HIV Test and Treat (T&T) and Re-Engage in Care Guidance

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September 2021
4th Edition

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INTRODUCTION

One goal of the Florida Department of Health (Department) is to ensure persons diagnosed with HIV are started on antiretroviral therapy (ART) as soon as possible and that persons living with HIV stay on ART consistently to obtain and sustain a suppressed viral load. This approach is based on a model first published in the British medical journal Lancet in 2007 and is now known as Test and Treat (T&T). In addition to benefitting an individual patient's health, viral suppression serves public health by preventing HIV transmission, an outcome commonly referred to as "Undetectable equals Untransmittable" (U=U).

This guidance presents an overview of relevant information for clinicians, including physicians, physician assistants, nurse practitioners and registered nurses, who are providing T&T in clinical settings. Important considerations for starting and monitoring a patient on T&T are presented below.

GETTING STARTED

T&T Is Indicated for the Following Individuals:

- Patients newly diagnosed with HIV (positive screening test or confirmed positive test)
- Patients returning to HIV care after a gap in treatment
- Patients who have lost insurance coverage or access to ART

Components of a T&T Intervention:

- Facilitation of same-day or next-day appointments using flexible scheduling options such as onsite or telehealth appointments
- Available onsite or same-day access to ART through issuance program, samples and/or medication vouchers
- Process to link clients to a full-time health care provider for both primary care and HIV-specific health care needs
- Process to refer clients for assistance with HIV patient care program eligibility, health insurance coverage and case management services

T&T Coding:

- Test and Treatment Initiation 5707
- Test and Treatment Re-Established HIV Care 5708

For further coding information: Department of Health HMS Service and Time Code 2020-2021

T&T Services Timeline:

Day one (or within two to three days):

- If clinic provider cannot see the patient in person or via telehealth the same day or within two to three days, contact the HIV/AIDS Section Telehealth team to provide the service.
- Clinician meets with patient for brief medical history, medication review, targeted exam, psychosocial needs assessment, risk reduction discussion and ART education and regimen selection.
- Obtain baseline labs (see below for list of labs required); can be ordered prior to visit or on same day that ART is started.

- Labs should be drawn at the T&T clinic site (if not drawn prior). If labs cannot be drawn, staff should follow up with patient daily to be sure baseline labs have been completed.
- Expedite linkage for HIV patient care program eligibility and case management within seven days of T&T visit.
- Schedule follow-up appointment if patient will be receiving HIV primary care at current county health department (CHD) location.

Days Three–Ten (follow-up)

- Call, or email through Department approved patient portal, to check on patient (recommended at three–four days post-ART start).
- Review baseline labs with patient; may be completed in person, via telehealth or over the phone with patient consent.
- Order opportunistic infection (OI) prevention medication as indicated (see Frequently Asked Questions for details).
- Adjust ART as needed/indicated.

Day >30 (follow-up)

- Monitor/ensure compliance with follow-up labs and appointments.
- If CHD does not provide HIV care, document in Health Management System (HMS) the provider assuming care and appointment date (be sure consent form is signed by the patient to send record to the outside provider).

Required Minimum Baseline Laboratory Tests for Initial T&T Services:

- Positive HIV 1/2 antigen/antibody (Ag/Ab) immunoassay blood-based test
- Absolute CD4 count with the percentage of CD4 cells
- Viral load HIV-1 ribonucleic acid polymerase chain reaction (HIV-1 RNA PCR) quantitative
- HIV-1 genotype resistance test for protease (PR) and reverse transcriptase (RT)
- Hepatitis panel (chronic) to include hepatitis A, B, and C or, at a minimum hepatitis B surface antigen (HBsAg) and hepatitis B surface antibody (HBsAb)
- Comprehensive metabolic panel (CMP) (ALT, AST, creatinine with estimated glomerular filtration rate [eGFR])
- Urinalysis macro or point-of-care urine dipstick for protein
- Rapid plasma reagin (RPR monitor with reflex to confirmation)
- Site-specific sexually transmitted infection screening
- Pregnancy test (all people of child-bearing potential)

Please refer to the chart on page 12 for additional information on tubes and coding for above lab tests.

RECOMMENDED REGIMENS

Unless patient is pregnant or trying to conceive, the following ART regimens are recommended for T&T (listed alphabetically; provide initial 30-day supply for all):

- Bictegravir/emtricitabine/tenofovir alafenamide 50/200/25 mg (Biktarvy), one tablet daily, **with or without food** (available through samples or issuance program).

OR

- Darunavir/cobicistat/emtricitabine/tenofovir alafenamide 800/150/200/10 mg (Symtuza), one tablet daily, **with food** (available through voucher or issuance program).

OR

- Dolutegravir 50 mg (Tivicay), one tablet daily, with tenofovir alafenamide 25 mg/emtricitabine 200 mg (Descovy), one tablet daily, both taken **with or without food**.

  NOTE: In cases of known resistance, at the provider's discretion, combinations of PI/INSTI plus or minus NRTI may be dispensed.

Throughout pregnancy and for people trying to conceive, the recommended 30-day ART regimen for T&T is as follows:

- Dolutegravir 50 mg (Tivicay), one tablet daily, with tenofovir disoproxil fumarate /emtricitabine 300/200 mg (Truvada), one tablet daily, both taken **with or without food**.

NOTE: Clinical trial data indicate that Dovato (dolutegravir/lamivudine) may be an option for T&T use for **newly diagnosed** persons with HIV. It is available through samples or via the manufacturer's patient assistance program.

Dovato does not provide adequate treatment for hepatitis B if coinfection is present. Please see Frequently Asked Questions, "Medications" for full discussion.

INSTI INTERACTIONS

Note: Integrase inhibitors (INSTIs) can interact with medications containing polyvalent cations, including prenatal vitamins. See following table.

INSTI Interactions with Polyvalent Cations

	Bictegravir (BIC)	**Dolutegravir (DTG)**
Antacids (e.g., Al, Mg, Ca)	Take BIC ≥ Two hours before or ≥ six hours after antacids containing Al or Mg Take BIC with antacids containing Ca with food	Take DTG ≥ two hours before or ≥ six hours after antacids containing Al, Mg, Ca
Polyvalent cation (e.g., Al, Ca, Fe, Mg, Zn) containing medications, including multivitamins, supplements, laxatives, sucralfate, and buffered medications	**Supplements containing Ca or Fe:** Take simultaneously with food or, if fasting, take BIC ≥ two hours before **Other polyvalent cations:** Take BIC ≥ two hours before or ≥ six hours after	**Supplements containing Ca or Fe:** Take simultaneously with food or, if fasting, take DTG ≥ two hours before or ≥ six hours after **Other polyvalent cations:** Take DTG ≥ two hours before or ≥ six hours after

Source: Clinical info INSTI drug interactions

FREQUENTLY ASKED QUESTIONS

General

Q: In what situations is it advisable to hold off on immediate ART initiation?

A: Hold off on immediate initiation for persons who appear obviously clinically ill. There are two OIs (cryptococcal meningitis and tuberculosis of the central nervous system) for which guidelines recommend delaying initiation of ART. These presentations are usually seen in hospital settings.

Persons brought to T&T with a preliminarily positive rapid HIV test who, on risk-factor assessment, are deemed to be at low risk of HIV infection and thus have a higher likelihood of false-positive HIV antibody testing might best be served by delaying T&T until the fourth generation HIV test results are available.

Q: What if the patient does not want to start ART?

A: This is the choice of the patient. In these situations, it is important to verify you have accurate contact information (and preferably more than one way to contact the patient) to follow up after a few days to assess how the patient is doing. It is very important to follow up to confirm linkage to care is successful.

Q: Can our CHD participate in T&T if we don't have an onsite HIV clinic?

A. Yes. Providers in sexually transmitted disease, adult health and family planning clinics can be trained to initiate HIV medications. The HIV/AIDS Section Telehealth team is available to provide training.

Q: If our CHD does not have an onsite clinician available or the clinician has not provided HIV medications before, are we able to participate in T&T for our communities?

A: Yes, your CHD can access the telehealth T&T clinicians and your patient can be seen at your local CHD or in the privacy of their home over a face-to-face Health Insurance Portability and Accountability Act (HIPAA) compliant computer connection (See Telehealth T&T process). Patients will need to have an HMS electronic health record opened and vital signs completed or reported when possible if accessing telehealth services from home. The telehealth clinician will document the care in your CHD's HMS record, including completing the issuance program medication documentation. A member of your CHD team will then need to arrange for the draw of initial laboratory specimens, provide issuance program medication, and link to ongoing HIV care within your community. The telehealth clinicians will assess the laboratories drawn at the baseline visit and discuss with a member of your CHD onsite team.

Q: What ICD10 code should be used for a T&T visit?

A: For a patient presenting with history of an AIDS diagnosis, use B20. Otherwise, at these initial visits, use Z21 to denote a diagnosis of asymptomatic HIV infection when you have a confirmed HIV-1/2 Ag/Ab immunoassay test result and R75 when you have a positive rapid test not yet confirmed.

Q: How do I obtain issuance medication?
A: Issuance medication is obtained from the online Pharmacy Forms System through the Bureau of Public Health Pharmacy (Central Pharmacy). If you do not have access to the online ordering system, refer to your CHD nursing director for guidance.

Q: How do I obtain pharmaceutical samples?
A: As a cost-savings measure for the Department, we encourage CHD practitioners to use manufacturer samples and vouchers for T&T clients in accordance with the Bureau of Public Health Pharmacy's policy DOHP 395-1, which states CHD practitioners are allowed to obtain manufacturer samples. A pharmaceutical representative contact sheet is available to clinicians and staff.

Q: What if there are barriers at the local CHD level to obtaining samples?
A: Please reach out to the HIV/AIDS Registered Nurse Consultant for the policy and assistance.

Q: What OIs should I be concerned about?
A: Please see HIV.gov's clinical guidelines for an introduction to OIs and treatments. A key point in initiating ART in T&T is to have a patient who appears healthy at that time. Persons who present with constitutional symptoms of fever, chills, night sweats, nausea, vomiting, etc. may need to have a clinical workup before starting ART. Practitioners need to review the baseline laboratory drawn at the T&T visit in a timely fashion and should prescribe OI prophylaxis as indicated by lab results.

Insurance

Q: If my patient has insurance, are we able to provide T&T medications?
A: For an insured patient, the best practice is to e-prescribe the medication to the pharmacy of the patient's choice and then call and speak with the staff at the pharmacy. Ask the staff to run the medication to see if prior authorization is required. If prior authorization is required or it will take more than a day to get the medication into the pharmacy, provide T&T issuance program or pharmaceutical samples of antiretroviral (ARV) medications to support the patient's initial therapy.

Q: What if the patient has an insurance plan for which our provider is not eligible for reimbursement?
A: This is decided at the local CHD level. Your CHD may support treatment initiation for out-of-network insured patients. In some instances, if the patient agrees, you can discuss their case with an in-network provider and collaborate to initiate lab and medication needs for the patient. In some instances, the insurance may not reimburse at as high of a level when the provider is out of network, but the reimbursement may be adequate to cover the costs of the T&T evaluation (CHD provider time and lab cost). If your CHD is not able to see the patient for reasons related to payer source, assist with immediate linkage to a provider in their network.

Labs

Q: Is a confirmed HIV test required before patients can present for T&T evaluations?
A: No, a patient should be offered a T&T evaluation based upon an initial HIV-positive screening test. The T&T clinician will determine the likelihood of a potential false-positive test and may wait to initiate T&T until there is a confirmatory HIV-1/2 Ag/Ab immunoassay blood-based test result. When the history or at-risk behaviors support the likelihood the screening HIV test will be confirmed positive, the patient should proceed through the T&T evaluation process and initiate ART.

Q: What if the patient's lab returns a positive HBsAg test result?
A: Your patient has hepatitis B infection. All the recommended T&T issuance program regimens contains two drugs active against hepatitis B: tenofovir alafenamide/emtricitabine or tenofovir disoproxil fumarate/emtricitabine (note: dolutegravir/lamivudine (Dovato) does not provide this coverage). The patient should be informed they need further evaluation with their primary care provider. It should be stressed not to stop taking their ARV medication, as serious flares of hepatitis B have occurred when treatment was abruptly stopped. Once the HBsAg is known to be positive, the patient should be contacted, and test results should be sent to the patient's primary care provider with consent of the patient.

If starting T&T with dolutegravir/lamivudine (Dovato) and positive HBsAg results, the regimen should be modified to include a second drug active against hepatitis B, such as tenofovir disoproxil fumarate or tenofovir alafenamide.

Medications

Q: Is the patient taking concomitant drugs that may interact with one or more of the T&T medications?
A: Obtain a thorough medication history, including over-the-counter medications. Drugs that may impair renal function (such as nonsteroidal anti-inflammatory drugs) may interact with tenofovir disoproxil fumarate or tenofovir alafenamide (lesser extent) containing regimens. Drugs that induce p-glycoprotein and/or CYP3A4 (such as carbamazepine, oxcarbazepine, phenytoin, rifabutin, rifampin) may interact with tenofovir alafenamide and protease-inhibitor containing regimens. Polyvalent cations may interact with INSTI containing regimens (see table above). Cobicistat (component of Prezcobix and Symtuza) is a boosting agent and can interact with many drugs, primarily through inhibition of CYP3A4, CYP2D6, and P-glycoprotein.

Use University of Liverpool's HIV Drug Interaction Checker to check for possible drug-drug interactions.

Q: How do you counsel the patient on the use of their ARV medications?
A: Provide the patient instructions on how to take their medications, including whether the medications need to be taken with food. Instruct patient on the importance of taking the medications at about the same time each day. **However, a patient does not need to stick with the time they took the first dose of medication at the T&T visit if that time is not the best time for them to remember to take the medication**. The patient can change to their

preferred dosing time on the next day and stick with that time from then on. Counsel the patient on the importance of not missing doses and the relationship of missing doses to the development of resistance, which could make the virus more difficult to treat and require the use of more medications. Counsel the patient on the importance of not running out of their medications, contacting the pharmacy in advance for refills and available resources to assist them in obtaining their medications should they lack insurance or have copays, deductibles or premiums that they cannot afford. Use the North Florida AIDS Education and Training Center Medication Information Sheets to assist in educating patients about their ARV regimen.

Q: What if a patient returns to us and states they cannot obtain their medication?
A: No patient should be turned away without medication if it is at all preventable. Provide the patient with samples or issuance program medication while the issue is addressed. The Florida AIDS Drug Assistance Program (ADAP) can assist uninsured clients or clients with insurance who need premium and/or copay assistance. Patients with private insurance can use pharmaceutical company copay cards based on eligibility.

Patients with high copays may require alternative copay assistance such as ADAP if the pharmaceutical company copay card does not provide coverage for the entire year. Individual drug manufacturers provide medications without charge for some low-income or uninsured patients through patient assistance programs accessible at their websites. Other copay programs (e.g., My Good Days or Patient Advocate Foundation) are available to assist patients with federally funded insurance (i.e., Medicare, Medicaid Tricare). Consider use of a local or mail-order specialty pharmacy to assist you in making sure patients with insurance can maintain access to their ARVs. Referral to a Ryan White case management agency is recommended.

Q: Am I restricted in the T&T program to the drugs on the T&T formulary?
A: No, any licensed practitioner may prescribe the medication of their choice, in consultation with their patient, for initiation of therapy.

Q: Why isn't Dovato available for T&T issuance?
A: Phase IIIb STAT trial data on Dovato use in a rapid T&T model for patients newly diagnosed with HIV was released in 2020. However, Dovato is not currently recommended for use by the Department of Health and Human Services (DHHS) Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV Considerations for Acute and Early HIV Infection in a T&T scenario where laboratory data are not available. DHHS Guidelines only recommend Dovato if HIV RNA is < 500,000 copies/mL, the patient does not have hepatitis B coinfection, and resistance testing results show no resistance to lamivudine. Practitioners using Dovato for T&T on the same day that the initial lab is drawn must review labs in a timely fashion to ensure safety with initiation on Dovato. Dovato is available to all practitioners through pharmaceutical samples or vouchers (one or the other, not both) shipped or delivered to the practitioner's office.

Q: As a practitioner in a CHD, am I able to receive and provide pharmaceutical samples and vouchers to my patients?
A: Yes, if approved by your local CHD administration. Please notify the HIV/AIDS Section Medical Team if your CHD would like assistance with receiving samples.

Ryan White

Q: If eligibility for Ryan White is not completed before the patient runs out of ART, can the T&T program use the issuance program to provide additional ART to prevent a lapse in medication?

A: Yes, the goal is to ensure no patient in need of ARV medication goes without.

Q. If my CHD does not have a relationship with a Ryan White lead agency, how are services reimbursed?

A: Services can be paid through several options depending on the client's situation:

- CHD bills client's insurance.
- Client self pays per CHD sliding fee schedule.
- CHD establishes a purchase order/contract with the local Ryan White lead agency to be reimbursed (for Ryan White eligible clients only).

For a T&T visit, most expenses are related to clinician time, medication and lab tests. Where a client does not have the means to self-pay or the CHD cannot bill the client's insurance, services will have to be covered with local funds.

- Medication can be provided without charge to the client through the Department Issuance Program or providers can use samples or vouchers.
- Clinician time provided through the HIV Telehealth Program bears no cost to the CHD. Local clinician time will have to be covered with local fees.
- Lab costs are typically where there is a challenge in finding funding.

Special Populations

Q: How do we address the high-risk patient who presents with acute viral syndrome symptoms with a high-risk exposure within the last 15 days (potential window of fourth generation Ag/Ab testing)?

A: Take a thorough health and sexual history, evaluating high-risk activity of the patient and their partner(s). Perform a rapid HIV test and draw blood for an HIV-1/2 Ag/Ab immunoassay test. If the patient has symptoms of acute HIV infection, draw an HIV-1 PCR RNA quantitative viral load. Initiate post-exposure prophylaxis (PEP) HMS Code 5705 with one of the T&T regimens and **follow up per PEP guidance**. Discuss safe sex practices while awaiting test results and follow-up. See also: PEP to Prevent HIV Infection Clinical Guidelines Program.

Q: What if the patient is pregnant, planning to become pregnant or not on adequate birth control?

A: Always refer to the latest update of the DHHS recommendations for use of ARVs during pregnancy. Symtuza and Biktarvy are not recommended for use during pregnancy. Truvada with Tivicay is a preferred ARV regimen option throughout pregnancy and for those who are trying to conceive. Tenofovir alafenamide is recommended as an alternative NRTI.

Q: How do you evaluate a patient who presents with a positive HIV-1/2 Ag/Ab immunoassay test result whose HIV-1 viral load returns an undetectable result?

A: In the case of an individual presenting with a positive HIV Ag/Ab combination assay who is then found to have an undetectable HIV viral load, one must consider the possibility of a false-positive HIV test. The HIV-1/2 Ag/Ab immunoassay test specificity is greater than 99.6 percent. For every 10,000 tests performed, as many as 40 may be false positive. False-positive test results have been reported during pregnancy.

When the HIV viral load returns as undetectable, repeat the test to confirm and assess the patient's history to determine if they would be considered at low risk for HIV infection. Consider whether the patient may have been on ART at the time of the viral load draw. Inquire as to any memory of signs and symptoms consistent with acute HIV seroconversion. Note a viral load result of 'Not Detected' means no evidence of HIV and thus the positive HIV antibody test result was a false-positive result. (Case example: HIV-1 in pregnancy with undetectable viral load)

TELEHEALTH RESOURCES

Telehealth services for T&T are available. Equipment costs are minimal and include a CHD computer with video camera and speakers. HIPAA compliant Doximity or Microsoft Teams is used and provided to the CHD at no cost. When anticipating a telehealth T&T patient, please contact one of the following staff members (start with the first person on the list and progress downward):

- Telehealth APRN – 850-694-4388
- Telehealth PA – 904-254-0258
- Administrative Assistant – 239-292-3054
- HIV/AIDS Section Medical Director – 850-519-3734

One of these staff members will accept the telehealth session and will establish a connection. A calendar invite will be sent to the contact person at the originating site with the date and time of the visit and the name of the provider seeing the patient. Before each telehealth encounter, test the system and problem-solve any connection issues.

ADDITIONAL GUIDANCE

- HIV/AIDS Medical Practice Guidelines
- Clinician Consultation Center
- Antiretroviral Drug Interactions
- Antiretroviral Patient Medication Information Sheets

LABORATORY TEST QUICK REFERENCE

TEST NAME	TUBE	TEST CODE QUEST	TEST CODE STATE	TEST CODE LABCORP
HIV 1/2 Ag/Ab Immunoassay (if no record confirmed HIV)	SST	**91431**	**0500**	**083935**
HIV-1 RNA, Quantitative Real Time PCR Viral Load	White top tube	**40085**	**0560**	**550430**
HIV-1 Genotype (RT, PR)	White top tube	**34949**	**0000570**	**551697**
Comprehensive Metabolic Panel (14)	SST	**10231**	**Does not run Test**	**322000**
Chronic Hepatitis Panel (HAV, HBV, HCV*)	SST	**6462**	**0380**	**303744**
CBC (Includes Diff/PLT)	Lavender	**6399**	**Does not run Test**	**005009**
Lymphocyte Subset Panel 5 (Absolute CD4 &CD4% Panel 5)	Lavender	**8360**	**000540** (CD4 and CD8 only)	**505008**
Urinalysis Macroscopic Urinalysis (POC dipstick)	Yellow top tube CHD	**6448**	**Does not run Test**	**003038**
RPR (monitor) with confirmation	SST	**799**	**0250**	**012005**
CT/GC (site specific)	Urine Rectal swab Oral swab	**Urine 11363** **Rectal 16506** **Oral 70051**	**0430 please indicate site: Urine, Rectal, Oral or Vaginal. <u>MUST</u> indicate "-SC" if self-collected (example: Rectal – SC)**	**Urine 183194** **Rectal 188672** **Oral 188698**