THE EFFI BARRY
TRAINING INSTITUTE

RAPID ART:

OVERVIEW, IMPLEMENTATION & BEST PRACTICES

DC | HEALTH
GOVERNMENT OF THE DISTRICT OF COLUMBIA

HealthHIV

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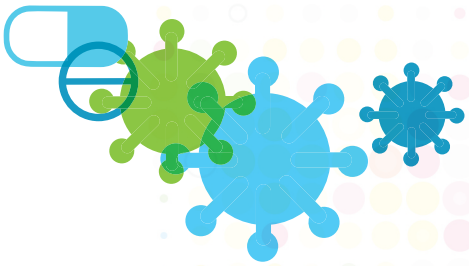
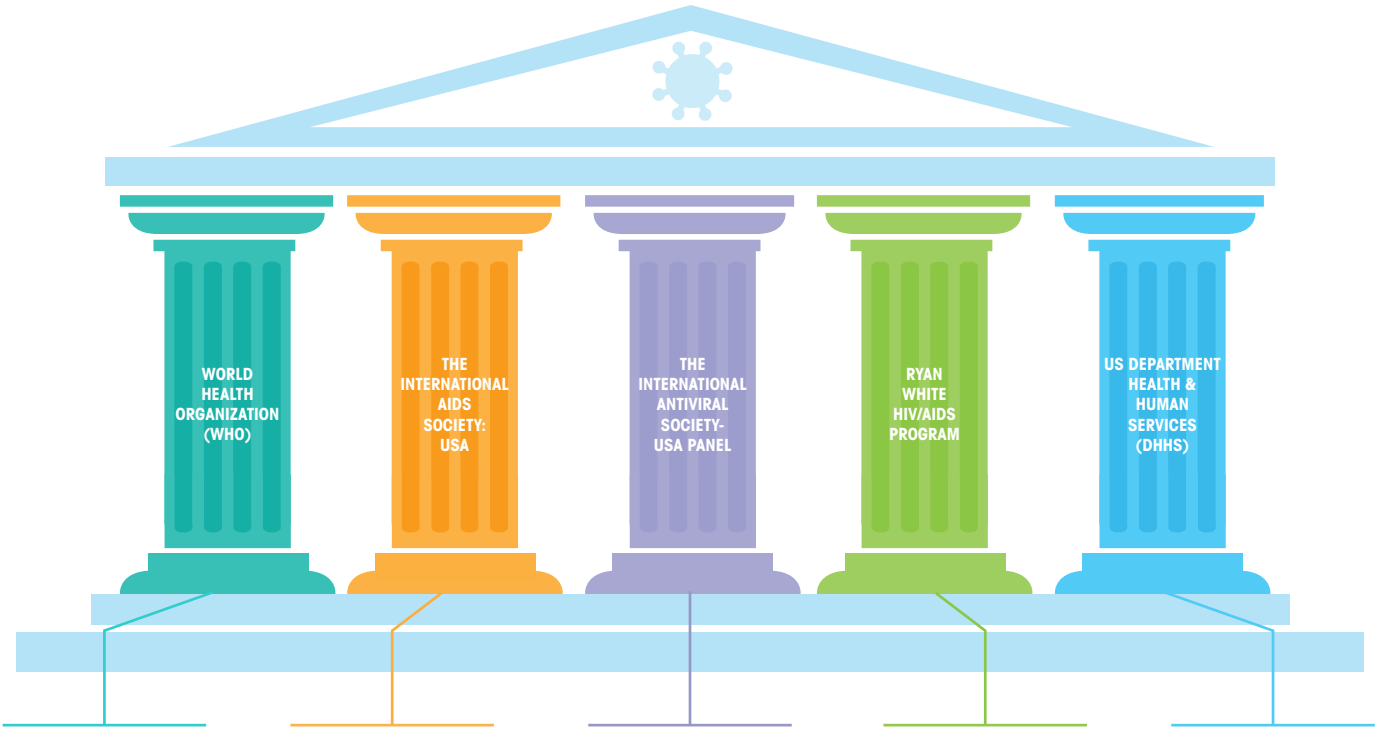


OVERVIEW OF RAPID ART

Attention has been focused over the last five years on how quickly antiretroviral therapy (ART) should be started once an HIV diagnosis has been confirmed. Since 2016, a number of randomized and non-randomized trials have shown rapid ART initiation and same-day start to improve time to viral suppression, reduce loss to care, and maintain adherence over time. Rapid ART initiation has been defined as from same day diagnosis and initiation to up to 2 weeks from day of diagnosis initiation. There is however, consensus on the offering of rapid ART initiation to all people living with HIV following a confirmed diagnosis and clinical assessment (recommendations follow). It's agreed that ART initiation should be offered on the day of initial diagnosis to people who are ready to start. There are barriers to implementation including the need for additional funding for dedicated staff and the formation of a multidisciplinary team to implementation and sustain such programs.

This rapid ART Implementation Toolkit has been created to:

EVIDENCE REVIEW: RECOMMENDATIONS FROM LEADING NATIONAL & INTERNATIONAL ORGANIZATIONS



The WHO strongly recommends that rapid ART initiation should be offered to people with HIV following confirmed diagnosis and clinical assessment. Rapid initiation of ART is defined as within seven (7) days of HIV diagnosis. The WHO further strongly recommends ART initiation on the same day as HIV diagnosis based on the person's willingness and readiness to start ART immediately, unless there are clinical reasons to delay. Both recommendations apply to all populations and age groups. People with advanced HIV disease should be given priority for clinical assessment and treatment initiation.[1]

As of October 16, 2018, The International AIDS Society-USA (IAS-USA) **recommends "rapid" or immediate start of ART upon diagnosis of HIV**. 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.[2]

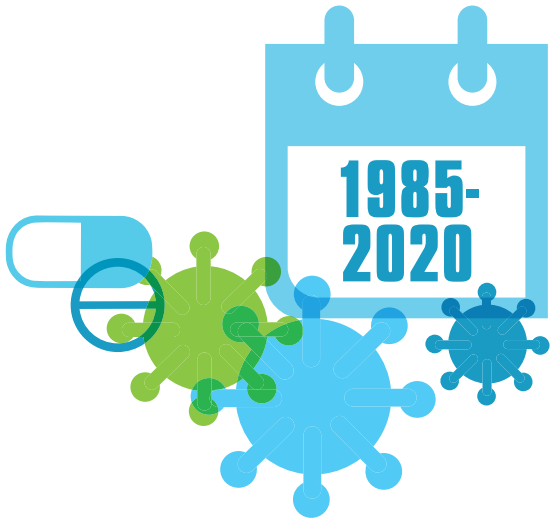
The International Antiviral Society – USA Panel 2018 recommendations state that ART should be initiated as soon as possible after diagnosis, including immediately after diagnosis, unless patient is not ready to commit to starting therapy (evidence rating A1a). Structural barriers that delay receipt of ART should be removed to allow newly diagnosed persons to receive ART at the first clinic visit after diagnosis, if they and their clinician determine that this approach is appropriate (evidence rating A1a).[3] The question of when to start ART is focused now on whether immediate ART (same day up to 14-days after diagnosis) is preferred.[4]

Making rapid start of ART the expectation for HIV health care systems is an urgent priority. Starting people with HIV on ART the same day that they are diagnosed has been shown to decrease the time to viral suppression and may also improve retention in care. Numerous financial and other challenges mean that most US clinics, health systems, and insurance programs do not currently have the capacity to offer rapid start to all newly diagnosed people or to all people who are being re-engaged in HIV care. The Ryan White Program is a federal program that provides a comprehensive system of care for people living with HIV. Is is uniquely situated to work with clinicians, health departments, and community stakeholders to overcome barriers to widespread adoption of rapid start of ART and ensure that they have the resources and the tools to make rapid start of ART (within 7 days of diagnosis) a reality.[5]

The DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents as of December 2019 states the following:
1) ART is recommended for all persons with HIV to reduce morbidity and mortality **(AI)** and to prevent the transmission of HIV to others **(AI)**;
2) the Panel recommends initiating ART immediately (or as soon as possible) after HIV diagnosis in order to increase the uptake of ART and linkage to care, decrease the time to viral suppression for individual patients, and improve the rate of virologic suppression among persons with HIV **(AII)**; and
3) when initiating ART, it is important to educate patients regarding the benefits of ART and to deploy strategies to optimize care engagement and treatment adherence **(AIII)**.[6] The AII and AIII ratings are interpreted to mean ART initiation on day of diagnosis, "remains investigational."[7] (See Evidence Rating Definitions.)

HIV & THE HISTORY OF ART

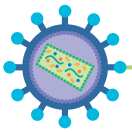
In the 1980's, the average life expectancy following an AIDS diagnosis was about one year. Today with combination drug treatment or ART started early in the course of infection, people with HIV can expect to live a near-normal lifespan. Since the first effective combination ARTs were created in 1996, treatment guidelines have fluctuated between starting early and starting late. Early on, it was thought to, "Hit hard, hit early," and start treatment right away.[9] Later, as the problems of adherence to difficult treatment regimens and subsequent viral drug resistance occurred, it was decided that ART should be delayed as long as possible in order to preserve its benefits. Given the toxicity and accompanying side effects of the original ARTs, some providers thought better to wait for treatment start until CD4 cell counts went below normal, thinking if the individual was stable with a normal CD4 count there was no reason to treat. Since then it's been discovered that the earlier treatment is started and the virus suppressed, the better the individuals do. Viral suppression is the key to Treatment as Prevention (TasP), reducing or stopping immune system inflammation, and preventing the occurrence of both AIDS and non-AIDS related morbidity and mortality. ART has come a long way since combination treatment began in 1996. Today, there are over 30 antiretroviral drugs available including several fixed dose combinations, which contain two or more medications from one or more drug classes in a single tablet. For many people this means only taking one pill a day. As a result of this success, engagement in care and starting treatment as soon as possible has become the standard of care. Rapid ART same-day initiation takes this idea to its logical conclusion, where individuals are connected and engaged in a supportive network of care, are started on ART within 7 days of their diagnosis (preferably same-day), and are virally suppressed and retained in care.



HIV & THE HISTORY OF ART

FDA Approval of HIV Medicines

1981



First AIDS cases are reported in the United States.

1985-1989

1987
Zidovudine (NRTI)

1990-1994

1991
Didanosine (NRTI)

1992
Zalcitabine (NRTI)

1994
Stavudine (NRTI)

1995-1999

1995
Lamivudine (NRTI)
Saquinavir (PI)

1996
Indinavir (PI)
Nevirapine (NNRTI)
Ritonavir (PI)

1997
Combivir (FDC)
Delavirdine (NNRTI)
Nelfinavir (PI)

1998
Abacavir (NRTI)
Efavirenz (NNRTI)

1999
Amprenavir (PI)

2000-2004

2000
Didanosine EC (NRTI)
Kaletra (FDC)
Trizivir (FDC)

2001
Tenofovir DF (NRTI)

2003
Atazanavir (PI)
Emtricitabine (NRTI)
Enfuvirtide (FI)
Fosamprenavir (PI)

2003
Epzicom (FDC)
Truvada (FDC)

2005-2009

2005
Tipranavir (PI)

2006
Atripla (FDC)
Darunavir (PI)

2006
Maraviroc (CA)
Raltegravir (INSTI)

2008
Etravirine (NNTRI)

2010-2014

2011
Complera (FDC)
Nevirapine (NNRTI)
Rilprivirine (NNRTI)

2012
Stribild (FDC)

2013
Dolutegravir (INSTI)

2014
Cobicistat (PE)

2015-2019

2015
Evotaz (FDC)
Genvoya (FDC)
Prezcobix (FDC)

2016
Descovy(FDC)
Odefsey (FDC)

2017
Juluca (FDC)

2018
Biktarvy (FDC)
Cimduo (FDC)
Delstrigo (FDC)
Doravirine (NNRTI)
Ibalizumab-uiyk (PAI)
Symfi (FDC)
Symfi Lo (FDC)
Symtuza (FDC)
Temixys (FDC)

2019
Dovato (FDC)

BASIC COMPONENTS OF THE INTERVENTION

Details of programs may vary depending on whether a program is clinic-based, hospital-based, works with a network of collaborative testing units or does testing off-site or on-site, has state expanded Medicaid or not, but the following are common elements to keep in mind:

Identify Rapid ART Candidates

After testing positive, all people should be considered eligible for the initiation of rapid ART if resources exist to do so. People with advanced HIV disease should be given priority for assessment and rapid ART initiation. ART contraindications would be covered by the clinician at the same-day medical visit.

Same-day Access to an HIV Care Provider

Individuals should have access to an appointment with an on-call HIV care physician or nurse practitioner. Requiring open slots in clinician templates works for walk-in sites and on-site testing locations.

- Off-Site Testing Network: Transportation via cab or car service from testing site to clinic.
- On-Site Testing Unit: Warm handoff to medical staff.

Counseling and Education

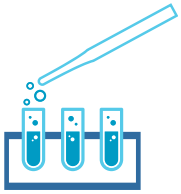
As part of the same-day 2-3 hour medical visit, counseling and education should be provided on HIV infection, risk reduction, sexual health, and the benefits of ART. People presenting for the first time or returning to care should undergo history and clinical examination to evaluate for significant opportunistic infections (such as signs and symptoms of TB and signs and symptoms suggesting meningitis) before rapid ART initiation is offered. An assessment of these contraindications for ART is made and the patient accepts or declines treatment.

Insurance Approval – Payment Assistance

Develop systems to provide for emergency drug assistance to help with paperwork and assure prioritization of pending applications.

Baseline Lab Testing

Although all patients with a reactive HIV test result should undergo baseline laboratory testing, it is not necessary to receive test results before initiating ART. The following checklist is from New York State Department of Health (NYSDOH):[11]



- HIV-1/2 antigen/antibody assay
- HIV quantitative viral load
- Baseline HIV genotypic resistance profile
- Baseline CD4 cell count
- Testing for Hepatitis A, B, and C viruses
- Comprehensive metabolic panel (creatinine clearance, hepatic profile)
- Sexually transmitted infection (STI) screening; see your local DOH, STI Care Guidelines
- Urinalysis
- Pregnancy test for individuals of childbearing potential.

BASIC COMPONENTS OF THE INTERVENTION

Pre-approved ART Regimens

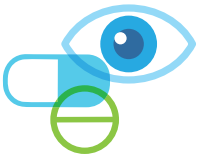
These are regimens that do not require genotype or baseline lab testing to begin and which take into account genotype prevalence in the region and resistance patterns. The preferred medications for rapid ART initiation are based on the established regimens for individuals who are ART- naive and are restricted to those that can be safely initiated in the absence of readily available baseline laboratory testing results. The preferred regimens have a high barrier to resistance, are well tolerated, and limit the potential for drug-drug interactions.[12] Initial regimens should be selected on the basis of patient preferences and clinical characteristics. See 5 Model Rapid ART Program links for sample Pre-approved, Preferred and Alternative Regimens.

Initiate ART Same-day

If the individual doesn't have to come back to get their medication, there is one less chance that they fall through the cracks and get lost to care.

5, 7, or 30-Day ART Starter Packs

The ART prescription is sent to the pharmacy and starter packs are made available as needed. Both the 5-day and the 30-day have proven to be effective, but most programs use a 30-day pack to give enough time for insurance approval or payment assistance to go through.



Directly Observed Administration of First Dose

Individuals accepting ART are offered the first dose at the clinic with the provider in the room for support.

24-48 Hour Phone Follow-up

Nurses contact patients with 48 hours to review lab results, ask about adherence, address pharmacy or side effects, and efforts are made to get the patient back into the clinic within 1-2 weeks.

Adjust ART Regimen Based on Lab Results[13]

If possible, follow up by telelphone with any patient who has initiated ART to assess medication adherence and tolerance within 24-48 hours. Once laboratory test results are available, ART should be discontinued if an HIV diagnosis is not confirmed. In this case, the patient may be assessed or referred for PrEP if there is ongoing risk of HIV exposure. If the HIV diagnosis is confirmed, the ART regimen may be adjusted if necessary. Further adjustments may be required if major resistance mutations are found that will compromise the effectiveness of the initial regimen. Arrangements should be made for a viral load test 4 weeks after ART initiation to assess adherence and troubleshoot any problems with maintaining treatment.

1-2 Week In-person Follow-up Appointment

Based on need and circumstances, set up in-person follow up within 1-2 weeks.

BEST PRACTICES FROM HRSA RYAN WHITE GLOBAL HIV/AIDS PROGRAMS[14]

DEVELOP

a Referral System

Have an efficient and reliable system in place to receive referrals from HIV-testing sites and other community sites to link people who have a new HIV diagnosis to care, or to reengage those previously lost to care. People with advanced HIV disease should be given priority for assessment and initiation.

USE

an HIV Care Manager or Linkage Coordinator

A navigator or linkage coordinator can serve as a single point of contact to facilitate the process. A peer navigator can also be helpful with insurance paperwork, accompaniment, and education.

CREATE

a multidisciplinary team to see the client on a same-day basis, if possible

Goals of the initial appointment should include medical evaluation, insurance enrollment or optimization, emotional support counseling, initial HIV education, baseline laboratory tests, and initiation of ART with starter packs when available.

ENSURE

follow-up care

A telephone check-in two to three days after the initial appointment and a follow-up appointment one to two weeks later help ensure that the individual is continuing ART. Follow-up care offers the opportunity to continue education and support.

ENGAGE

patients through high-intensity support

Provide intensive patient services and support to engage and reengage people with HIV, such as case management, counseling, mental health services, substance misuse treatment, and education on the importance of remaining in care; offer strategies to address multiple needs, such as transportation and housing assistance.

FIVE MODEL RAPID ART PROGRAMS

The following flow-charts represent simplified program steps for five active rapid and same-day ART initiation programs: San Francisco, New York City, Washington, DC, Atlanta and New Orleans.

Ward 86 RAPID (Rapid ART Program for Individuals with an HIV Diagnosis), UCSF, San Francisco, CA

In 2013, San Francisco's RAPID began as a pilot to address diagnosis of acute HIV infection and provide same-day initiation of ART. The concept is that viral suppression is not sufficient to restore immunologic health. Initiating ART during acute/early infection may improve CD4+ T cell recovery and decrease the overall size of the HIV reservoir.

In the pilot, Ward 86 clinic within the Zuckerberg San Francisco General Hospital would be notified by pager of a new HIV diagnosis. Patients came directly from the testing site to Ward 86, and were met by an on-call RAPID provider. Medical history, baseline labs, and counseling were followed by ART initiation, unless clearly contraindicated. A 5-day starter pack was given, with the care provider directly observing the first dose, and scheduling an up to a 7-day follow up appointment. The initial provider the patient worked with became the long term provider for that patient.

THREE IMPORTANT RESULTS FROM THEIR 2013-2016 STUDY OF RAPID INCLUDE:

1. Time from HIV diagnosis to first HIV care visit decreased from 8 days to 5 days
2. Time from first HIV care visit to ART initiation decreased from 27 days to 1 day
3. Time from HIV diagnosis to HIV suppression to <200 copies/mL decreased from 134 days to 61 days

FIVE MODEL RAPID ART PROGRAMS

JumpstART in Sexual Health Clinics, New York, NY

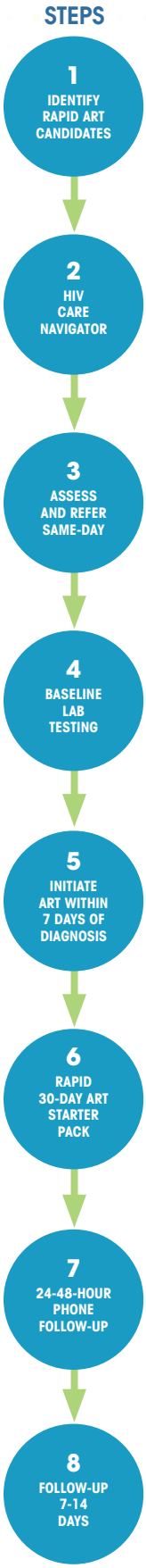
Since 2016, New York City's Health Department's Sexual Health Clinics JumpstART have expanded to 8 clinics. The New York State Department of Health AIDS Institute (NYSDOH AI) and New York City Department of Health and Mental Hygiene (NYC DOHMH) have made the initiation of ART on the same day that an individual has a reactive result on an HIV screening test, or is diagnosed with HIV, or on the first clinic visit the recommended standard of care for HIV treatment in New York. STD Clinics—renamed Sexual Health Clinics—were chosen because of their ability to attract persons at highest risk who may face obstacles to accessing needed services elsewhere; easy access for all through 8 locations in high incidence neighborhoods; and existing STI services that dovetail with new biomedical interventions.

KEY CHARACTERISTICS

Key characteristics of the program include expanded access (walk-ins, evenings, services rendered without regard for ability to pay, no documentation needed, and ages 12 and up with no parental notification); a multidisciplinary team including a navigator, medical provider and social worker; and recognition that JumpstART requires in-depth counseling and time including:

1. Medical Provider: 1-2 hours
2. Patient Navigator: 1-2 hours plus follow-up
3. Patient total clinic time: 3-4 hours

Most patients prescribed a regimen of Descovy and Tivicay unless contraindications.[19, 20, 21]



FIVE MODEL RAPID ART PROGRAMS

DC Health Rapid ART (DCHRA) Programs, Washington, DC

Begun in 2019 at the DC Health and Wellness Center's STD Clinic, and funded by HAHSTA (HIV/AIDS, Hepatitis, STD and TB Administration), DCHRA's aim is to start patients on ART within 7 days of diagnosis, and achieve viral suppression within 60 days.

KEY CHARACTERISTICS

Key characteristics in this developing program include:

1. 30 day starter packs before client leaves the clinic
2. Community partners
3. Updated criteria for receiving care through Ryan White HIV/AIDS Program (RWHAP) so that rapid ART can begin before eligibility has been documented (ie: a grace period)[22, 23]

FIVE MODEL RAPID ART PROGRAMS

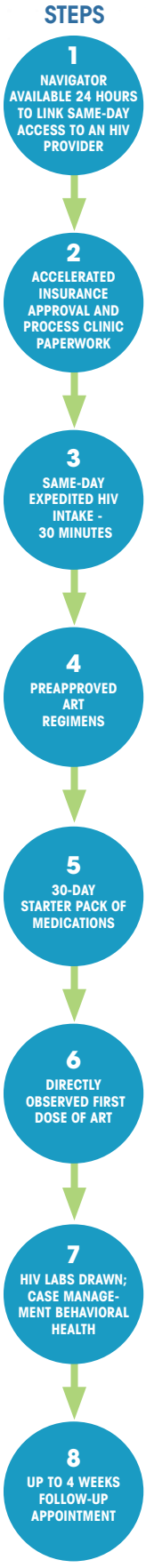
Rapid Entry and ART in Clinic for HIV (REACH), Atlanta, GA

Begun in May 2016, the Infectious Diseases Program of the Grady Health System—the largest HIV care provider in Georgia—launched a program entitled Rapid Entry and ART in Clinic for HIV (REACH). REACH aimed to improve and quicken access to ART by removing institutional barriers for their majority walk-in or ambulatory, un- or underinsured population. Their goal was ART initiation within 72 hours. Streamlining was successful decreasing time to first attended provider visit (17 to 5 days), time to viral suppression (77 tot 57), and time to ART Initiation (21 to 7 days).[24] Georgia does not have expanded Medicaid and Grady is a hospital-based system. When funding ran out there were problems sustaining the resource intensive program.

KEY CHARACTERISTICS

Key characteristics addressed specific points where patients in the past could be turned away. These included:

1. Removal of eligibility and administrative requirements with a 30 day grace period on required but missing documents
2. Required open slots on provider template for walk-ins and up to 72 hours scheduling accommodation
3. Buy-in at multiple levels to change decades of built up policies and practices[25, 26]



FIVE MODEL RAPID ART PROGRAMS

Crescent Care Start Initiative (CCSI), New Orleans, LA

Begun on December 1, 2016, the Federally Qualified Health Center (FQHC) CrescentCare in New Orleans partnered with the New Orleans Department of Health to begin an all new Rapid ART program called CrescentCare Start Initiative (CCSI). CCSI aimed to start all newly diagnosed HIV positive patients on ART within 72 hours of diagnosis. Since beginning the program more that half of all tested patients have consistently been started on ART within 24 hours of diagnosis.[27]

KEY CHARACTERISTICS

Key characteristics of implementation plan included:

1. CCSI leveraging their existing testing sites, their STD clinic, and the clinic's referral network
2. A navigator being made available 24 hours a day to coordinate new diagnosis procedures and conduct warm in-house hand-offs
3. A streamlined intake process was streamlined on HIV
4. First dose of therapy directly observed
5. Use of newer medications with less history of resistance to minimize the chance of treatment failure[28]

BENEFITS TO INTERVENTION

The evidence is strong and clear in 2020 to recommend early initiation of ART - on the same day as diagnosis if possible, or a maximum of up to 7 days from diagnosis - as the standard of care. The measurable goals of treatment include:

1. Viral suppression as measured by HIV-1 RNA level below the limits of detection;
2. Immune reconstitution as measured by an increase in or maintenance of the CD4 cell count; and
3. Reduction in HIV-associated complications, including AIDS- and non–AIDS-related conditions. These are all addressed in the benefits listed below:

- The individual with HIV benefits from reduced **morbidity and mortality (illness and death)**[29,30]
    - In resource-rich settings, life expectancy of patients with HIV infection with access to early ART is approaching that of the general population.[31] A number of randomized clinical trials have demonstrated the benefits of ART in reducing HIV-related morbidity and mortality, irrespective of the degree of immune suppression at treatment initiation.[32] Therefore ART should be recommended to all individuals with HIV infection
- Reduce the **risk of transmission** to others
    - Antiretroviral treatment as prevention (TasP) is associated with greater reductions in HIV transmission than any preventive modality to date[33]
- The earlier the individual starts ART the **less complications of comorbidities** AIDS and non-AIDS specific[34]
- Reduce **community viral load**
- Improve **immune system recovery** as measured by increase in CD4 T cell counts
- Reduce the size of the person's **HIV reservoir**
- Reduce **treatment delays**
- Improve **retention in care**
- Improve **viral suppression** at 12 months
- **Patient is empowered** to fight the virus day 1 by taking medication before leaving, knowing it's in their own hands to help themselves
- **Patient makes a strong connection** to and engagement with the Rapid ART initiation multidisciplinary team on-site
- **An equity issue** is addressed with young Black men who many times are not offered first line medications. Rapid ART by definition offers the best combination therapy as a starting regimen

BARRIERS TO IMPLEMENTATION

- **Rapid ART initiation takes a lot of resources to work effectively.** It also effectively requires change in the way most organizations do testing and treatment. But in order to achieve treatment goals, providers have to extend themselves more to access those who are harder to reach..

- **Before the intervention, patients with an HIV diagnosis had to wait 4 to 5 weeks before starting ART.** There are several reasons for the delay. First, it can take up to 2 weeks or more to **sort out patients' insurance**, which is often provided through the Ryan White HIV/AIDS program. Second, providers frequently choose to postpone treatment until they **know the status of their kidney and liver functions and their CD4 cell counts. HIV drug-resistance testing** is also recommended for patients with HIV before selecting an ART regimen, tacking on even more time. Finally, the price of the medication and whether payers will even cover the expense is yet another challenge.

- There has to be **buy-in at multiple levels** (funders, local health systems, clinic administration, and clinic staff, including pharmacists and nurses). Staff needs to understand the intervention along with its benefits and challenges. Staff non-readiness for implementation can be a factor to address.

- **Reluctance of providers to prescribe** ART with minimal laboratory data. Providers have to be shown the data on success in addition to being given an explanation of the checks in place. For example, a phone check-in no longer than 24-48 hours post clinic visit and a face to face appointment no longer than 7 days post initiation of ART.

- **Scheduling** and provider availability. Rigid and packed schedules make flexibility to address same-day needs bureaucratically challenging. Dealing with walk-ins is particularly challenging because if they can't get a same-day appointment, many times they are lost to care.

- **Lack of transportation** to medical appointments or pharmacies. Cabs and car services are effective but expensive.

BARRIERS TO IMPLEMENTATION

- **Unstable housing** is a healthcare issue. It is a responsivity issue in that housing may be a bigger priority for a client than treatment. These issues can be worked on together.

- Untreated or undertreated **substance use and/or mental disorders** are two more responsivity needs that need to be addressed in tandem in order to effectively begin treatment.

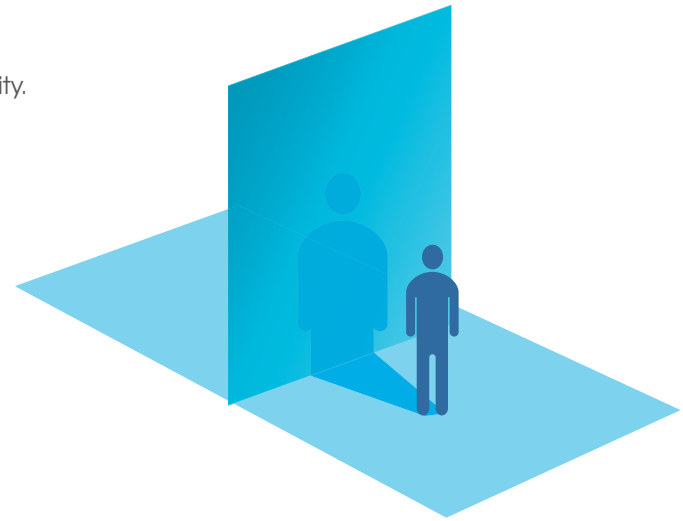
- **Institutional barriers** such as cumbersome entry criteria and limited appointment availability need to be considered. The Atlanta program addressed long standing bureaucracy with the help of a peer navigator to fill out paperwork, and keeping provider templates with open slots for walk-ins. A community advisory board, existing patients and providers may be able to provide solution based suggestions.

- **Insurance and who pays for it?** Finding insurance coverage answers can be time consuming. Getting 30-day starter packs of ART gives the provider and the client time to figure it out.

- **Provider disbelief** in patient readiness.

- **Coverage** of on call status of clinicians/prescribers.

- **Drug procurement** and sustainability.



AN IMPLEMENTATION MODEL

The Practical, Robust Implementation and Sustainability Model **(PRISM)** Framework (see Model Page 19) was developed to provide a practical, actionable model that could be used by both practitioners and researchers to plan and guide interventions, implementation strategies, adaptations, and factors related to sustainability. The following is a sample approach to planning a Rapid ART pilot program at your site.

1. CREATE a multidisciplinary stakeholder workgroup (patient, leadership, managers, and staff) to plan the intervention. The workgroup should conduct focus groups and/or individual interviews with stakeholders to assess the intervention at the different PRISM domain levels. Examples of Organizational Characteristics questions and Patient Perspective questions are listed below to identify the current barriers and facilitators for the intervention and the recipients.

2. PLANNING PHASE:

PRISM DOMAIN: INTERVENTION

Organizational Characteristics Questions

a. What barriers to Rapid ART initiation exist at your facility?
b. Are there any specific personnel (roles) at your site that are needed to support the running of a Rapid ART program?
c. Tell me about your experience with similar interventions?
d. How do you think Rapid ART program would best fit into your current workflow? What would be ideal?

Patient Perspective Questions

a. What suggestions would you have to help build a Rapid ART program here?

PRISM DOMAIN: RECIPIENTS

Organizational Characteristics Questions

a. Tell me about current patient linkage to care services with ART?
b. How much support does Rapid ART have from key managers, leaders, staff, testing and or clinical partners?
c. How do you think Rapid ART will affect your job responsibilities and workload?

Patient Perspective Questions

a. What are patient demographics?
b. Who are we not reaching?
c. Who is falling through the cracks and at what point(s)?

PRISM DOMAIN: IMPLEMENTATION & SUSTAINABILITY INFRASTRUCTURE

Organizational Characteristics Questions

1. What resources (personnel, system-wide, or others) need to be in place for Rapid ART to occur?
2. (Post implementation) Was there any information you wish you had prior to starting your RADID ART Program?

3. SAMPLE ORGANIZATIONAL ASSESSMENT OF READINESS FOR CHANGE TEMPLATE:

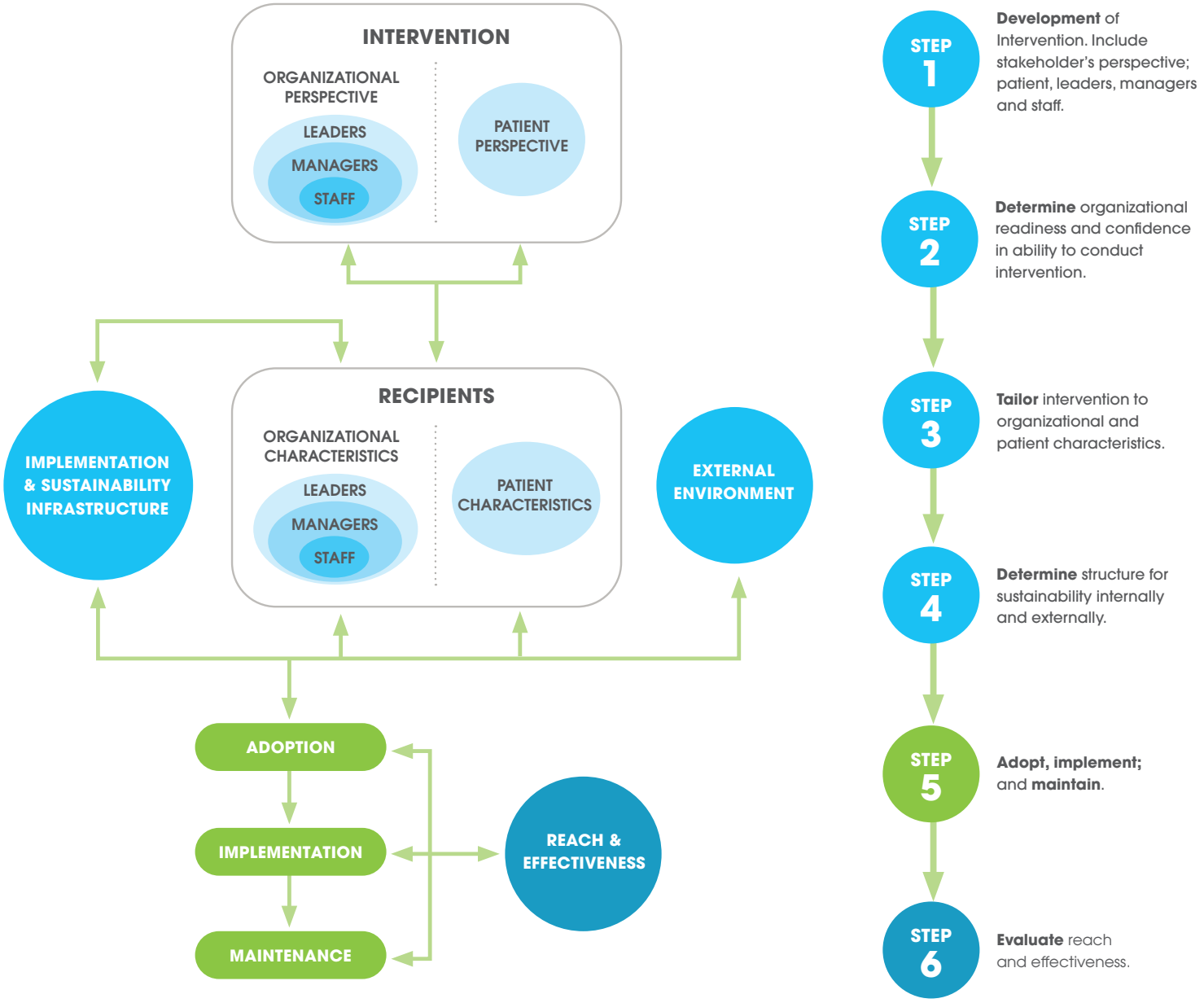
TCU (Texas Christian University) ORC-SA (Organizational Readiness for Change – Social Agency staff version)
http://ibr.tcu.edu/wp-content/uploads/2013/10/ORC-SA.pdf[37]

4. CLIENT SURVEY ON RAPID ART:

UNAIDS/WHO 2015 Reference:
https://www.unaids.org/sites/default/files/media_asset/JC2763_PopulationBasedSurveys_en.pdf

AN IMPLEMENTATION MODEL

THE PRACTICAL, ROBUST IMPLEMENTATION & SUSTAINABILITY MODEL (PRISM)



ADDITIONAL RESOURCES

Scientific articles on Rapid ART implementation and evaluation

a. Geng EH, Havlir DV (2017) The science of rapid start—From the when to the how of antiretroviral initiation. PLoS Med 14(7): e1002358. https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002358

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e. Ward 86. https://hividgm.ucsf.edu/hiv-primary-care-clinic.

Links to educational Videos targeted to clinicians but accessible to implementers

a. VideosSan Francisco & New Orleans: https://www.clinicaloptions.com/hiv/programs/rapid-art-initiation/video-module/rapid-art-video

b. Videos and Slide Sets: Atlanta: https://www.clinicaloptions.com/hiv/programs/rapid-art-initiation/clinicalthought

Washington DC HAHSTA and Ryan White Program resources

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DEFINITIONS AND IMPORTANT TERMS*

*Glossary adapted from **AIDSinfo Glossary of HIV/AIDS-Related Terms, 2018, 9th Edition, HHS NLM & NIH** with additional sources cited.

Adherence	Taking medications (or other treatment) exactly as instructed by a health care provider. In other words, taking the **correct** medication, **when** instructed to take it, **how** it's prescribed and in the **manner** prescribed. The benefits of strict adherence to an HIV regimen include sustained viral suppression, reduced risk of drug resistance, improved overall health and quality of life, and decreased risk of HIV transmission. Benefits of adherence to ART include: 
Adverse Drug Reaction or Event	An undesirable or unwanted experience associated with the use of a drug or other medical product. Examples include resistance to a drug or a bad side effect.
AIDS Drug Assistance Programs (ADAPs)	Federally funded programs that provide medications and other HIV-related services to low-income, uninsured, and underinsured people with HIV/AIDS. Services of AIDS Drug Assistance Programs (ADAPs) are available in all 50 states and U.S. territories.
AIDS Education and Training Centers (AETCs)	Regional centers that conduct education and training programs for health care providers who treat people living with HIV/AIDS. Training is targeted at providers who serve minority populations, the homeless, rural communities, prisoners, community and migrant health centers, and Ryan White HIV/AIDS Program-funded sites. AIDS Education and Training Centers (AETCs) serve all 50 states and many U.S. territories. https://aidsetc.org/
AIDSinfo	The federal website offering HIV/AIDS medical practice guidelines and information on HIV-related clinical trials and drugs for health care providers, researchers, people affected by HIV/AIDS, and the general public. Information is also available by phone, email, and postal mail. https://aidsinfo.nlh.gov/
Antibody	A protein (your body's defense) produced by ß lymphocytes (B cells) in response to an antigen (invader). Antibodies bind to and help destroy antigens.
Antibody Differentiation Test	A type of antibody test that can distinguish HIV-1 antibodies from HIV-2 antibodies. When an initial HIV antibody test result is positive, an antibody differentiation test is done to determine whether a person has HIV-1 or HIV-2. The test is done using a sample of blood.
Antigen	Any substance that triggers an immune response. Antigens include body invaders like bacteria, viruses, and allergens such as pollen.
Antigen/Antibody Combination Test	A type of HIV test that can detect HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen (a protein that forms the HIV core). Antigen/antibody combination tests can detect HIV earlier than tests that only detect HIV antibodies. The test is done using a sample of blood.
Antiretroviral (ARV)	A drug used to prevent a retrovirus, such as HIV, from replicating. The term primarily refers to antiretroviral (ARV) HIV drugs.
Antiretroviral Therapy (ART)	Also called Combination Therapy, Combined Antiretroviral Therapy (cART), and Highly Active Antiretroviral Therapy (HAART). The daily use of a combination of HIV medicines (called an HIV regimen) to treat HIV infection. A person's initial HIV regimen generally includes three antiretroviral (ARV) drugs from at least two different HIV drug classes. The use of fewer than three agents is not recommended for initiating treatment. These agents belong to six distinct classes of drugs: the nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs, NtRTIs), the non-nucleoside reverse transcriptase inhibitors (NNRTIs), the protease inhibitors (PIs), the fusion inhibitors (FIs), the CCR5 co-receptor antagonists, and the integrase strand transfer inhibitors (INSTIs).[38]
Baseline	An initial measurement used as the basis for future comparison. For people with HIV, baseline testing includes CD4 count, viral load (HIV RNA), and resistance testing. Baseline test results are used to guide HIV treatment choices and to monitor the effectiveness of antiretroviral therapy (ART).
Boosting	Using an antiretroviral (ARV) drug (or other drug) to increase the effectiveness of another ARV drug. For example, drugs in the protease inhibitor (PI) ARV drug class are often boosted with the drug cobicistat. Cobicistat interferes with the breakdown of the PI, which allows the PI to remain in the body longer at a higher concentration.

DEFINITIONS AND IMPORTANT TERMS*

*Glossary adapted from **AIDSinfo Glossary of HIV/AIDS-Related Terms, 2018, 9th Edition, HHS NLM & NIH** with additional sources cited.

CD4 Count	Also known as CD4 Cell Count and CD4 T Lymphocyte Count. A laboratory test that measures the number of CD4 T lymphocytes (CD4 cells) in a sample of blood. In people with HIV, the CD4 count is the most important laboratory indicator of immune function and the strongest predictor of HIV progression. The CD4 count is also used to monitor a person's response to antiretroviral therapy (ART).
CD4 Percentage	Also known as CD4 Cell Percentage and CD4 T Lymphocyte. Percentage of white blood cells that are CD4 T lymphocytes (CD4 cells). In certain cases, such as in children with HIV who are younger than 5 years of age, CD4 percentage is used rather than CD4 count to assess HIV progression or response to antiretroviral therapy (ART).
CD4 T Lymphocyte	Also known as CD4 Cell and Helper T Cell. A type of lymphocyte. CD4 T lymphocytes (CD4 cells) help coordinate the immune response by stimulating other immune cells, such as macrophages, B lymphocytes (B cells), and CD8 T lymphocytes (CD8 cells) to fight infection. HIV weakens the immune system by destroying CD4 cells.
Class-Sparing Regimen	An antiretroviral (ARV) drug regimen that purposefully excludes all ARV drugs from a specific drug class. Class-sparing regimens are used to save specific ARV drugs for future use in case a regimen needs to be changed because of toxicity or drug resistance. A class-sparing regimen may also be used to avoid adverse effects associated with a specific drug class.
Coinfection	When a person has two or more infections at the same time. For example, a person living with HIV may also have a hepatitis C virus (HCV) coinfection, a tuberculosis (TB) coinfection, or both.
Contraindication	A situation in which a particular treatment or procedure should not be used because it could be potentially harmful. For example, use of a specific drug may be contraindicated during pregnancy.
Cross Resistance	Resistance to one or more drugs that occurs as a result of previous exposure to a similar drug. For example, HIV resistance to one nonnucleoside reverse transcriptase inhibitor (NNRTI) drug may produce resistance to all drugs in the NNRTI drug class, including drugs never used. Excluding all drugs in a drug class from an HIV regimen (class sparing) is a strategy used to prevent cross resistance.
Deoxyribonucleic Acid (DNA)	One of two types of genetic material found in all living cells and many viruses. (The other type of genetic material is RNA.) Deoxyribonucleic acid (DNA) carries the genetic instructions for the development and function of an organism. DNA allows for the transmission of genetic information from one generation to the next.
Department of Health and Human Services (HHS)	The primary federal agency for protecting the health of all Americans and providing essential human services. The Department of Health and Human Services (HHS) works closely with state and local governments, and many HHS-funded services are provided at the local level by state or county agencies, or through private sector grantees. The agency's 11 operating divisions, including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH), collectively administer more than 100 programs. https://www.hhs.gov/
Directly Observed Therapy (DOT)	A method of drug administration in which a health care professional watches as a person takes each dose of a medication. Directly observed therapy (DOT) is used to ensure the person receives and takes all medications as prescribed and to monitor response to treatment. DOT is widely used to manage tuberculosis (TB). In HIV treatment, DOT is sometimes called directly administered antiretroviral therapy (DAART). When used with rapid ART initiation the physician is there to show support for the client as they take this important first step in treatment.
Dosage	The administration of individual doses of a medication as part of a medication regimen, usually expressed as quantity per unit of time. For example, a prescribed dosage might consist of 25 mg of a medication given 3 times a day for 6 days.

DEFINITIONS AND IMPORTANT TERMS*

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Dose	The quantity of a medication to be given at one time, or the total quantity of a medication administered during a specified period of time. For example, a patient might receive an initial medication dose of 50 mg, and during the entire course of treatment, receive a total medication dose of 500 mg.
Drug Interaction	A reaction between two (or more) drugs or between a drug and a food or supplement. An existing medical condition can also cause a drug interaction. A drug interaction can decrease or increase the action of the drug(s) or cause adverse effects.
Drug Resistance	Also called Resistance. When a bacteria, virus, or other microorganism mutates (changes form) and becomes insensitive to (resistant to) a drug that was previously effective. Drug resistance can be a cause of HIV treatment failure.
Durable Virologic Suppression	Lifelong suppression or lowering of the viral load (amount of HIV in the body) to undetectable.
Enzyme-Linked Immunosorbent Assay (ELISA)	Also called Enzyme Immunoassay. A laboratory test to detect the presence of HIV antibodies in the blood or oral fluid. The immune system responds to HIV infection by producing HIV antibodies. A positive result on an enzyme-linked immunosorbent assay (ELISA) must be confirmed by a second test for a person to receive a definitive diagnosis of HIV infection.
Evidence Rating A1a	A panel of experts in HIV research and patient care convened by the International Antiviral Society–USA reviewed data published in peer-reviewed journals, presented by regulatory agencies, or presented as conference abstracts at peer-reviewed scientific conferences since the 2016 report, for new data or evidence that would change previous recommendations or their ratings. Comprehensive literature searches were conducted in the PubMed and EMBASE databases through April 2018. Recommendations were by consensus, and each recommendation was rated by strength.
Evidence Rating AI, AII, AIII	Rating of recommendation: A = strong recommendation. Rating of evidence: I = Data from randomized controlled trials; II = Data from well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion.
Fixed Dose Combination (FDC)	Two or more drugs contained in a single dosage form, such as a capsule or tablet. An example of a fixed-dose combination (FDC) HIV drug is Atripla (a combination of efavirenz, emtricitabine, and tenofovir DF). By reducing the number of pills a person must take each day, fixed-dose combination drugs can help improve adherence to an HIV treatment regimen.
Health Resources and Services Administration (HRSA)	The primary federal agency for improving access to health care services for people who are uninsured, isolated, or medically vulnerable. Through its HIV/AIDS bureau, the Health Resources and Services Administration (HRSA) administers the Ryan White HIV/AIDS Program, the largest federal program focused exclusively on HIV/AIDS care.
Hepatitis C Virus Infection (HCV)	Infection with the hepatitis C virus (HCV). HCV is usually transmitted through blood and rarely through other body fluids, such as semen. HCV infection progresses more rapidly in people with HCV/HIV coinfection than in people who have HCV infection alone.
HIV Continuum of Care	Also known as HIV Care Continuum and HIV Treatment Cascade. (See CDC HIV Care Continuum. PDF. (2019, July). CDC, Washington DC.) The steps or stages of medical treatment for HIV. The continuum of care begins when someone receives an HIV diagnosis, and includes finding the right health care, starting antiretroviral therapy (ART), adhering to treatment, and staying in care. The ultimate goal of the continuum of care is virological suppression. The continuum of care can also refer to a model used by epidemiologists and other health care professionals to monitor the success of HIV-related programs and to identify and address gaps in HIV-related services. This model measures linkage to care, retention in care, and sustained viral suppression among people with HIV.

DEFINITIONS AND IMPORTANT TERMS*

*Glossary adapted from **AIDSinfo Glossary of HIV/AIDS-Related Terms, 2018, 9th Edition, HHS NLM & NIH** with additional sources cited.

HIV Navigation	The process of helping someone with HIV access HIV-related medical and social services across the continuum of care.
Immunodeficiency	Inability to produce an adequate immune response because of an insufficiency or absence of antibodies, immune cells, or both. Immunodeficiency disorders can be inherited, such as severe combined immunodeficiency; they can be acquired through infection, such as with HIV; or they can result from chemotherapy.
Immunosuppression	When the body's ability to mount an immune response to fight infections or disease is reduced. Immunosuppression may be caused by certain diseases, such as HIV, or by radiotherapy or chemotherapy. Immunosuppression may also be deliberately induced by drugs used to prevent rejection of transplanted organs.
Informed Consent	A communication process between a person and a health care provider or researcher to ensure that the person understands all relevant facts associated with a medical procedure or clinical trial. Before undergoing the procedure or participating in the trial, the person must sign an informed consent form that indicates understanding of the risks and benefits involved and of the risks and benefits of other options.
Latent HIV Reservoir	Resting CD4 cells (or other cells) that are infected with HIV but not actively producing HIV. Latent HIV reservoirs are established during the earliest stage of HIV infection. Although antiretroviral therapy (ART) can reduce the level of HIV in the blood to an undetectable level, latent reservoirs of HIV continue to survive. When a latently infected cell is reactivated, the cell begins to produce HIV again. Although ART can suppress HIV levels, ART cannot eliminate latent HIV reservoirs. For this reason, ART cannot cure HIV infection.
Life Cycle	Also known as Replication Cycle. The series of steps that HIV follows to multiply in the body. The process begins when HIV encounters a CD4 cell. The seven steps in the HIV life cycle are: 1) binding; 2) fusion; 3) reverse transcription; 4) integration; 5) replication; 6) assembly; and 7) budding.
Modified Directly Observed Therapy (m-DOT)	A variation of directly observed therapy (DOT). Modified-DOT (m-DOT) is when a health care professional watches a person take some, but not all, medication doses.
Mutation	A permanent change in the genetic material of a cell or microorganism. Some mutations can be transmitted when the cell or microorganism replicates. Some HIV mutations cause the virus to become resistant to certain antiretroviral (ARV) drugs.
Navigator	A trained professional who helps people and their families access and understand medical and social services. Navigators can include social workers, case managers, community health workers, or patient navigators.
Office of AIDS Research (OAR)	The office of the National Institutes of Health (NIH) that coordinates the scientific, budgetary, legislative, and policy elements of the NIH HIV/AIDS research program. https://www.oar.nih.gov/
Office of Minority Health (OMH)	A federal office whose primary responsibility is to improve the health of racial and ethnic minority populations, including Black Americans, Hispanic Americans, American Indians, Alaskan Natives, and Pacific Islanders. The Office of Minority Health (OMH) develops or advances policies, programs, and practices that address health, social, economic, environmental, and other factors that impact the health of minority populations, including those specifically affected by HIV/AIDS. https://www.minorityhealth.hhs.gov/
Phenotypic Antiretroviral Resistance Test	Also known as Phenotypic Assay. A type of resistance test that measures the extent to which a person's strain of HIV will multiply in different concentrations of antiretroviral (ARV) drugs. Resistance testing is used to guide selection of an HIV regimen when initiating or changing antiretroviral therapy (ART).
Qualitative Transcription-Mediated Amplification Assay	A type of viral load test. Viral load tests are used to diagnose acute HIV infection, guide treatment choices, and monitor response to antiretroviral therapy (ART).

DEFINITIONS AND IMPORTANT TERMS*

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Quantitative Branched DNA Assay (bDNA)	A type of viral load test. Viral load tests are used to diagnose acute HIV infection, guide treatment choices, and monitor response to antiretroviral therapy (ART).
Rapid ART Initiation, Treatment Upon Diagnosis, Immediate ART	Most sites the use the World Health Organization's definition of rapid ART initiation: starting ART within seven days from the day of HIV diagnosis. Some Individual Programs define it as within 48 or 72 hours of diagnosis, or as long as two weeks from diagnosis in order to either work within their resource constraints or their target goals.
Rapid Test	A type of HIV antibody test used to screen for HIV infection. A rapid HIV antibody test can detect HIV antibodies in blood or oral fluid in less than 30 minutes. There is also a rapid antigen/antibody test available. A positive rapid HIV antibody test must be confirmed by a second test for a person to be definitively diagnosed with HIV.
Resistance Associated Mutations (RAMs)	The potential result when an individual fails to achieve and maintain virologic suppression.
Resistance Testing	Also known as a Resistance Assay. Laboratory testing to identify which, if any, antiretroviral (ARV) drugs will not be effective against a person's specific strain of HIV. Resistance testing is done using a sample of blood. There are two types of resistance testing: genotypic and phenotypic. Resistance testing is used to guide selection of an HIV regimen when initiating or changing antiretroviral therapy (ART).
Ribonucleic Acid (RNA)	One of two types of genetic material found in all living cells and many viruses. (The other type of genetic material is DNA.) There are several types of ribonucleic acid (RNA). RNA plays important roles in protein synthesis and other cell activities.
Risk of Immune Reconstitution Inflammatory Syndrome (IRIS)	IRIS is a clinical syndrome characterized by new or worsening infectious and noninfectious complications observed after the initiation of ART. The risk of IRIS increases when ART is begun at low CD4 cell counts (<100 cells/mm3) or with the presence of specific opportunistic infections. Although the risk of IRIS is not a contraindication to initiating ART, clinicians and patients should be aware that the risk of developing IRIS is increased among individuals with lower CD4 counts. Patients at increased risk should be informed of the potential for a paradoxical clinical worsening after ART initiation.[39]
Ryan White HIV/AIDS Program	Also known as the CARE Act and RWHAP. The largest federally funded program providing HIV-related services to low-income, uninsured, and underinsured people with HIV/AIDS. The program's services are available in all 50 states, the District of Columbia, and U.S. territories.
Same-day ART, Same-day Start	Same-day ART is diagnosis to initiation within 24-hours and prior to leaving the provider's office.
Seroconversion	The transition from infection with HIV to the detectable presence of HIV antibodies in the blood. When seroconversion occurs (usually within a few weeks of infection), the result of an HIV antibody test changes from HIV negative to HIV positive.
Superinfection	When a person who already has HIV acquires a second, different strain of HIV. Superinfection may cause HIV to advance more rapidly. Superinfection can also complicate treatment if the newly acquired strain of HIV is resistant to antiretroviral (ARV) drugs in the person's current HIV treatment regimen.
Toxicity	Also known as Drug Toxicity. The extent to which a drug causes adverse effects. Drug toxicity is one of the factors considered when selecting antiretroviral (ARV) drugs to include in an HIV treatment regimen.
Treatment as Prevention (TasP)	A term that describes the reduced risk of HIV transmission that occurs when HIV medicines lower a person's viral load to undetectable levels. Treatment as prevention (TasP) reduces the risk of HIV transmission through sex or needle sharing, and from mother to child during pregnancy, birth, and breastfeeding.

DEFINITIONS AND IMPORTANT TERMS*

*Glossary adapted from **AIDSinfo Glossary of HIV/AIDS-Related Terms, 2018, 9th Edition, HHS NLM & NIH** with additional sources cited.

Treatment Regimen	A structured treatment plan designed to improve and maintain health. Recommended regimens for the initial treatment of HIV generally include a combination of three or more antiretroviral (ARV) drugs from at least two different HIV drug classes.
Treatment-Experienced	When a person with HIV is currently taking or has previously taken antiretroviral (ARV) drugs.
Treatment-Naïve	When a person with HIV has never taken antiretroviral (ARV) drugs.
Viral Load (VL)	The amount of HIV in a sample of blood. Viral load (VL) is reported as the number of HIV RNA copies per milliliter of blood. An important goal of antiretroviral therapy (ART) is to suppress a person's VL to an undetectable level—a level too low for the virus to be detected by a VL test.
Viral Load Test	A laboratory test that measures the amount of HIV in a blood sample. Results are reported as the number of copies of HIV RNA per milliliter of blood. Examples of viral load tests include quantitative branched DNA (bDNA), reverse transcriptase-polymerase chain reaction (RT-PCR), and qualitative transcription-mediated amplification. Viral load tests are used to diagnose acute HIV infection, guide treatment choices, and monitor response to antiretroviral therapy (ART).
Viral Suppression	When antiretroviral therapy (ART) reduces a person's viral load (HIV RNA) to an undetectable level. Viral suppression does not mean a person is cured; HIV still remains in the body. If ART is discontinued, the person's viral load will likely return to a detectable level.
Window Period	The time period from exposure to HIV infection to when the body produces enough HIV antibodies to be detected by standard HIV tests. The length of the window period varies depending on the test used. During the window period, a person can have a negative result on an HIV test despite having HIV.
World Health Organization (WHO)	The agency of the United Nations that provides global leadership on health-related matters. Responsibilities of the World Health Organization (WHO) include shaping the global health research agenda, setting health standards, promoting evidence-based policy options, providing technical support to countries, and monitor-ing and assessing health trends. https://www.who.int/

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THE EFFI BARRY TRAINING INSTITUTE

The Effi Barry Training Institute provides trainings and technical assistance to support current and prospective HAHSTA grantees and community-based organizations in the Fee-for-Service business process; basic HIV service competencies; advanced skills in health care systems, data and health informatics; high-impact prevention programs, including biomedical; and emerging evidence-based or informed approaches through a series of group-level trainings, boot camps, community forums, and individual consultation.

Rooted in the idea of holistic, integrated, patient-centered care, HealthHIV capacity building efforts help develop an organization's ability to improve patient outcomes and increase efficiencies, while remaining organizationally sustainable. The agency's unique approach involves structuring sustainable systems and services that span the HIV care continuum. HealthHIV's ability to diagnose and address multisystem challenges is enhanced by a comprehensive team of expert consultants and focuses on achieving measurable outcomes. By remaining data and outcomes driven, HealthHIV employs state-of-the-art, and state-of-the-sciences approaches to improve health care delivery.

EffiBarryInstitute.org

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