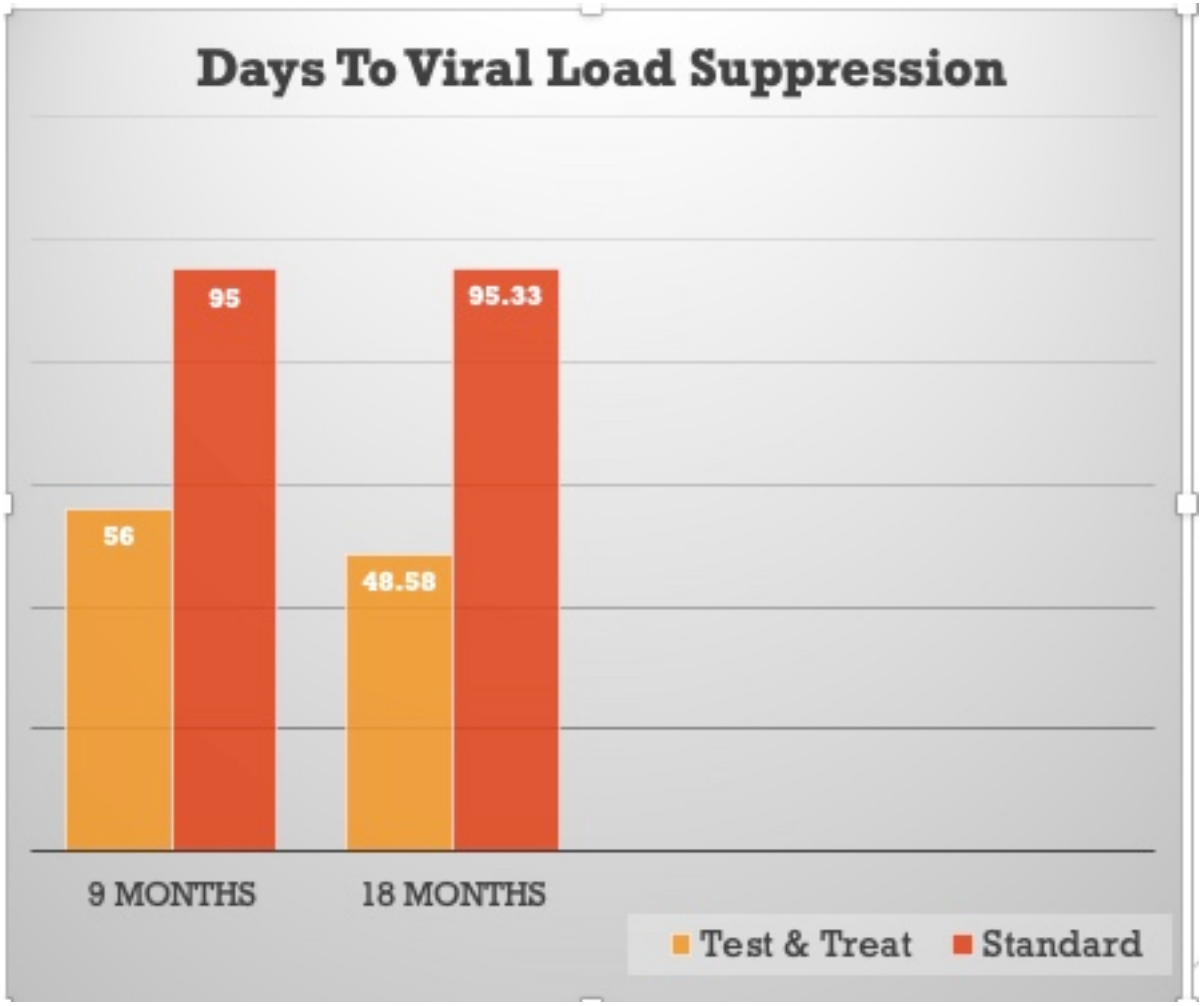
VIROLOGIC OUTCOMES



RESULTS


Days To First Physician Appointment
46
42.91
6
5.41
9 MONTHS
18 MONTHS
Test & Treat
Standard

RESULTS


Days To Viral Load Suppression
95
95.33
56
48.58
9 MONTHS
18 MONTHS
Test & Treat
Standard

PATIENT CASE

- MSM. Diagnosed 1 day prior. Previous male partner reported that he is HIV positive and that the patient needs to get tested. Admits to not using condoms with the previous partner and was in a relationship with him for 2 years but broke up Jan 2017 with no further sexual relations with him.

- He has had a few other partners since then and did use condoms. Now he is in a relationship for about 1 year with current male partner who is HIV negative and they always use condoms and his current partner was previously on PrEP but no longer.

- Pt lived in Mexico where he was tested and was HIV negative 3 yrs ago but moved to Ireland for 6 months and then moved to Tulsa after his breakup above about 2 years ago. Denies IVDA, tattoos, or blood transfusions.

PATIENT HISTORY

- Risk factors
- Partner history and status, use of condoms?
- Previous testing
- Review other medical history and meds

HIV MEDICATION READINESS SCALE

Choices:

- 0 = not at all ready (patient refuses to do so)
- 1 = somewhat not ready (patient does not think s/he can do so)
- 2 = unsure (patient needs more information before doing so)
- 3 = somewhat ready (patient accepts s/he has to do so)
- 4 = completely ready (enthusiastic; agrees completely to do so)

HIV MEDICATION READINESS SCALE

HIV Medication Readiness Scale:

- Ready to take medications for a long time 4
- Ready to carry the medications with you to all of your activities 4
- Ready to take the pills each day as prescribed 4
- Ready to change your lifestyle to take your medications at a specified time daily 4
- Ready to use an alarm or cell phone to remind you to take your pills 4
- Ready to go to bed and wake up at consistent times to avoid missing doses 4
- Ready to continue taking medications even if you feel ill 4

ANY ALARMING SYMPTOMS?

Symptoms:

- Cough no
- Fever no
- Night sweats no
- Weight loss no
- Persistent headache no

- Active tuberculosis and cryptococcal meningitis are contraindications for rapid start of ART.

VERBAL CONSENT

- The patient understands that initiation of ART without baseline laboratory data could lead reactivation tuberculosis, emergence of opportunistic infections, or a regimen switch at a later date based on resistance testing. However, rapid initiation of ART can lead to improved engagement and retention in care and adherence to treatment. These risks and benefits were discussed with the patient, and the patient agrees to proceed. All new patient labs will be drawn today. The patient's readiness scale was assessed, and the patient is willing to comply.

IMMEDIATE LAB FOLLOW UP

- If CD4 < 200, we will need to initiate PJP prophylaxis.
- If quantiferon positive, then patient will need to obtain an immediate CXR to rule out active TB.

ADHERENCE COUNSELING

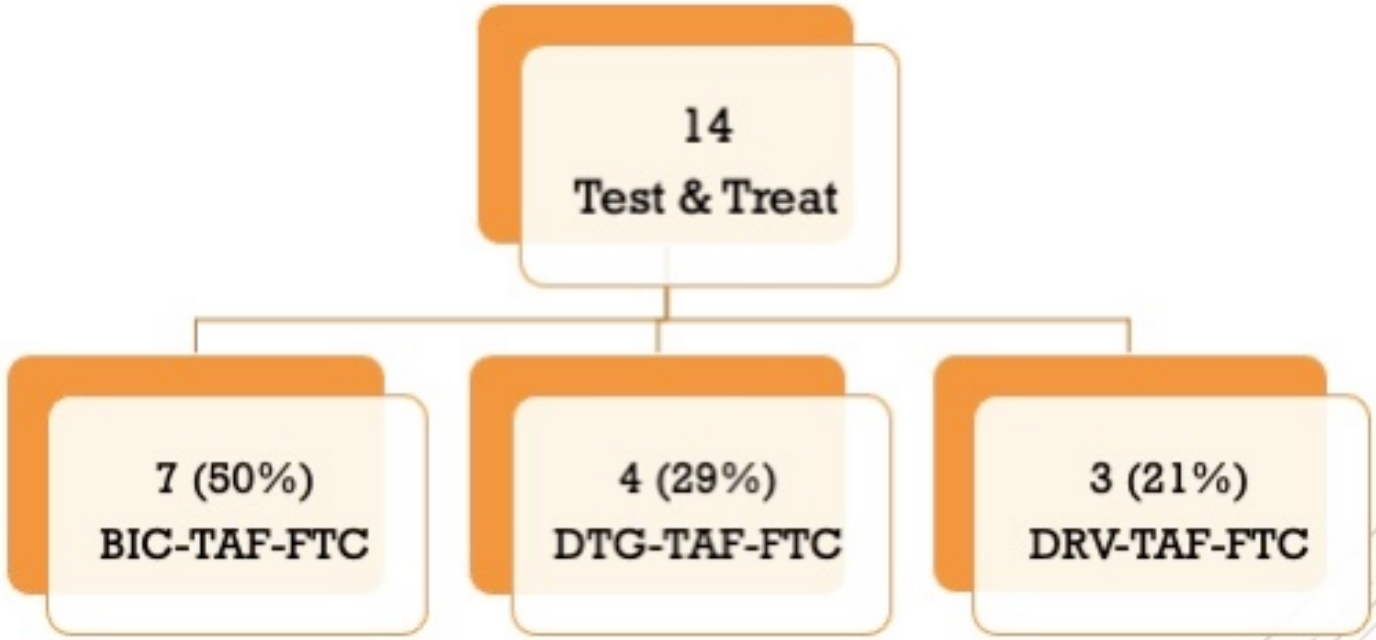
- Show videos from www.helpstopthevirus.com
  - The Goal of Undetectable
  - 5 Reasons to Stick To Treatment
- Discuss the importance of use of condoms and disclosure of status
- Discuss the importance of adherence to daily therapy
- Discuss noncompliance can lead to resistance to medications, AIDS, death, and transmission to others
- Discuss the benefit of meds to long-term prognosis and that HIV is a chronic illness, not a death sentence.

EVALUATION

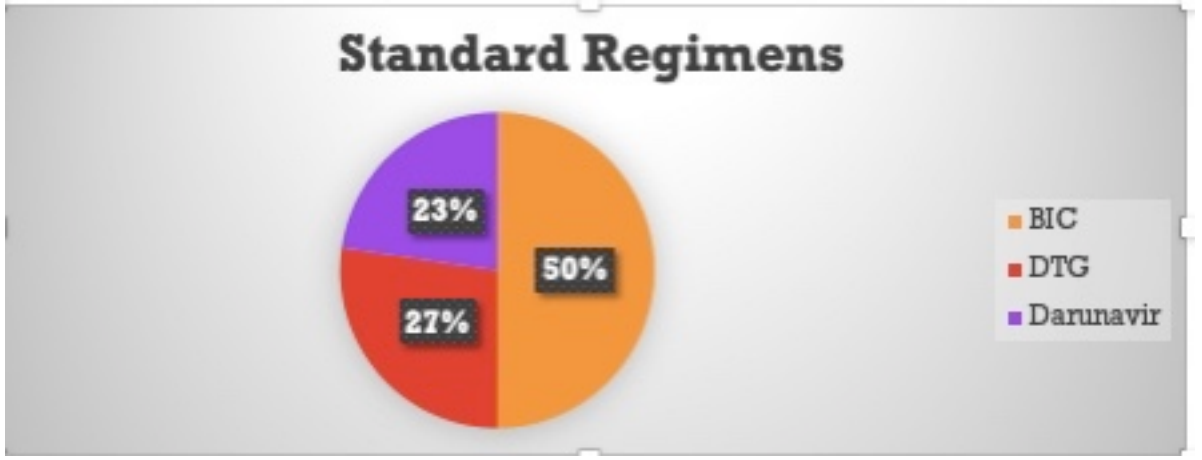
- 2 rapid or 1 serologic test to confirm HIV diagnosis
- Within 14-day window of new diagnosis
- HIV Medication Readiness Scale
- No alarming symptoms
- Verbal consent obtained
- Adherence and prevention counseling completed

REGIMENS – 9 MONTHS

- Time to physician appointment decreased from 46 days to 6 days
- Time to viral load suppression decreased from 95 days to 56 days



REGIMENS – 18 MONTHS



START TREATMENT

- Take with/without food at same time daily
- Potential side effects
- Use pill boxes or phone/alarm reminders/apps to assist
- Review drug-drug interactions
- Confirm HDAP approval and/or insurance coverage
- Provide instructions and phone # on pre-printed sheet for patient to call pharmacy today
- Provide samples if waiting period for drug access

LABS TODAY

- CD4
- Viral load
- CBC
- CMP
- Lipid panel
- RPR
- Quantiferon
- Urine GC/CL
- Hepatitis panel
- Genosure
- HLA B5701
- Toxoplasma antibodies
- HCG test if female (optional)

TEST & TREAT PROTOCOL

PSR

Case Manager
Peer Advocate

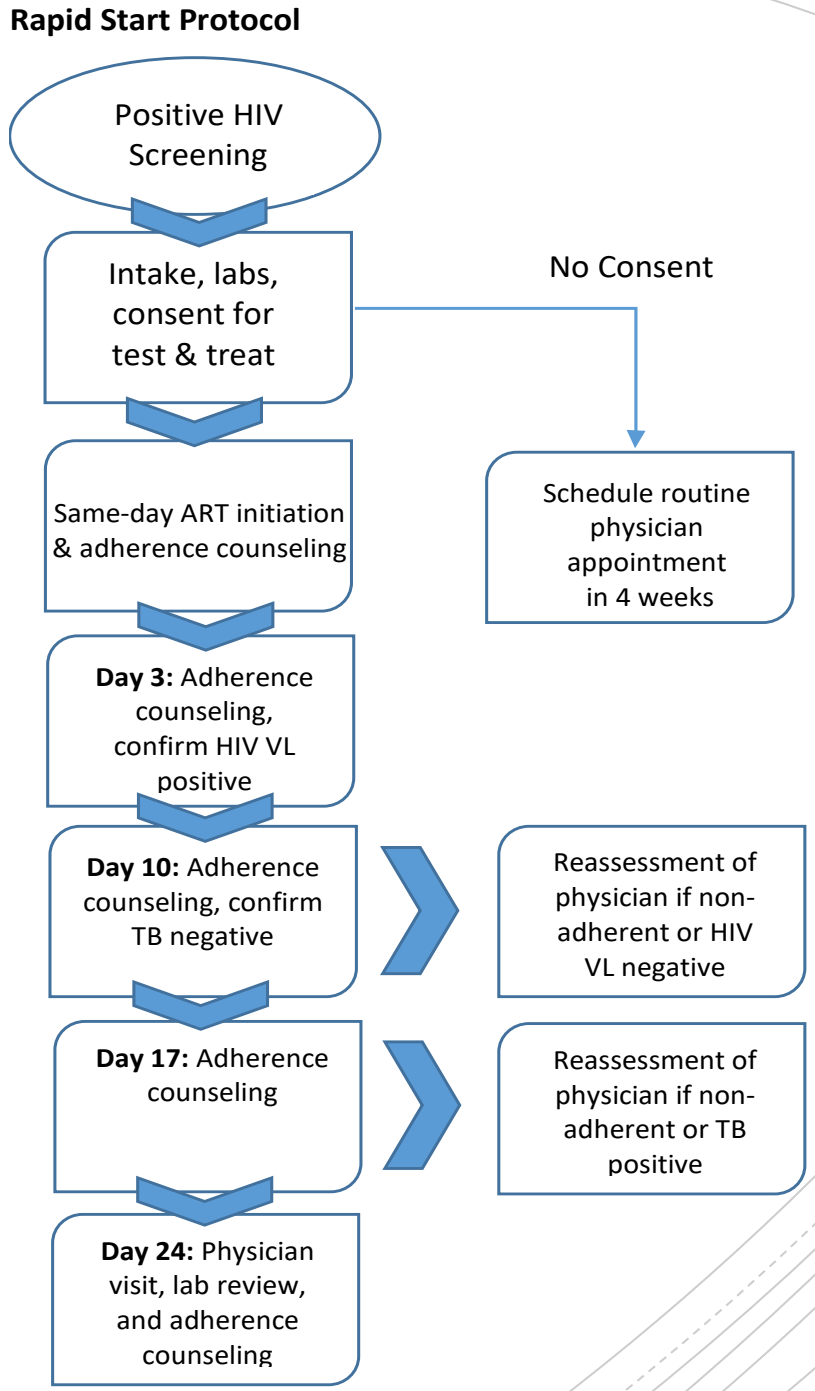
Physician

Case Manager
(phone)

Case Manager
(in-office)

Case Manager
(phone)

Physician



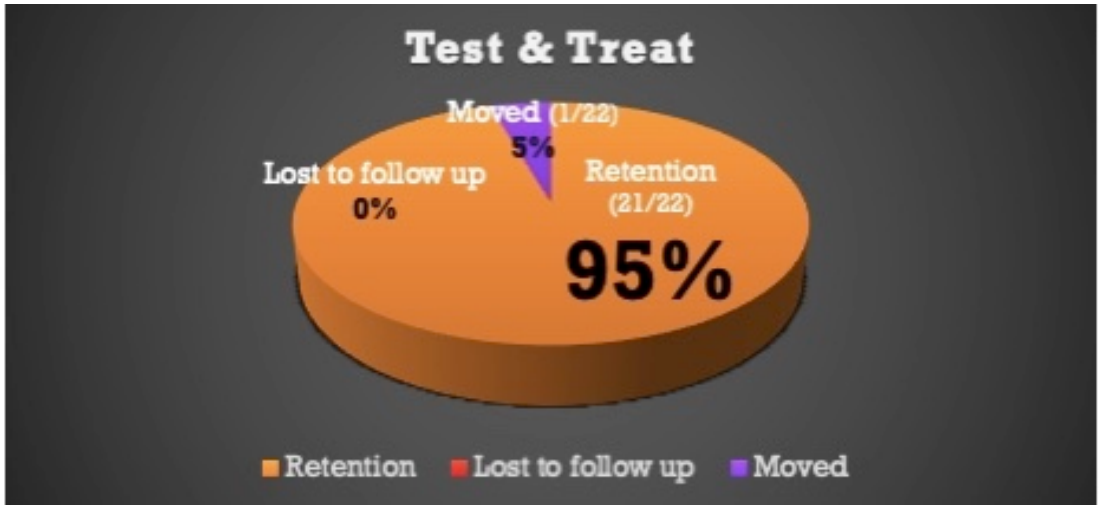
FOLLOW UP

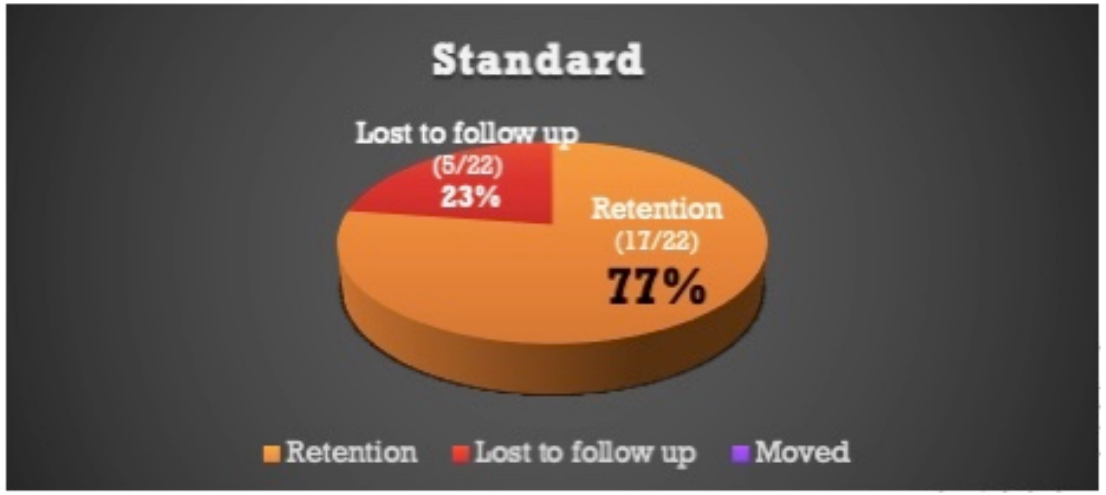
- Day 3: adherence phone call, verify HIV VL positive and assess need for PJP prophylaxis
- Day 10: adherence visit, verify quantiferon negative
- Day 17: adherence phone call
- Day 24: physician visit, review labs, re-draw labs to assess response to therapy, adherence counseling

CASE FOLLOW UP

- Initial visit and labs: 7-26-19 (CD4=328, VL=1933)
- Started on BIC-TAF-FTC same-day with co-pay card.
- Case manager follow up Day 3, 10, & 17.
- Next visit Day 24 and labs: 8-28-19 (CD4=366, VL=UD)
- Genosure: no resistance
- Quantiferon neg
- Hepatitis panel negative
- Partner HIV negative and on PrEP
- Retained in care. Last visit 6-1-20. Last CD4=551, VL=UD

RETENTION


Test & Treat
Moved (1/22)
5%
Lost to follow up
0%
Retention
(21/22)
95%
Retention
Lost to follow up
Moved


Standard
Lost to follow up
(5/22)
23%
Retention
(17/22)
77%
Retention
Lost to follow up
Moved

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