Shelby County Rapid Linkage to HIV Care and ART Initiation Program

Standard Operating Procedures

Version 1.0 (May 23, 2024)





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I. Introduction

The Memphis-Shelby County rapid linkage to HIV care and antiretroviral therapy (ART) program (branded "ConneXtion" in English or "ConeXión" in Spanish) is being implemented as part of the United States (US) and Memphis Ending the HIV Epidemic Initiatives. The goals of the 2019 US Ending the HIV Epidemic Initiative are a national 75% decrease in incident HIV cases within 5 years and a 90% decrease in incident HIV cases within 10 years (1). Specific to ART initiation, one goal of the Memphis Ending the HIV Epidemic—End HIV 901-- is for 90% of individuals newly diagnosed with HIV to initiate ART within 72 hours of diagnosis (2). The goal of the program outlined in this document is to rapidly link people in Shelby County newly diagnosed with HIV to ART initiation on the same day, or within 72 hours of HIV diagnosis.

Purpose of this document

- a. Provide rationale for rapid linkage to HIV care and ART initiation
- b. Serve as a practical guide for rapid linkage program components
- c. Propose evaluation metrics for this rapid linkage program

II. Rationale for rapid linkage to HIV care and ART initiation

The US Department of Health and Human Services (3), World Health Organization (4), and International Antiviral Society-USA (5) all endorse initiation of ART as soon as possible following HIV diagnosis. These recommendations are supported by the START (6) and TEMPRANO (7) trials which both compared early with delayed ART initiation and found that early ART initiation led to significant reductions in morbidity and mortality. Additionally, rapid ART initiation has been shown to be acceptable to both patients and providers (8). Following is a summary of the individual-level benefits of rapid ART initiation:

- Decreased immune activation (9,10)
- Improved CD4+ cell recovery (11)
- Decreased size of HIV reservoir (10,12)
- Decreased HIV and non HIV-related morbidity and mortality (6,13–16)
- Reduced time from HIV diagnosis to linkage to care, ART initiation, viral suppression (8,9,17–20)
- Improved long-term retention in HIV care (8)

There are also <u>population-level benefits</u> to rapid ART initiation. Viral suppression has been shown to be 100% effective at reducing sexual HIV transmission (i.e. **Treatment as Prevention [TasP]**) (21–25) resulting in the **Undetectable=Untransmittable (U=U)** messaging endorsed by the US Centers for Disease Control and Prevention (26).

III. Eligibility Criteria for Rapid ART

This initiative will serve individuals for whom the risk of starting ART without the knowledge of baseline chemistries or resistance testing is assessed to be low.

- a. People newly* diagnosed with HIV:
 - Laboratory-based HIV testing confirmation based on <u>CDC guidelines</u> (27) typically using the <u>4th generation HIV testing algorithm</u> (28); OR

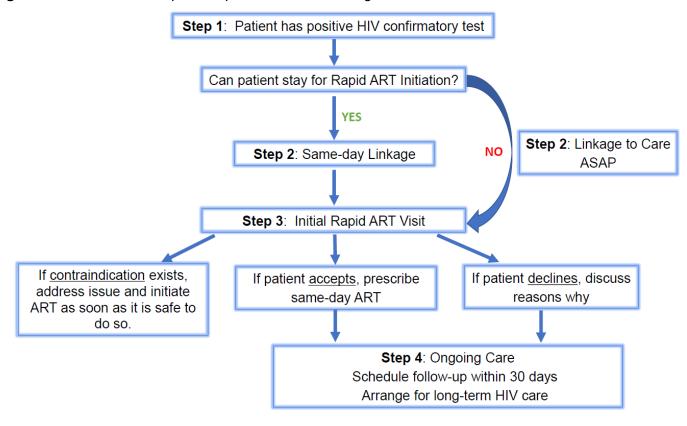
- ii. Two point-of-care rapid FDA-approved HIV tests from different test types or different manufacturers (orthogonal) according to <u>TDH Double Rapid HIV</u> <u>Testing Guidelines</u> (29)
- b. Contraindications include:
 - i. A suspected intracranial opportunistic infection (i.e. TB or cryptococcal meningitis) or cytomegalovirus retinitis based on HIV care provider assessment using <u>US DHHS Guidelines for the Prevention and Treatment of</u> <u>Opportunistic Infections in Adults and Adolescents</u> (30).
 - ii. Patients not willing or ready to start ART

Consideration of expanding to people re-engaging in HIV care will be considered in future protocols.

IV. Operations

A person with a new HIV diagnosis (Section IIIa, above) can proceed through the following steps to achieve the goal of rapid ART initiation.

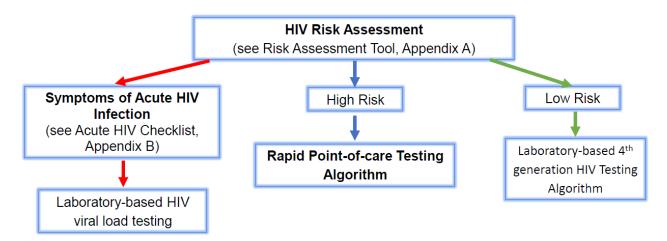
Figure 1. Flow Chart of Steps in Rapid ART Initiation Program



Step 1: Confirmation of HIV Diagnosis (Figure 2)*

- Rapid point-of-care HIV <u>screening</u> will be performed among all clients identified as high risk (See HIV Risk Assessment Tool, Appendix A) with an INSTI® rapid HIV antibody test via finger stick (1 minute). If HIV screening was performed at another facility and the result report is verified, then proceed straight to HIV confirmation if HIV screen was positive.
- 2. Rapid point-of-care HIV <u>confirmation</u> will be performed among all those screening positive by INSTI® with an OraQuick® rapid HIV antibody test via finger stick (20 min).
- 3. Patients with signs or symptoms of acute HIV, regardless of HIV screening or confirmatory results, will have an HIV-1 qualitative RNA testing performed via venipuncture (**See Acute HIV Assessment Tool, Appendix B**).
- 4. Patients with a positive INSTI® screening result and a negative OraQuick® confirmatory result should have blood drawn via venipuncture for 4th generation HIV testing.
- 5. A confirmed HIV diagnosis will be defined as above (Section III.a Eligibility Criteria).
- Results of rapid confirmatory tests should be documented on PH-1600 Reporting Form and reported per the <u>TN Department of Health Double Rapid HIV Testing Guidelines</u> (29). The PH-1600 Reporting Form should be submitted to TDH at https://is.gd/TNReportableDiseases. A copy of this form can be given to the client for their own documentation of test results.
- 7. Laboratory-based 4th generation HIV testing can be performed for clients identified as low risk (**See HIV Risk Assessment Tool, Appendix A**).

Figure 2. Confirmation of HIV Diagnosis



^{*}Persons testing negative for HIV should be informed about PrEP as current <u>CDC PrEP</u> <u>quidelines</u> (31) state that all sexually active adolescents (weighing at least 77 pounds or 35 kilograms) and adults are eligible for PrEP. Please see <u>getpreptn.com</u> or <u>preplocator.org</u> for current PrEP providers in the Memphis, Shelby County area.

Step 2: Linkage of person newly diagnosed with HIV-infection to medical care

- 1. If a patient is not able or willing to complete their initial HIV provider visit (~30 minutes) at the time of their HIV diagnosis, HIV testing staff will:
 - a. Deliver HIV post-test counselling and education per Tennessee Department of Health "HEAT" or similar training (see Section VI. Recommended Trainings)
 - b. Administer a psychosocial assessment (acute mental health issues, housing stability, transportation needs, food insecurity, HIV status disclosure, stigma reduction)
 - c. Discuss partner HIV testing and prevention services
 - d. Determine the patient's insurance status and enroll the patient in Ryan White if eligible (including presumptively).
 - e. Arrange for a "warm handoff" or direct verbal communication of patient contact information between HIV testing and treatment teams.
- 2. If a patient is willing to stay for rapid linkage to care and ART initiation, HIV testing and care staff will arrange for a "warm handoff" of patient physically between teams. Here a "warm handoff" requires HIV testing site staff personnel physically escorting a client to an HIV treatment site or HIV treatment site staff picking a patient up at the HIV testing site and escorting them back to the HIV treatment site.

Table 1. HIV Treatment Site Warm Handoff Contacts*

HIV Treatment Site	Age of Patient	Contact number
Adult Special Care Clinic	≥18 years	Larry Dean
		901-671-5535
		901-545-8125
		ljdean@regionalonehealth.org
Christ Community Health	≥18 years	Angela Sims
Services		901-842-2397
Broad, Hickory Hill, and		angela.sims@christchs.org
Orange Mound Locations		
Christ Community Health	≥18 years	Kineather Barksdale
Services		901-842-1443
Frayser, Raleigh, and Third		kineather.barksdale@christchs.org
Locations		
St. Jude Children's	Everyone ≤17 years	Robin Bell
Research Hospital	18-21 years if	901-857-7783
	preferred by patient	robin.bell@stjude.org

^{*}Any HIV treatment site in Memphis, Shelby County is eligible to participate if they meet SOP requirements and provide a signed Memorandum of Understanding (see Appendix C).

Step 3: Initial Rapid Linkage to Care and ART Initiation Visit

- 1. HIV treatment staff will deliver post-test counselling and education, administer a psychosocial assessment, discuss partner services, determine the patient's insurance status, and enroll the patient in Ryan White if not already completed in Step 2.
- 2. The content and duration of visit will be determined by provider and client preference as well as individual site protocols. At a minimum, the client will see an HIV provider for brief (~30 minute), targeted medical history and physical exam assessment (Table 2, below) to determine eligibility and identify an appropriate rapid ART regimen. The presence of any symptoms consistent with an intracranial opportunistic infection (i.e. TB or cryptococcal meningitis) or cytomegalovirus retinitis are contraindications to rapid ART initiation (see US DHHS Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents) (30).

Table 2. Components of Targeted History during Rapid ART Initiation Visit

HIV History	Medical History
Date of last negative HIV test and prior HIV	Co-morbidities (particularly liver or kidney
tests	disease)
PrEP or PEP use	Medications
Sexual practices and serostatus of partners	Drug allergies
Substance use and Injection drug use	Review of systems (to identify Opportunistic
practices*	Infections, seroconversion, acute mental
	health issues)
	Pregnancy and childbearing plans

*Persons reporting injection drug use should be referred to Syringe Services Programs (SSPs). Please see https://www.tn.gov/health/health-program-areas/std/std/syringe-services-program.html for current SSPs in the Memphis, Shelby County community.

- 3. If there are concerns for opportunistic infection contraindications (see Section III.b. Eligibility Criteria), the patient will undergo evaluation/treatment and return to clinic for ART initiation.
- 4. If there are no concerns for opportunistic infection, then the patient will be counselled on the risks (i.e., immune reconstitution syndrome) and benefits (both individual- and population-level) of rapid ART initiation. The concepts of TasP and U=U, viral load monitoring, and importance of adherence, and therapy goals will also be included (See Section VI Recommended Trainings). Patients will be advised of the importance of close contact with the health system during early months of treatment, and about contacting the clinic immediately with any concerns. Emphasis will be placed on listening to patient concerns and conveying to the patient that they will have additional questions through this process and that the team is happy to address these questions as they arise.
- 5. If the patient <u>declines</u> rapid ART initiation, the provider will discuss reasons for declining and schedule a follow-up appointment within 30 days. If the patient prefers, a follow-up appointment can be made with another HIV treatment provider. HIV treatment providers should arrange for a "warm hand-off" of patient information between teams.

- 6. If the patient <u>agrees</u> to rapid ART initiation, ART will be prescribed and a 30-day follow-up appointment will be made (**See Tables 3 and 4 for rapid ART initiation regimens**):
 - a. If the patient has immediate drug coverage (private insurance, TennCare, Medicare), then a 30-day supply of ART will be prescribed via pharmacy of patient choice.
 - b. If the patient has Ryan White (necessitating drug shipment from Nashville Pharmacy Services in Nashville, Tennessee) or no drug coverage, then 7-to-30-day supply of ART will be dispensed from the on-site sample supply and a prescription for another 30-day supply of ART will be sent to the appropriate pharmacy. The sample supply is intended to cover the period until drug assistance or insurance becomes active. The client will need to provide documentation showing proof of residency and income within 30 days of presumptive Ryan White enrollment or they will be disenrolled. Request for rapid eligibility for Ryan White Part B drug assistance must be approved and tracked by the TDH Ryan White Program. On-site sample medications may be distributed by nurses, clinicians, or pharmacists and do not need to be distributed by a provider with prescribing privileges.
 - c. The patient is encouraged to take their first dose of medication while still in the clinic if feasible.

Table 3. Rapid ART regimens (32)

Preferred Rapid ART regimens

- Dolutegravir 50mg once daily + tenofovir alafenamide (TAF)/emtricitabine (FTC) 1 tablet once daily OR tenofovir disoproxil fumarate (TDF)/FTC OR TDF/lamivudine (3TC) 1 tablet once daily
- Bictegravir/TAF/FTC 1 tablet once daily

Reasonable Rapid ART regimens

- Darunavir/cobicistat/TAF/FTC 1 tablet once daily
- Darunavir 800 mg once daily + ritonavir 100 mg once daily + TAF/FTC (or TDF/FTC or TDF/3TC) 1 tablet once daily

Preferred Rapid ART regimens during pregnancy or for women planning pregnancy

- Dolutegravir 50mg once daily + TDF/FTC 1 tablet once daily
- Raltegravir 400mg twice daily +TDF/FTC 1 tablet once daily

*Dolutegravir had previously been associated with a small increase in risk of neural tube defects in infants born to women taking dolutegravir at conception (33) although more recent data have not supported this association (34). Providers should discuss risks and benefits of dolutegravir and alternative ART and select a regimen through shared decision making. TAF, bictegravir, and elvitegravir/cobicistat/TAF/FTC are not currently recommended in pregnancy.

Table 4. Rapid ART regimens in special circumstances

Preferred Rapid ART regimens for those with recent PrEP or PEP exposure at the time of HIV-infection or since the time of HIV-infection while awaiting genotype results

- Darunavir/cobicistat/TAF/FTC 1 tablet once daily
- Darunavir 800 mg once daily + ritonavir 100 mg once daily + TAF/FTC (or TDF/FTC or TDF/3TC) 1 tablet once daily

The following regimens are contraindicated for rapid ART initiation:

- 2-drug ART regimens, e.g., dolutegravir/rilpivirine, dolutegravir/3TC, boosted darunavir + 3TC, and others (high risk of virologic failure if transmitted resistance is present)
- Abacavir (results of HLA B5701 testing will not be available, and risk of abacavir hypersensitivity reaction in persons with HLA B5701 allele is substantial)
- NNRTIs (efavirenz, rilpivirine, doravirine, etravirine) (results of pretreatment genotype will not be available and likelihood of transmitted NNRTI mutation is high)
- 7. Following receipt of ART, patient will proceed to the laboratory for the following baseline testing:
 - a. Quantitative HIV viral load
 - b. HIV genotype
 - c. CBC with differential and CD4+ cell count
 - d. Comprehensive metabolic panel (including creatinine and liver function tests)
 - e. Syphilis testing, and gonorrhea/chlamydia testing of urine, rectum, and throat (guided by sites of exposure).
 - f. Hepatitis A IgG
 - g. Hepatitis C IgG
 - h. Hepatitis B surface Ag, Hepatitis B surface Ab, Hepatitis B total core Ab
 - i. Pregnancy test (if appropriate)
 - j. Interferon gamma release assay, Toxoplasma IgG, HLA-B5701 genotyping, and G6PD testing may also be considered

Step 4: Follow-up Care

<u>Within 72 hours of Rapid ART Initiation Visit</u>: If feasible, HIV treatment site staff calls the patient to provide psychosocial support, assess for clinical symptoms or side effects, and encourage patient to fill their long-term prescription. Clinical symptoms will be relayed to the provider for follow-up.

<u>Day 30</u>: The patient has a follow-up appointment, ideally with the provider that would see them long-term. At this visit, laboratory results will be reviewed and the provider will assess for clinical symptoms or side effects. ART may be adjusted as appropriate. Routine primary HIV care is scheduled either at current facility or another facility of patient preference. HIV treatment providers should arrange for a "warm hand-off" of patient information between teams.

Ongoing: Access to the case management team is available to provide ongoing support with education and coping with stigma, HIV disclosure, and other psychosocial issues (mental health, substance use, unstable housing, immigration, insurance, food insecurity, transportation, etc.). Appointment reminders via phone call or text will be made and missed appointments will be immediately addressed.

V. Proposed Performance Measures

Assessment and trending of performance measures is important to determine success of the rapid ART program the need for future improvements.

Table 5. Rapid ART Performance Measures

Performance Measure	Goal
Proportion of positive rapid INSTI® HIV screening tests confirmed by a second rapid OraQuick® confirmatory HIV test	90%
Median time from positive HIV screening test to confirmatory HIV testing	1 business day
Proportion of patients newly diagnosed with HIV who complete a same-day HIV provider visit (or as soon as possible within 72 hours)	90%
Median time to linkage to from HIV diagnosis date	3 business days
Proportion of patients newly diagnosed with HIV who initiate same-day ART (or as soon as possible within 72 hours)	90%
Median time to ART initiation from HIV diagnosis date	3 business days
Median time to viral suppression (VL<200) from HIV diagnosis date	120 days
Disparities in the above patient related performance measures based on age, race/ethnicity, gender, insurance status	No differences in above performance measures

VI. Recommended Training for HIV Testing and Treatment Site Staff

Table 6 describes the recommended trainings suggested for HIV testing and treatment site staff providing rapid ART. Staff training should be tracked and reviewed periodically. *HEAT training is REQUIRED for all staff performing HIV testing and Disease Intervention Specialists using test kits provided by the Tennessee Department of Health. All virtual and inperson TDH training information can be found at https://www.seaetc.com/education-training/.

 Table 6. Recommended Trainings

Training Subject	Source	Trainees	Frequency
HIV Education, Access, and Testing (HEAT) Training	TDH	Staff who perform HIV testing and Disease Intervention Specialists	Once*
General HIV Training https://www.hiv.uw.edu/	University of Washington National HIV Curriculum	Healthcare providers (nurses, mid-level providers, physicians) without previous HIV care experience	Once
General Rapid ART Initiation	SEAETC Archived Webinar	All Staff	Once
Motivational Interviewing	SEAETC Archived Webinar	All Staff with direct client contact	Once
U=U/Treatment as Prevention	SEAETC Archived Webinar TDH	All Staff	Once
Unconscious Bias/Cultural Humility https://www.seaetc.com/wp- content/uploads/2021/07/Stigma- Handbook-June-2021.pdf	SEAETC Cultural Humility and Reducing Stigma Discrimination Provider Handbook	All Staff	Annually
End the Syndemic Language Guide https://endthesyndemictn.org/wp- content/uploads/2021/03/ETS- Language-Guidance- 03 15 21.pdf	TDH	All Staff	Annually

Trauma Informed Care	SEAETC Archived Webinar	All Staff	Annually
Early Intervention Services Refresher Course	TDH	Early Intervention Services Staff	Annually

VII. Rapid ART Testing and Treatment Site Communication

Site communication for successful rapid ART programs is essential.

- Website https://endhiv901.org/ will have monthly administrative updates by Memphis Connect To Protect HIV Community Coalition Leadership to ensure up-to-date information regarding community services is available
- Quarterly in-person or virtual meetings will be coordinated by Memphis Connect To Protect HIV Community Coalition Leadership for participating site members to discuss program successes and challenges
- Rapid ART champions for each participating site have been identified and will serve as points of contact for cross-site communication

Site Name	Champion Name	Champion Contact
Adult Special Care Clinic	Nathan Summers	901-448-3291
		nsummer2@uthsc.edu
Christ Community Health	Tanyelle Dunlap	901-842-2394
Services		tanyelle.dunlap@christchs.org
Shelby County Health	Misty Hayes-Winston	901-356-1699
Department		misty.hayes-
		winton@shelbycountytn.gov
Le Bonheur HIV Community	Remera Cage	901-287-4731
Network		remera.cage@lebonheur.org
St. Jude Children's Research	Nehali Patel	901-595-4646
Hospital		nehali.patel@stjude.org

VIII. Stigma Reduction Recommendations

Engagement in evidence-based interventions shown to reduce intersectional stigma related to HIV status, race, and sexual/gender identity. Participation in stigma reduction activities are encouraged among HIV testing and treatment sites participating in Memphis Rapid ART initiation.

- Environmental Change: Snap Out Stigma Clinic Displays (35)
 - o https://snapoutstigma.com/
 - Displays boards of choice available on-loan for limited time periods or as re-prints available for purchase
 - Contact: Latrice Pichon, PhD (<u>lcpichon@memphis.edu</u>)



• Staff trainings when hired and annually (See Section VI. Recommended Trainings)

IX. Acknowledgements

The Shelby County Rapid Linkage to HIV Care and ART Initiation Program Committee (Appendix D) would like to acknowledge the Connect to Protect (C2P) Memphis HIV Community Coalition for the feedback and input on this document. Support was provided by the Tennessee Department of Health and Tennessee Center for AIDS Research (National Institutes Health P30 AI110527) and Centers for Disease Control and Prevention (PS21-002).

X. References

- 1. Ending the HIV Epidemic [Internet]. HIV.gov. [cited 2023 Feb 24]. Available from: https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview
- 2. End HIV 901 [Internet]. 2020 [cited 2023 Feb 24]. Available from: https://endhiv901.org/
- 3. What's New in the Guidelines | NIH [Internet]. 2022 [cited 2023 Feb 24]. Available from: https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/whats-new-guidelines
- 4. Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy [Internet]. [cited 2023 Feb 24]. Available from: https://www.who.int/publications-detail-redirect/9789241550062
- 5. Saag MS, Benson CA, Gandhi RT, Hoy JF, Landovitz RJ, Mugavero MJ, et al. Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults: 2018 Recommendations of the International Antiviral Society-USA Panel. JAMA. 2018 Jul 24;320(4):379–96.
- 6. INSIGHT START Study Group, Lundgren JD, Babiker AG, Gordin F, Emery S, Grund B, et al. Initiation of Antiretroviral Therapy in Early Asymptomatic HIV Infection. N Engl J Med. 2015 Aug 27;373(9):795–807.
- 7. TEMPRANO ANRS 12136 Study Group, Danel C, Moh R, Gabillard D, Badje A, Le Carrou J, et al. A Trial of Early Antiretrovirals and Isoniazid Preventive Therapy in Africa. N Engl J Med. 2015 Aug 27;373(9):808–22.
- 8. Pilcher CD, Ospina-Norvell C, Dasgupta A, Jones D, Hartogensis W, Torres S, et al. The Effect of Same-Day Observed Initiation of Antiretroviral Therapy on HIV Viral Load and Treatment Outcomes in a US Public Health Setting. J Acquir Immune Defic Syndr 1999. 2017 Jan 1;74(1):44–51.
- 9. Lama JR, Ignacio RAB, Alfaro R, Rios J, Cartagena JG, Valdez R, et al. Clinical and Immunologic Outcomes After Immediate or Deferred Antiretroviral Therapy Initiation During Primary Human Immunodeficiency Virus Infection: The Sabes Randomized Clinical Study. Clin Infect Dis Off Publ Infect Dis Soc Am. 2021 Mar 15;72(6):1042–50.
- 10. Jain V, Hartogensis W, Bacchetti P, Hunt PW, Hatano H, Sinclair E, et al. Antiretroviral therapy initiated within 6 months of HIV infection is associated with lower T-cell activation and smaller HIV reservoir size. J Infect Dis. 2013 Oct 15;208(8):1202–11.
- 11. Kelley CF, Kitchen CMR, Hunt PW, Rodriguez B, Hecht FM, Kitahata M, et al. Incomplete peripheral CD4+ cell count restoration in HIV-infected patients receiving long-term antiretroviral treatment. Clin Infect Dis Off Publ Infect Dis Soc Am. 2009 Mar 15;48(6):787–94.
- 12. Ananworanich J, Schuetz A, Vandergeeten C, Sereti I, de Souza M, Rerknimitr R, et al. Impact of multi-targeted antiretroviral treatment on gut T cell depletion and HIV reservoir seeding during acute HIV infection. PloS One. 2012;7(3):e33948.

- 13. Baker JV, Peng G, Rapkin J, Abrams DI, Silverberg MJ, MacArthur RD, et al. CD4+ count and risk of non-AIDS diseases following initial treatment for HIV infection. AIDS Lond Engl. 2008 Apr 23;22(7):841–8.
- 14. Moore DM, Hogg RS, Chan K, Tyndall M, Yip B, Montaner JSG. Disease progression in patients with virological suppression in response to HAART is associated with the degree of immunological response. AIDS Lond Engl. 2006 Feb 14;20(3):371–7.
- 15. Strategies for Management of Antiretroviral Therapy (SMART) Study Group, El-Sadr WM, Lundgren JD, Neaton JD, Gordin F, Abrams D, et al. CD4+ count-guided interruption of antiretroviral treatment. N Engl J Med. 2006 Nov 30;355(22):2283–96.
- 16. Rosen S, Maskew M, Fox MP, Nyoni C, Mongwenyana C, Malete G, et al. Initiating Antiretroviral Therapy for HIV at a Patient's First Clinic Visit: The RapIT Randomized Controlled Trial. PLoS Med. 2016 May;13(5):e1002015.
- 17. Halperin J, Butler I, Conner K, Myers L, Holm P, Bartram L, et al. Linkage and Antiretroviral Therapy Within 72 Hours at a Federally Qualified Health Center in New Orleans. AIDS Patient Care STDs. 2018 Feb;32(2):39–41.
- 18. Hoenigl M, Chaillon A, Moore DJ, Morris SR, Mehta SR, Gianella S, et al. Rapid HIV Viral Load Suppression in those Initiating Antiretroviral Therapy at First Visit after HIV Diagnosis. Sci Rep. 2016 Sep 6;6:32947.
- 19. Colasanti J, Sumitani J, Mehta CC, Zhang Y, Nguyen ML, Del Rio C, et al. Implementation of a Rapid Entry Program Decreases Time to Viral Suppression Among Vulnerable Persons Living With HIV in the Southern United States. Open Forum Infect Dis. 2018 Jun;5(6):ofy104.
- 20. Coffey S, Bacchetti P, Sachdev D, Bacon O, Jones D, Ospina-Norvell C, et al. RAPID antiretroviral therapy: high virologic suppression rates with immediate antiretroviral therapy initiation in a vulnerable urban clinic population. AIDS Lond Engl. 2019 Apr 1;33(5):825–32.
- 21. Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med. 2011 Aug 11;365(6):493–505.
- 22. Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, et al. Antiretroviral Therapy for the Prevention of HIV-1 Transmission. N Engl J Med. 2016 Sep 1;375(9):830–9.
- 23. Bavinton BR, Pinto AN, Phanuphak N, Grinsztejn B, Prestage GP, Zablotska-Manos IB, et al. Viral suppression and HIV transmission in serodiscordant male couples: an international, prospective, observational, cohort study. Lancet HIV. 2018 Aug;5(8):e438–47.
- 24. Rodger AJ, Cambiano V, Bruun T, Vernazza P, Collins S, van Lunzen J, et al. Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy. JAMA. 2016 Jul 12;316(2):171–81.

- 25. Rodger AJ, Cambiano V, Bruun T, Vernazza P, Collins S, Degen O, et al. Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. Lancet Lond Engl. 2019 Jun 15;393(10189):2428–38.
- 26. FAQ Prevention Access Campaign [Internet]. [cited 2023 Feb 24]. Available from: https://preventionaccess.org/faq/
- 27. Centers for Disease Control and Prevention (CDC). Revised surveillance case definition for HIV infection--United States, 2014. MMWR Recomm Rep Morb Mortal Wkly Rep Recomm Rep. 2014 Apr 11;63(RR-03):1–10.
- 28. Centers for Disease Control and Prevention. Quick Reference Guide Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations [Internet]. 2014 Jun [cited 2023 May 15]. Available from: https://www.cdc.gov/hiv/pdf/guidelines_testing_recommendedlabtestingalgorithm.pdf
- 29. Tennessee Department of Health. Double Rapid HIV Testing Guidelines [Internet]. 2019 Oct [cited 2023 May 15]. Available from: https://www.tn.gov/content/dam/tn/health/program-areas/std/TDH-Double-Rapid-HIV-Testing-Guidelines.pdf
- 30. United States Department of Health and Human Services. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents [Internet]. [cited 2023 May 15]. Available from: https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/whats-new?view=full
- 31. Centers for Disease Control and Prevention. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States-2021 Update [Internet]. [cited 2023 May 15]. Available from: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf
- 32. Coffey S, Bacon O. Immediate ART Initiation and Restart: Guide for Clinicians [Internet]. [cited 2023 May 15]. Available from: https://aidsetc.org/sites/default/files/media/document/2023-03/ncrc-rapid-art-full.pdf
- 33. Zash R, Holmes L, Diseko M, Jacobson DL, Brummel S, Mayondi G, et al. Neural-Tube Defects and Antiretroviral Treatment Regimens in Botswana. N Engl J Med. 2019 Aug 29;381(9):827–40.
- 34. R. Zash, L. Holmes, M. Diseko, D. Jacobson, G. Mayondi, A. Isaacson, S. Davey, J. Mabuta, M. Mmalane, T. Gaolathe, S. Lockman, J. Makhema, R. Shapiro. Update on neural tube defects with antiretroviral exposure in the Tsepamo study, Botswana [Internet]. [cited 2023 Feb 24]. Available from: https://programme.aids2020.org/Abstract/Abstract/11299
- 35. Pichon LC, Stubbs AW, Teti M. Snap out stigma photovoice project in the U.S. South. BMC Health Serv Res. 2022 Jun 20;22(1):795.

XI. Appendix A: HIV Risk Assessment Tool (English)

TO PROMPTLY SERVE YOU, YOU MUST COMPLETE ALL QUESTIONS BELOW YOUR PERSONAL AND MEDICAL RECORD INFORMATION HELD IN THIS CLINIC IS STRICTLY CONFIDENTIAL

Please print and fill out complet	tely		C	linic	:#
Appointment time:			Clini	c check	in time:
Name	Date of Birth	//	SSN#:		/
Marital Status (circle one): Single	Married	Divorced	Widowed	Sep	arated
Address	City	S	tate	Zip Co	ode
Home Phone # ()	Cell	Phone () _			
Race (circle one): White Black Asian	American Indian/Al	askan Hawaiian	/Pacific Islande	r Multi	iple Races Other
Ethnicity (circle one): Hispanic	Non-Hispanic				
What sex were you assigned at birth (circle one)? Male	e Fem:	ale Dec	lined to	o answer
What is your current gender identity (circle one)?				
Male Female	Transgender Male	Trans Man/Fo	emale to Mal	e	
Transgender Female/Trans Woman	/Male to Female	Genderq	ueer O	ther	
Person to notify in case of an emerger	ā				
Name	Addr	ress			
Phone ()	Relat	tion to you			
n order to better serve you today, yo rom available services such as testin	our health care pro g for HIV and Sex	vider would lil ually Transmi	ke to assess h tted Diseases	ow you (STDs)	may benefit
	In the PAST 12	MONTHS:			
1. What gender of sex partners have ye	ou had (circle all that	apply)? Men	Women	Transge	ender/Non-binar
2. Have any of your male partners had	sex with other men?	No male sex pa	artners Yes	No	I don't know?
3. Have you injected drugs or had sex	with someone who ha	as injected drugs	? Yes	No	I don't know?
4. Had sex with someone who you kno	ow has HIV?		Yes	No	I don't know?
5. Been treated for gonorrhea, chlamy	dia, or syphilis?		Yes	No	I don't know?
6. Exchanged sex for money, drugs, or	other items/needs?		Yes	No	I don't know?
7. Had sex without a condom with mo	re than one person?		Yes	No	I don't know?

8. Served time in prison or had sex with someone who has spent time in prison?

Yes

No

I don't know?

Appendix B: HIV Risk Assessment Tool (Spanish)

PARA SERVIRLE PRONTAMENTE, COMPLETE TODAS LAS PREGUNTAS SU INFORMACIÓN PERSONAL Y FICHA CLINICA SON ESTRICTAMENTE CONFIDENCIALES

30 INFORMACION LESSONAL I FICHA CLINIC	CA SON ESTRICTAMENTE CONTIDENCIALES
Por favor imprima y complete este formulario	Clínica#

Hora de la cita:	Hora de llegada a la c				
Nombre	Fecha de nacimie	nto/	SSN#:_		/
Estado civil (marque uno): Solte	ro(a) Casado(a)	Divorciado(a)	Viudo(a))	Separado(a)
Dirección	Ciudad	Est	ado (Código po	ostal
Teléfono domicilio # ()		Celular () _	-	-	
Raza (indique uno): Asiático	Blanco Nativo	o-estadounidense o nat	ivo de Alaska	Neg	ro
Nativo de Haw	ái o de las islas del Pacífi	co Varias Razas	s	Otra	
Etnicidad (indique uno): Hispano	o No Hispano				
Sexo asignado al nacer (indique un	o): Hombre	Mujer P	refiero no 1	esponde	r
¿Con cuál género se identifica? (inc	dique uno)				
Hombre Mujer	Hombre tra	ansgénero/Hombre	trans/Muj	er a hom	bre
Mujer transgénero/Mujer trans	s/Hombre a mujer	Queer	Otro		
En caso de emergencia, notificar a Nombre		ión			
El proveedor de salud quisiera durante su visita (por ejem	_				
	En el ÚLTI.	MO AÑO:			
1. ¿Cuál es el género(s) de su(s) pareja			Hombre	Mujer	Transgénero/ No-binario
2. ¿Si su pareja(s) se identifica como h			nes sexuales	con otros	
		n(s) no se identifica mo hombre	Si	No	No sé
3. ¿Usted, o su pareja sexual, se inyect	an drogas?		Si	No	No sé
4. ¿Ha tenido sexo con alguien que ust	ed sabe que tiene VIH?		Si	No	No sé
5. ¿Ha recibido tratamiento para gonor	rea, clamidia o sífilis?		Si	No	No sé
6. ¿Ha intercambiado sexo por dinero,	drogas u otros artículos	/necesidades?	Si	No	No sé
7. ¿Ha tenido sexo sin condón con más	de una persona?		Si	No	No sé
8. ¿Ha estado encarcelado o ha tenido en prisión?	relaciones sexuales con	alguien que estuvo	Si	No	No sé

Appendix C: Acute HIV Checklist

The presence of any one of the following symptoms could indicate acute HIV
infection may indicate the need for HIV viral load testing regardless of HIV screening
or confirmatory test results.

Fevers
Fatigue
Lymphadenopathy or enlarged lymph nodes
Tonsilitis or enlarged tonsils
Sore throat
Arthralgias (joint aches) and myalgias (muscle aches)
Diarrhea
Rash

Source: Centers for Disease Control and Prevention

https://www.cdc.gov/hiv/pdf/prep_gl_patient_factsheet_acute_hiv_infection_english.pdf

Appendix D. Shelby County Health Department Rapid Linkage to HIV Care and ART Initiation Program Committee Members

- Aditya Gaur, St. Jude Children's Research Hospital
- Aimalohi Ahonkhai, Vanderbilt University Medical Center
- Andrea Stubbs, St. Jude Children's Research Hospital
- Angela Sims, Christ Community Health Services
- April Pettit, Vanderbilt University Medical Center
- Audrey VanWylen, Christ Community Health Services
- Benjamin Andrews, Christ Community Health Services
- Bruce Randolph, Shelby County Health Department
- Carla Harvey, Shelby County Health Department
- Carolyn Audet, Vanderbilt University Medical Center
- Cedric Robinson, Shelby County Health Department
- Christina Underhill, Le Bonheur Children's Hospital HIV Community Network
- Courtney Tipper, Shelby County Health Department
- Cristóbal Valdebenito, University of Memphis School of Public Health
- Dana Moore, Le Bonheur Children's Hospital HIV Community Network
- Daniel Thompson, Christ Community Health Services
- Dominick White, Christ Community Health Services
- Erica Williams, Shelby County Health Department
- Jocelyn Meeks, Le Bonheur Children's Hospital HIV Community Network
- Kandis Scurlock, Shelby County Health Department
- Kathy Esposito, Le Bonheur Children's Hospital HIV Community Network
- Kimberly Truss, Tennessee Department of Health
- Kineather Barksdale, Christ Community Health Services
- Larry Dean, Regional One Adult Special Care Clinic
- Latrice Pichon, University of Memphis School of Public Health
- Lesa Williamson, Christ Community Health Services
- Lela Gregory, Tennessee Department of Health
- Lorrie Brooks, Shelby County Health Department
- Maretta Cox, Regional One Adult Special Care Clinic
- McCaa Russum, Christ Community Health Services
- Melissa Wright, Regional One Adult Special Care Clinic
- Melody Evans, Shelby County Health Department
- Meredith Brantley, Tennessee Department of Health
- Misty Hayes-Winston, Shelby County Health Department
- Nathan Summers, Regional One Adult Special Care Clinic
- Nehali Patel, St. Jude Children's Research Hospital
- Pamela Talley, Tennessee Department of Health
- Peter Rebeiro, Vanderbilt University Medical Center
- Phyllis Phillips, Shelby County Health Department
- Remera Cage, Le Bonheur Children's Hospital HIV Community Network
- Robertson Nash, Tennessee Department of Health
- Robin Bell, St. Jude Children's Research Hospital
- Sharron Moore-Edwards, Regional One Adult Special Care Clinic
- Shaunda Bonner, Shelby County Health Department
- Sherry Cohen, Shelby County Health Department

- Shunsetha Alexander, Shelby County Health Department
- Susan Steppe, Le Bonheur Children's Hospital HIV Community Network
- Talechia Swims, Le Bonheur Children's Hospital HIV Community Network
- Tamara Crutcher, Shelby County Health Department
- Tanyelle Dunlap, Christ Community Health Services
- Tereva McGee, Le Bonheur Children's Hospital HIV Community Network
- Veronyca Washington, Shelby County Health Department