TEST & TREAT/RAPID ACCESS
Miami-Dade County Overview
for Medical Practitioners

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REVISED

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(revisions highlighted in yellow)

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BEHAVIORAL SCIENCE RESEARCH

MIAMI-DADE HIV/AIDS PARTNERSHIP

MIAMI-DADE COUNTY

World Health Organization Recommendations

"WHO [World Health Organization] recommends ART for all people with HIV as soon as possible after diagnosis…Huge reductions have been seen in rates of death and infections [from HIV/AIDS] when use is made of a potent ARV [antiretroviral] regimen, particularly in the early stages of disease" (World Health Organization, 2019, para. 1).

Test & Treat/Rapid Access Goal for Miami-Dade County

For all people with HIV who are not in care, facilitate immediate access to HIV medical care and antiretroviral therapy (ART) to improve client health outcomes, reduce viral load in the community, and get the number of new HIV infections to zero.

Why is Test & Treat/Rapid Access Important?

- **Shortens** the lag time between diagnosis and engagement in care for treatment-naïve (newly diagnosed) persons with HIV (Crowley & Bland, 2018)
- **Facilitates** rapid re-engagement of PLWH who had been in care before (Berger et al., 2015)
- **Immediately acts to reduce viral load levels** to suppress further infections, while allowing refinements in treatment strategy if subsequent analyses suggests more appropriate ARVs would be preferable (Crowley & Bland, 2018)

➢ *Note: since 2012, updated federal treatment guidelines recommend offering ART immediately upon diagnosis, and several randomized trials have validated this recommendation (see N Engl J Med., 2015, 795-807)*

Miami-Dade County
Test & Treat/Rapid Access Data

- The data in these graphics represent 2,821 people with HIV who were linked to Ryan White Program care through the local TTRA process from July 2, 2018 through June 24, 2022.

- All TTRA Ryan White Program (RWP) clients included in this analysis had a recorded baseline viral load measurement and were prescribed HIV ART as part of the TTRA protocol. Clients who were subsequently determined to be ineligible for RWP Part A services or were determined to be HIV-negative were removed from this analysis.

- Some people with HIV who initially enrolled in TTRA declined to participate, or were administratively removed (see next page).

Miami-Dade County
Test & Treat/Rapid Access Data - Reasons for Decline / Removal

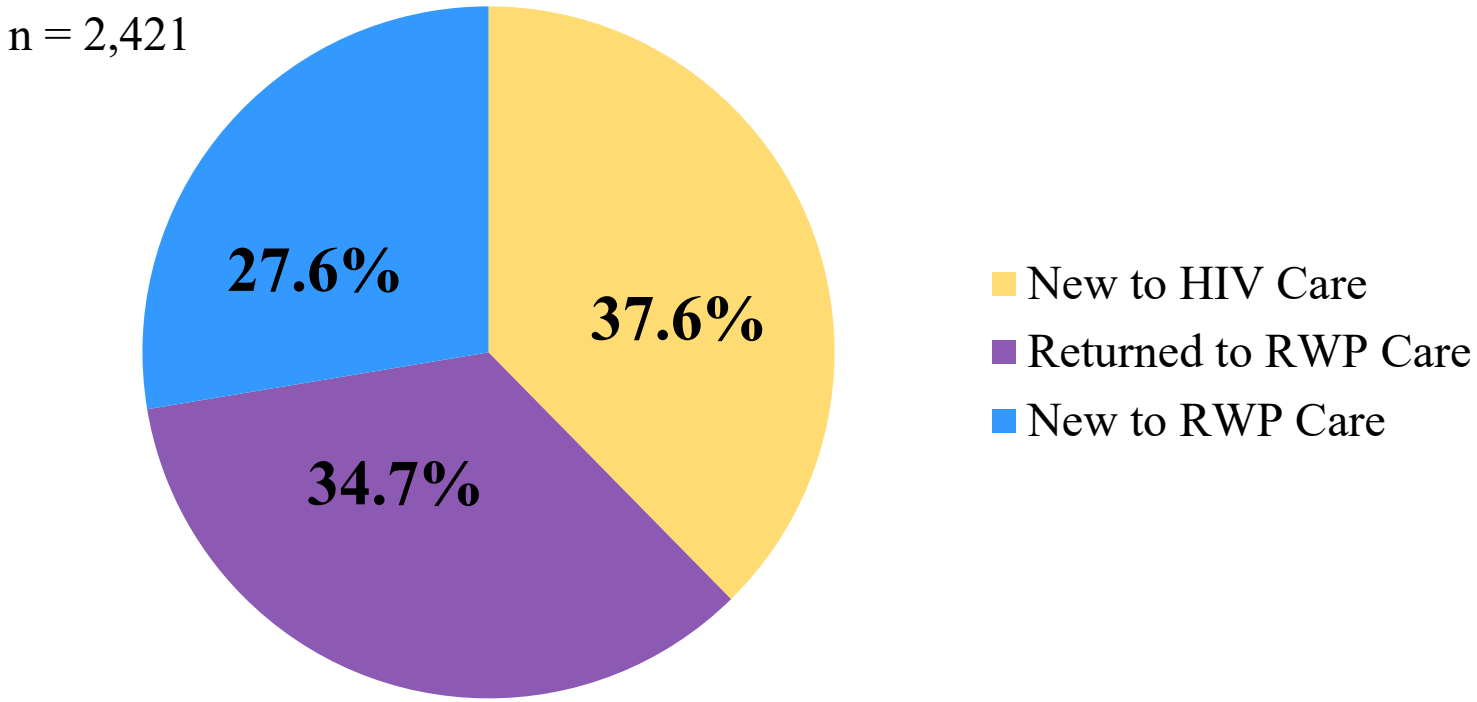
Forty-four (44) people with HIV were initially enrolled in TTRA, but were administratively removed or declined to continue participation, including:

- 20 who had entered TTRA inappropriately, since they were already in RWP care, had existing prescriptions or medications from previous treatment, or were existing RWP clients who wanted to change primary providers.
- 16 who refused to continue with TTRA, no reason given, or stated that they were not ready to start HIV/AIDS treatment immediately;
- Four were referred to General Revenue for non-TTRA formulary/protocol medications;
- Two had insurance, and used that resource rather than the RWP;
- One was determined to be ineligible for treatment by the RWP; and
- One requested counseling before starting ARVs.

Definitions of the TTRA Clients in this Analysis

- **New to HIV Care:** completely new HIV/AIDS diagnosis, client never in care before.
- **New to RWP Care:** previously diagnosed HIV positive but had never received services from the Miami-Dade County Ryan White Part A/MAI Program (RWP).
- **Returned to RWP Care:** previously in local RWP care, had been lost to RWP care for some period of time, and are now returning to care through TTRA.
  - *Note: the "lost to care" timeframe is not specified. Clients may be considered lost to care if they had missed multiple medical appointments in a row or had been off medications for a few months. This category is not used for clients who are already adherent to RWP care and simply do not wish to wait for a regularly-scheduled appointment.*

Distribution of People with HIV Entering Miami-Dade Part A TTRA*
(July 2, 2018 through July 24, 2022)



*Two clients (0.1%) were not categorized

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Viral Load of Clients Enrolled in TTRA

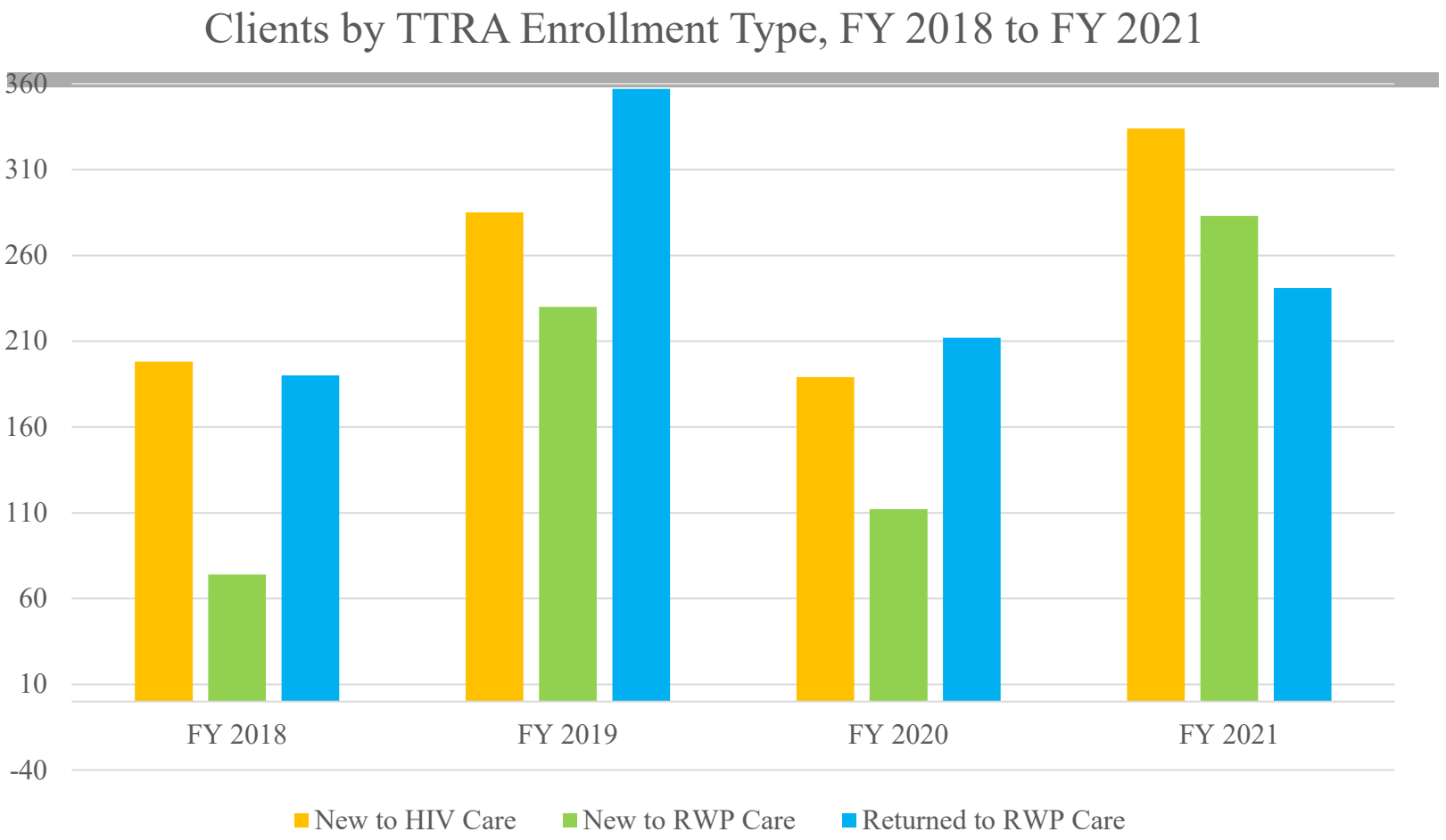
- **New to HIV Care:** 1,062 (37.6%) of the 2,821 clients tested and enrolled in TTRA were newly-diagnosed (treatment-naïve). Of these clients, **728 (69%) are reportedly virally suppressed**.

- **New to RWP Care:** 778 (27.6%) of the 2,821 clients entering through TTRA were previously diagnosed and may have previously been in treatment but had not received services through the RWP (26%). Of these clients, **611 (79%) are virally suppressed**.

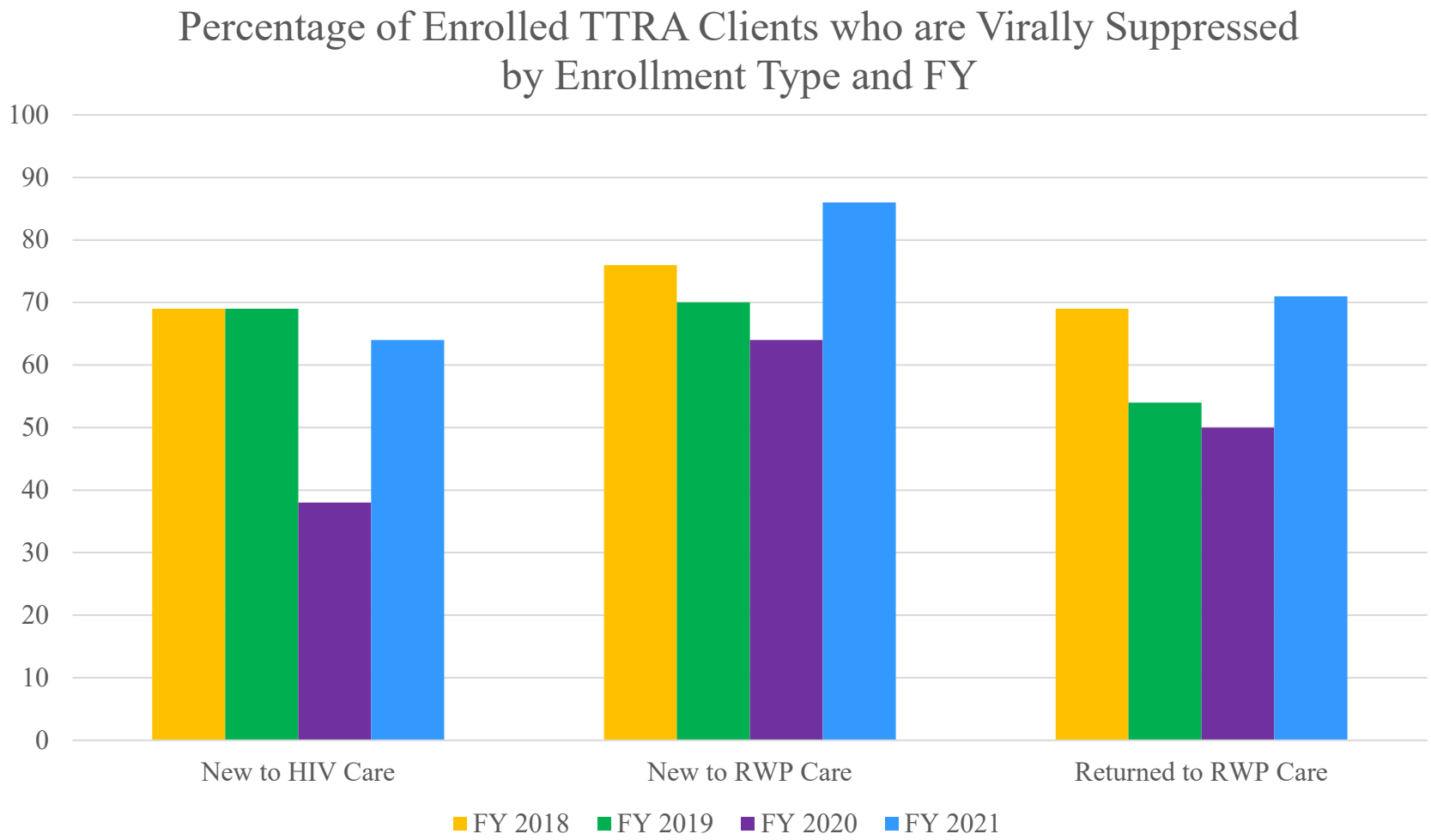
- **Returned to RWP Care:** 979 (34.7%) of the 2,821 clients were local RWP clients who had been lost to care. Of these clients, **688 (70%) are virally suppressed**.

Note: Two clients were not categorized.

Comparison of TTRA Enrollments by Fiscal Year (FY)



Comparison of Viral Suppression by Fiscal Year (FY)



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TTRA Impact on Client Health

- The following three elements of the TTRA process in Miami-Dade County have a demonstrated immediate impact on client health:

  1. Diagnosis with an immediate path to medical care;
  2. Medical care with an immediate path to ARV medication;
  3. ARV medication with an immediate path to viral load suppression.

- Especially among the newly-diagnosed, the sooner the clients are placed on ART, the sooner viral loads are suppressed and the greater the number of clients who are unable to transmit HIV to others.

TTRA Impact on Client Health (continued)

"The probability of a transmitted mutation impacting negatively on a first current regimen success is low, and if identified early through genotyping has relatively low probability of affecting a second regimen choice."

-- Michael A. Kolber, Ph.D., M.D.
Professor of Medicine; Vice Chair for Clinical Affairs, Department of Medicine; Director, Comprehensive AIDS Program; Director, Adult HIV Services, Department of Medicine
University of Miami Miller School of Medicine

- To date, there has been no evidence of harm to a treatment-naïve PLWHA when a client who is started on a **recommended regimen for rapid initiation** is switched to another regimen due to tolerance, simplification or genotypic concerns within 30-60 days.

Appendix:

The Test & Treat/Rapid Access Protocol

Test & Treat/Rapid Access Protocol

- Conduct abbreviated, first medical visit with focus on treating the client's HIV within 3 days of TTRA enrollment date; preferably same day, but not more than 7 days later; using CPT codes 99201, 99202, 99203, or 99204 (for new patients) **or** 99211, 99212, 99213, or 99214 (for established patients; i.e., those served in same medical group within the past 3 years)
  - *NOTE: Part A/MAI services to TTRA clients with a preliminary positive test result who are ultimately determined to be HIV negative will need to be disallowed from Part A/MAI reimbursement.*
- Write **two** prescriptions (one for the TTRA pharmacy; one for referral to other source of access to medications – **maximum 5 refills**)
- Order **appropriate, initial labs (see pages 22 & 23)**

Test & Treat/Rapid Access Protocol (continued)

- Prescribe ART within 3 days of TTRA enrollment date, preferably same day, but not more than 7 days later
- **Recommended 30-day ART regimens for local TTRA include:***
  - bictegravir/tenofovir alafenamide/emtricitabine (Biktarvy®) (see page 20);
  - dolutegravir/lamivudine (Dovato®) (if considering this ART, see pages 17 & 18);
  - dolutegravir (Tivicay®) plus tenofovir alafenamide/emtricitabine (Descovy®);
  - darunavir/cobicistat (Prezcobix®) plus Descovy®;
  - darunavir/cobicistat/emtricitabine/tenofovir alafenamide (Symtuza®) (if considering this ART, see page 19)

** To prescribe another ARV medication, please use the local General Revenue Short-Term Medication Assistance referral process.*

Test & Treat/Rapid Access Protocol (cont'd)

- ARV regimen for women of childbearing potential (or for women presenting with pregnancy potential on inadequate contraception):
  - ❖ dolutegravir (Tivicay®) + emtricitabine/tenofovir disoproxil fumarate (Truvada®)
  - ❖ dolutegravir (Tivicay® + emtricitabine/tenofovir alafenamide (Descovy®)
  - ❖ darunavir (Prezista®) + ritonavir (Norvir®)

NOTE: Tivicay® has replaced Isentress® as a regimen appropriate and recommend regimen for women at all stages of pregnancy – conception to birth.

Test & Treat/Rapid Access Protocol (cont'd)

If considering prescribing **dolutegravir/lamivudine (Dovato®),** please note:

- ✓ Contact ViiV Healthcare for vouchers or Patient Assistance Program; www.viivconnect.com

- ❖ *Indication*: Dovato® is indicated as a complete regimen for the treatment of HIV-1 infection in adults with no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen **with no history of treatment failure and no known substitutions associated with resistance to the individual components**.

  - ✓ *Note*: Dovato® phase III registrational trials enrolled participants with a screening viral load of 1,000 to ≤500,000 copies/mL though 2% of participants did rise above that viral load threshold by baseline measurements and **the FDA labeled indication for initial therapy does not restrict use based on baseline viral load**.

Test & Treat/Rapid Access Protocol (cont'd)

- If considering prescribing **Dovato®: (continued)**

✓ *Boxed Warning*: All patients with HIV-1 should be tested for the presence of HBV **prior to or when initiating** Dovato®. Emergence of lamivudine-resistant HBV variants associated with lamivudine-containing antiretroviral regimens has been reported. If Dovato® is used in patients co-infected with HIV-1 and HBV, additional treatment should be considered for appropriate treatment of chronic HBV; otherwise, consider an alternative regimen. Severe acute exacerbations of HBV have been reported in patients who are co-infected with HIV-1 and HBV and have discontinued lamivudine, a component of Dovato®. Closely monitor hepatic function in these patients and, if appropriate, initiate anti-HBV treatment.

✓ This regimen added to TTRA requires the practitioner to be responsible in addressing this risk by assessing lab results in a timely fashion.

Test & Treat/Rapid Access Protocol (cont'd)

If considering prescribing **darunavir/cobicistat/emtricitabine/tenofovir alafenamide (Symtuza®)**, please note:

Providers may prescribe this medication, but they must use the voucher provided by Janssen Pharmaceuticals to cover the cost of this medication as the Florida Department of Health cannot be invoiced for this medication.

If you need additional vouchers, please contact Sam Quintero, Senior Community Liaison – Florida, Janssen Infectious Diseases and Vaccines, by email to squinte6@its.jnj.com or phone call to 305-794-7362; or contact Andrew Werner by email to AWerner4@its.jnj.com or phone call to 786-371-9651; or Tyler Johnson by email to BJohns73@its.jnj.com or phone call to 954-336-4877; or call the health department patient care coordinators for additional vouchers.

Test & Treat/Rapid Access Protocol (cont'd)

If considering prescribing **Bictegravir/tenofovir alafenamide/emtricitabine (Biktarvy®)**, please note:

Samples of Biktarvy® (or any Gilead product) can be requested by contacting the Gilead representative for Miami-Dade, as follows:

Cesar Pizarro by phone at 305-283-9014; or email to Cesar.Pizarro@gilead.com

Test & Treat/Rapid Access Protocol (cont'd)

- ART picked up at pharmacy by client and treatment starts, within 7 days of TTRA enrollment, preferably same day as initial medical visit or next day

- Client coordinates with medical case management staff to establish eligibility for RWP Part A and ADAP as soon as possible, preferably within 14 days of initial TTRA enrollment
  - Timely ADAP enrollment is critical to ensure on-going access to ART;
  - Timely Part A enrollment is necessary for access to on-going medical care and other core medical and support services.

- Schedule additional follow-up medical visits, labs and diagnostics, as needed, AFTER Part A/MAI program eligibility and on-going payer source is determined

Allowable Lab Tests Under TTRA

-- **HIV-1 genotype resistance tests** (CPT 87900, 87901, and 87906),

**** IMPORTANT: order a genotype test at initiation of care for all newly diagnosed clients and for all return to care clients ****

-- HIV 1,2 Ag/Ab, preferred (CPT 87389), if HIV diagnosis is not confirmed

-- Complete Blood Count (CPT 85025 or 85027)

-- Comprehensive Metabolic Panel (ALT, AST, creatinine [eGFR] (CPT 80053),

-- CD4 count (CPT 86360 or 86361),

-- HIV-1 RNA PCR (viral load) (CPT 87536),

-- Hepatitis B surface antigen (if indicated; CPT 87340); also recommended:

- HBsAg (87340; 87341); HBsAb (86706 qualitative; and 86317 quantitative); HBcAb total (86704), and HBcAb IgM antibody (86705)
- Note: if HBV vaccine verified, do not need to order HBsAG

-- urinalysis (CPT 81000, 81001, and 81003),

-- pregnancy test (if indicated, CPT 81025)

-- NOTE: CPT code 36415 (collection of venous blood by venipuncture) is also an allowable procedure under TTRA.

Possible Additional Labs under TTRA

Order the following labs under TTRA, ONLY IF the client is symptomatic or Part A eligibility has been confirmed:

-- RPR (rapid plasma reagin) test for syphilis [CPT 86592 qualitative; or 86593 quantitative and 86780 (qualitative or semiquantitative immunoassay)]

-- Gonorrhea (CPT 87590, 87591, 87592, and 87850)

-- Chlamydia (CPT 87486 or 87491 NAAT; 87485 or 87490 DNA probe)

References

Berger, M. E., Sullivan, K. A., Parnell, H. E., Keller, J., Pollard, A., Cox, M. E., Clymore, J. M., & Quinlivan, E. B. (2015). Barriers and facilitators to retaining and reengaging HIV clients in care: A case study of North Carolina. *Journal of the International Association of Providers of AIDS Care (JIAPAC), 15*(6), 486-493.

Crowley, J. S., & Bland, S. E. (2018). *Leveraging the Ryan White Program to make rapid start of HIV therapy standard practice.* Washington D.C.: O'Neill Institute for National and Global Health Law.

World Health Organization (WHO). (2019). *HIV/AIDS: Treatment and care*. [web page]. Retrieved February 27, 2019 at https://www.who.int/hiv/topics/treatment/en/.

TTRA Champions in Miami-Dade County

Part A OAHS & MCM Subrecipients:

- AIDS Healthcare Foundation
- Borinquen Health Care Center
- CAN Community Health
- Care 4 U Community Health Center
- Care Resource Community Health Centers
- Citrus Health Network
- Community Health of South Florida
- Empower U Community Health Center
- Jessie Trice Community Health System
- Latinos Salud
- Miami Beach Community Health Center
- Public Health Trust/Jackson Health System
- University of Miami

Other Stakeholders:

- Florida Department of Health (in Tallahassee and in Miami-Dade County)
- Miami-Dade County Office of Management & Budget (Part A/MAI Recipient)
- Miami-Dade HIV/AIDS Partnership (local HIV/AIDS planning council)

Questions? Please contact:

- **Clinical:**
  Dr. Andrea Sciberras
  HIV/AIDS Medical Director
  Andrea.Sciberras@flhealth.gov

- **FDOH Process – Access to HIV testing and medications:**
  Kira Villamizar, B.S., M.P.H.
  STD/HIV Prevention Program Director
  Florida Dept. of Health in Miami-Dade
  1350 NW 14th Street, 4th Floor, Rm. 401
  Miami, FL 33125
  (305) 575-5424
  Kira.Villamizar@flhealth.gov

- **Part A Process: Access to Part A, incl. medical visit, labs & mental health services:**
  Carla Valle-Schwenk
  Program Administrator
  Miami-Dade County
  Ryan White Part A Program
  111 NW 1st Street, 22nd Floor
  Miami, FL 33128
  (305) 375-3546
  Carla.ValleSchwenk@miamidade.gov