THE EFFI BARRY
TRAINING INSTITUTE

ART
ANTIRETROVIRAL THERAPY BASICS:

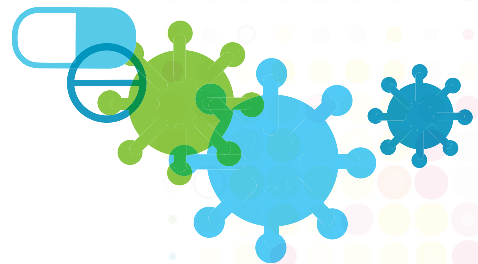
A PRIMER

DC | HEALTH
GOVERNMENT OF THE DISTRICT OF COLUMBIA

HealthHIV

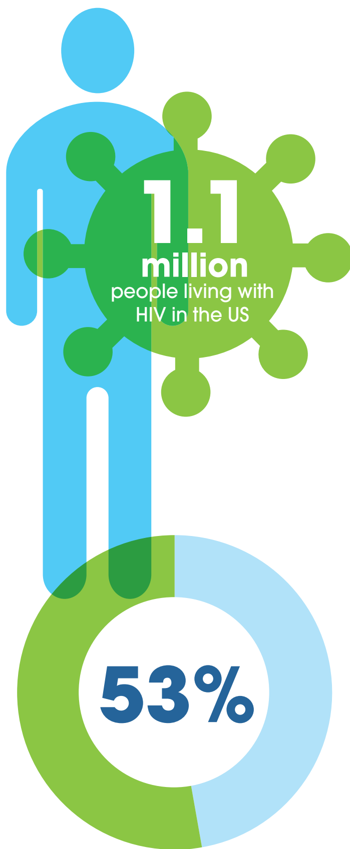
TABLE OF CONTENTS

Target Audience	3
Background	3
HIV & ART History	4
ART Basics	5
Defining Adherence	8
Medication Resistance	11
The HIV Care Continuum	12
U=U	13
Assessing Readiness: Stages + Processes of Change	14
Creating an Adherence Plan	17
Adherence Plan Template	19
HIV Medication Adherence Assessment Tool	20
ART Basics Knowledge Check	21
References	22



TARGET AUDIENCE

The target audience for this Antiretroviral Therapy (ART) toolkit is Ryan White Part A providers in a direct service role. Some of these direct services include: EIS, ADAP services, pharmaceutical assistance, community-based health services, home health care, hospice, services, medical case management, treatment adherence services, nutrition therapy, mental health services, oral health, and/or substance abuse related services. The materials contained in this toolkit can be accessed digitally or downloaded and printed to use with clients.



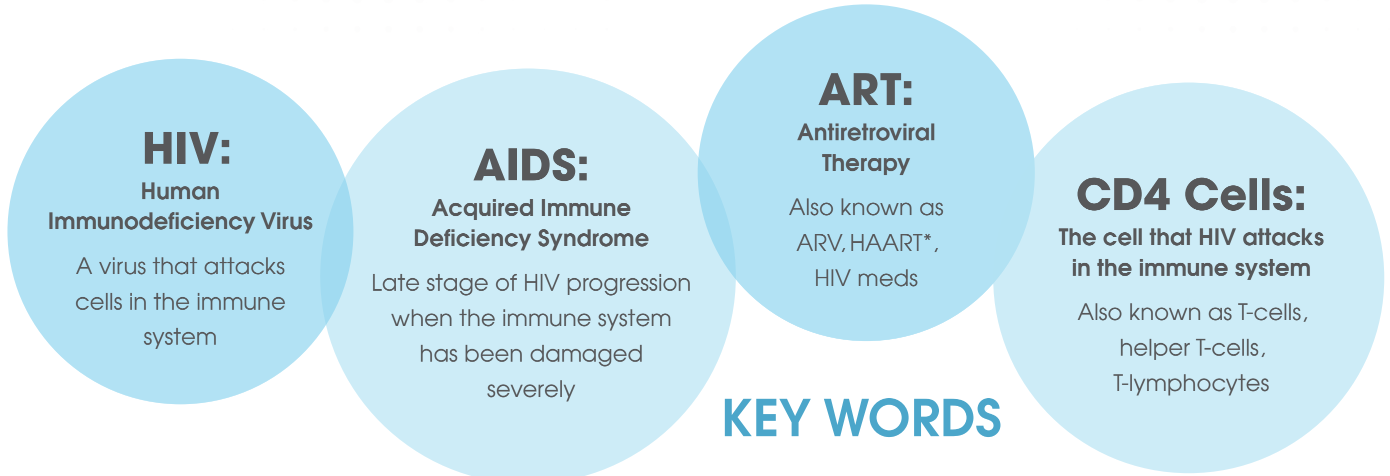
Nearly half of people living with HIV in the US are not virally suppressed

BACKGROUND

There are approximately 1.1 million people living with HIV in the US.[1] According to the Centers for Disease Control (CDC), in 2018 approximately 38,000 people in the US were diagnosed with HIV, and the majority of these diagnoses occurred in Southern states (AL, AR, DE, DC, FL, GA, KY, LA, MD, MS, NC, OK, SC, TN, TX, VA, WV).[2] The CDC estimates that 15% of people with HIV do not know their status, and just over half (53%) have achieved viral suppression.[3] These statistics indicate the need for further improvements in ART adherence.

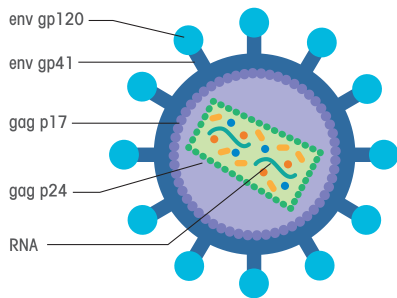
Nearly half of people living with HIV in the US are not virally suppressed, leading to increased incidence of opportunistic infections and a higher likelihood of transmitting HIV to others. Upon receiving an HIV diagnosis, it is important to begin ART as soon as possible. ART is recommended for all people living with HIV. Adhering to ART can help people with HIV live a long healthy life, and improve quality of life.

HIV & ART HISTORY



*HAART: highly active antiretroviral therapy

HUMAN IMMUNODEFICIENCY VIRUS

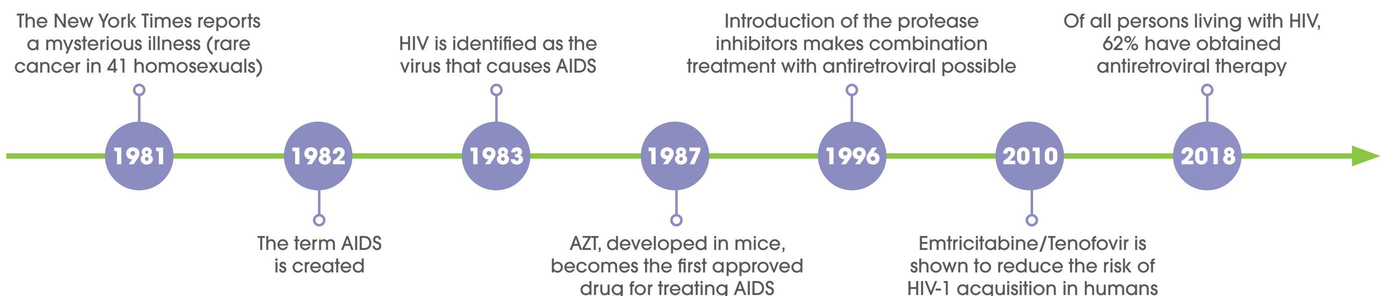


HIV is a retrovirus, a virus made up of RNA. Retroviruses have an enzyme called reverse transcriptase which changes RNA into DNA after entering a host cell. HIV uses the "CD4" cell as a host cell, changing it from a helper cell in the immune system into new HIV. AIDS is the late stage progression of HIV. An AIDS diagnosis is indicative of the immune system having experienced significant damage.

An AIDS diagnosis is given under any of the following circumstances:

- Less than 200 CD4 cells per cubic millimeter of blood
- CD4 cells accounting for less than 14 percent of all lymphocytes
- One or more opportunistic infections

Once a person receives an AIDS diagnosis, the diagnosis remains regardless of their CD4 cell count increasing after taking medication. The term AIDS was created in 1982, a year after the New York Times reported a "rare cancer" among homosexual men. In 1983, HIV was identified as the virus that causes AIDS. In 1987, AZT became the first approved drug to treat AIDS.[4] AZT was prescribed at high doses, and many were concerned about intolerable side effects and if the drugs were worse than the disease.[4] In 1996, protease inhibitors were approved. This class of medication became part of combination highly active antiretroviral therapy which drastically reduced viral load for many people living with HIV.

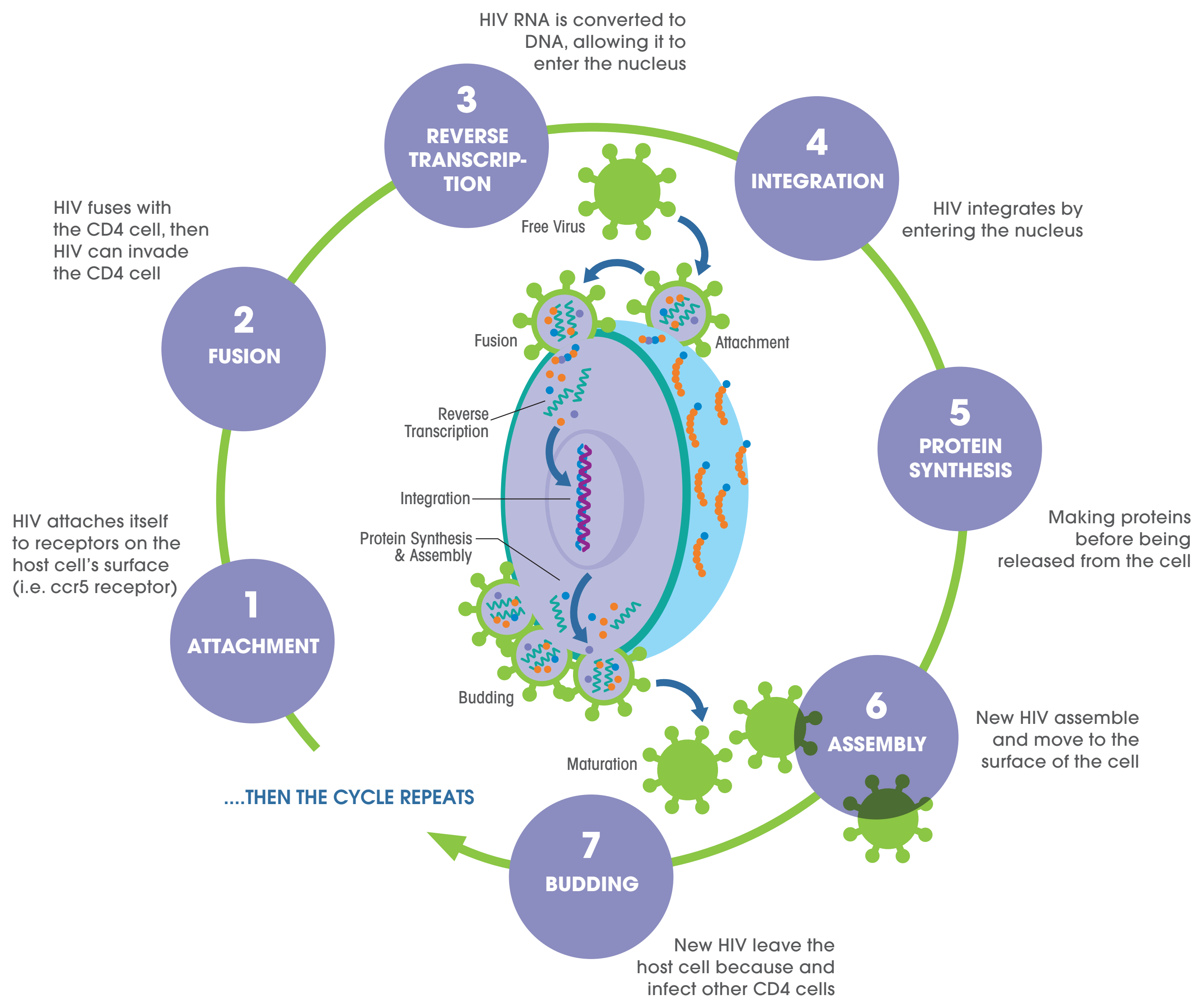


ART BASICS

The goal of ART is to reduce HIV viral load to undetectable levels.

Undetectable levels means there is so little HIV in the blood that it is not detectable on a standard viral load test. Additionally, taking ART as prescribed allows the immune system to regenerate itself, CD4 cells to increase, and for people living with HIV to have the chance to live a longer and healthier life.

In order to understand the basics of ART, it's important to first understand how HIV works in the body. HIV destroys the immune system by attaching to CD4 cells, fusing with them, changing their DNA and replicating itself to release more HIV in the blood.



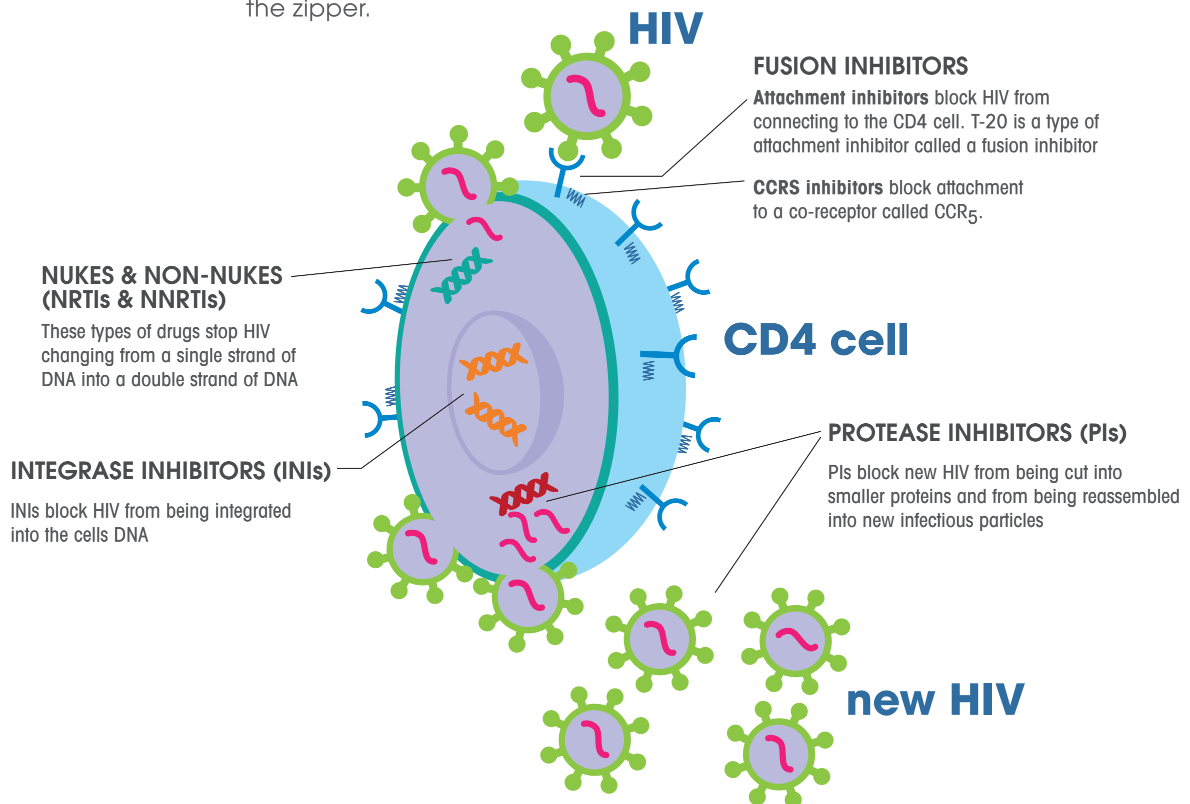
ART BASICS

There are five main classes of ART:

1	2	3	4	5
Fusion Inhibitors	**Nukes**	**Non-Nukes**	**Integrase Inhibitors**	**Protease Inhibitors**

Each class of ART attempts to stop HIV from replicating at each part of the HIV life cycle. This is how each class works:

Fusion Inhibitors	Nukes	Non-Nukes	Integrase Inhibitors	Protease Inhibitors
Fusion inhibitors work outside the CD4 cell, stopping HIV from fusing to it.	Reverse transcriptase (the process of converting RNA to DNA) is like trying to zip a zipper. Nukes and non-nukes try to stop that process. Nukes try to confuse reverse transriptase by providing an additional track for the zipper.	Non-nukes work along side nukes trying to stop RNA from converting into DNA by being an object to block the zipper, jamming it up.	Integrase inhibitors stop HIV DNA from entering the nucleus of the CD4 cell, inhibiting replication.	Protease inhibitors are designed to block the process of creating protein so new HIV can no longer assemble, bud, and make new copies.



Treatment Training Manual. (2016, January). Retrieved from http://i-base.info/ttfa/section-3/5-how-hiv-drugs-work-main-types-of-drugs/

ART BASICS

Combination therapy (using drugs from multiple classes) has been shown to suppress viral replication so progression to AIDS is significantly slowed, and the likelihood of drug resistance is dramatically reduced. In addition to these classes, there are other types of HIV meds, like the CCR5 inhibitors and post-attachment inhibitors. These medications are designed to block HIV from attaching to receptors on the CD4 cell.

There are many reasons why adhering to HIV medications can be challenging for people living with HIV. In recent years, many single dose regimens have been approved, which is especially helpful for those experiencing pill burden. Pill burden refers to the challenge associated with taking a large number of pills. The single pill regiments include multiple classes of drugs and are still part of combination therapy.

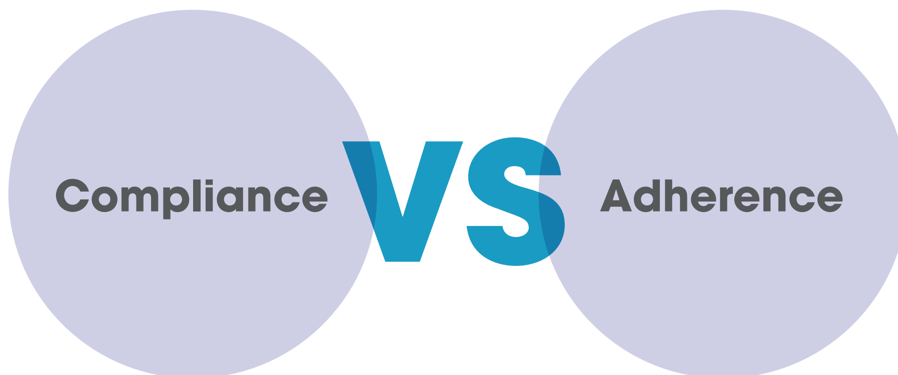
Clinicians recommend ART for all people with HIV regardless of CD4 cell count in order to reduce morbidity or mortality due to HIV. This includes pregnant women. ART should be initiated as soon as possible after receiving an HIV diagnosis. It is important to discuss ART decisions with a provider and to strategize together on how to create a medication adherence plan.

SINGLE PILL REGIMENS:

- Atripla
- Biktarvy
- Cabenuva
- Complera
- Delstrigo
- Dovato
- Genvoya
- Juluca
- Odefsey
- Stribild
- Symfi and Symfi Lo
- Symtuza
- Triumeq

DEFINING ADHERENCE

Adherence refers to taking medication (or other treatment) exactly as instructed by a health care provider. This includes getting prescriptions filled. Patients need to have enough knowledge, motivation, skills, and resources in order to adhere to medication plans fully. Some providers may use the word "compliance," but "adherence" is the preferred term because it implies that the medication plan is agreed upon by patients and their clinicians.



Non-compliance was historically used to describe a client not taking medications as prescribed. It is a problematic term because it has a pejorative connotation, and implies a one-sided relationship where the clinical provider gives instructions and the client decides not to follow them. The client's decision is an act of rebellion, a lack of understanding or being irrational. Clients who don't follow instructions are viewed as uncooperative or maladaptive. The word compliance is paternalistic and does not take into consideration that the client has a choice, and may have very real barriers to surmount on their path to taking medications as prescribed.

The word adherence is preferred as it implies a joint approach to a medication plan. Adherence emphasizes a communication process between the clinical provider and client that considers any individual or environmental factors that may influence a client's decision to take medications. It also takes into account that the client has the ultimate right to decide whether or not to take medication, not the clinical provider.[5]

There are many ways people can be non-adherent to their medication, some examples include:

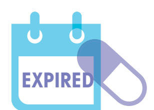
NOT PICKING UP A PRESCRIPTION

NOT GETTING PRESCRIPTIONS REFILLED

SKIPPING DOSES

TAKING AN INAPPROPRIATE AMOUNT OF MEDICATIONS

TAKING MEDS AT THE WRONG TIME



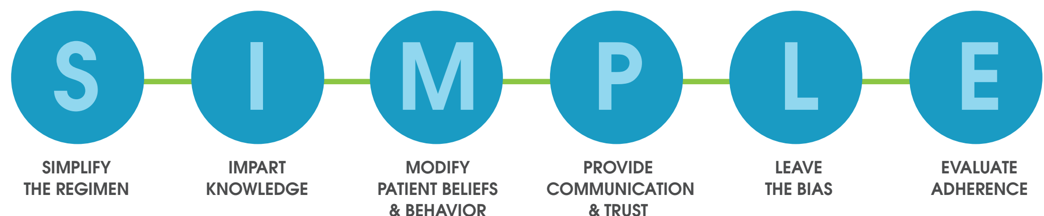
TAKING EXPIRED MEDICATIONS

DEFINING ADHERENCE

Intentional Non-Adherence VS **Unintentional Non-Adherence**

There are two types of non-adherence, intentional and unintentional. In cases where clients are purposely deciding not to take medication as described, the non-adherence is referred to as intentional, an active process whereby clients choose to deviate from the treatment regimen. When a client simply has a hard time remembering to take their medication daily, the non-adherence is unintentional, a passive process in that the patient may be careless or forgetful.[6]

Different approaches should be taken to improve adherence based on whether non-adherence is intentional or unintentional. If a client is intentionally practicing non-adherence, consider the strategies in **the SIMPLE approach:**



Additionally, a provider should consider recruiting family and friends for support if the client agrees. Involving other members of the health care team may help as well as providing referrals to community support groups. When someone faces challenges with adherence but is successful, this can be formally recognized as reassurance.

Unintentional medication non-adherence can be equally challenging, but there are many options to help clients who forget to take their meds, like:

ALARMS

PILL BOXES

PILL KEY CHAINS

KEEPING MEDICATION WHERE IT CANNOT BE FORGOTTEN (I.E. NEAR THE REFRIGERATOR, THE REMOTE CONTROL, OR THEIR TOOTHBRUSH).

Clients who forget to take their medications can do a trial run with jelly beans or other candies before starting medications and risking missing doses.

DEFINING ADHERENCE

Intentional Non-Adherence VS **Unintentional Non-Adherence**

Before beginning medications, it is important to help the client assess how well the medication fits into their lifestyle. If a person decides to adhere to medication, contingency plans should be made for when routines change in order to prevent missing doses. There are many benefits to adhering to medication that clients should be reminded about:

- sustained viral suppression
- reduced risk of medication resistance
- better overall health
- improved quality of life
- decreased risk of HIV transmission

There are many factors associated with poor medication adherence, including:

- **Unstable housing**
- **Low health literacy**
- **Work outside the home**
- **Depressed mood**
- **Lack of perceived efficacy**
- **Active alcohol or substance use**
- **Lack of advanced disease**
- **Concern over side effects**
- **Challenges with daily schedule**
- **Dosing and food requirements**
- **Age related challenges**

Over time, HIV medication regimens have improved and most side effects are manageable. The benefits to taking HIV medications typically outweigh the risk associated with side effects. There are many benefits to medication adherence, including:

- sustained viral suppression
- decreased risk of transmission of HIV to others
- overall improved health and quality of life

When clients are not feeling any symptoms related to HIV, they may not feel the need to take their medications but missing doses can lead to drug resistance - causing the medications not to work anymore.

Clinicians should encourage patients to adhere as closely as possible to the prescribed doses for all HIV regimens. While it is ideal to be 100% adherent to medication, it is understood that sometimes people miss doses. In order to ensure sustained viral suppression, a person is expected to take their HIV medications at least 95% of the time (which is approximately 14 missed doses over the course of one year).

MEDICATION RESISTANCE

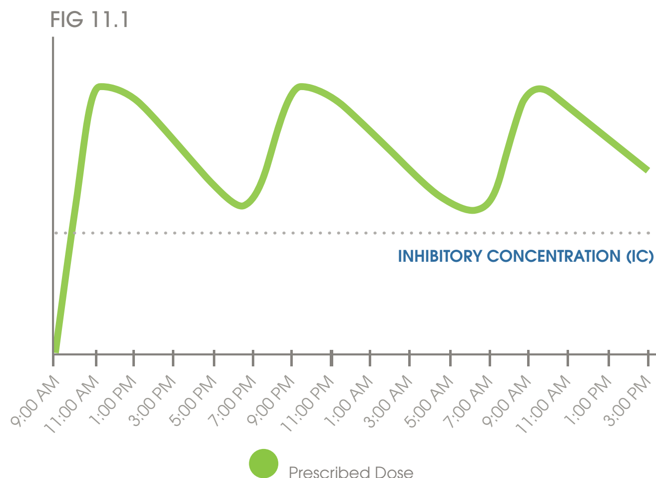
In order to stop HIV from reproducing, the proper amounts of medication must stay in the body. To achieve this, medication must be taken correctly every day.

If medications are not taken as prescribed, viral load can increase, CD4 count can decrease, and resistance can occur. The World Health Organization (WHO) defines drug resistance as the ability of HIV to mutate and reproduce itself in the presence of ART.[7]

HIV drug resistance is a problem because it means that the type of HIV a person has is no longer affected by the medication, usually due to missed doses. The development of medication resistance can limit treatment options.

The lowest concentration of medication in the blood to stop HIV from replicating is called the inhibitory concentration (IC). Medication levels must remain above the inhibitory concentration. The following diagram illustrates proper medication adherence with medication levels above the inhibitory concentration line over the course of a day:

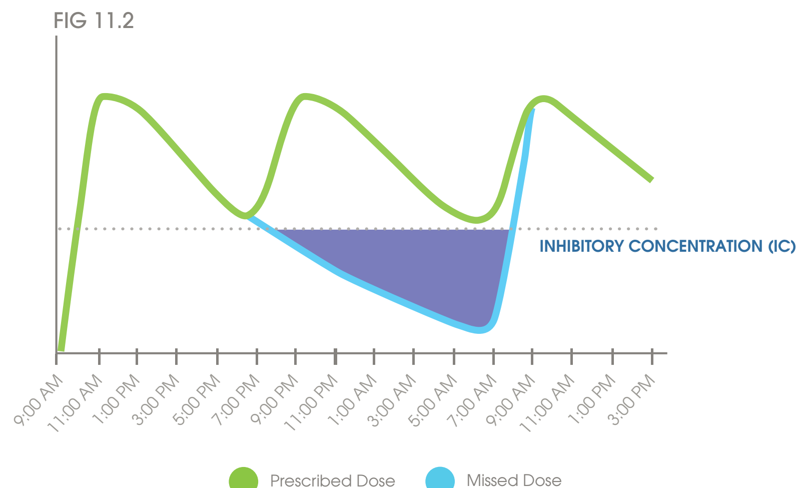
FIG 11.1



As shown in the diagram (Fig 11.1), the wavy line above the IC has peaks (high point) and troughs (low point). The wavy line represents the times when a person takes their HIV medications. The peaks are when medication is at it's highest effective level in the body, and the troughs are when the medication is at it's lowest effective level. When the medication gets to the trough, it is time to take it again. **The goal is to have a consistent wavy line of medication that never goes below the lowest level for it to be effective (the IC).**

The following diagram (Fig 11.2) illustrates what happens when the amount of medication in the body falls below the IC (when someone skips or otherwise misses a dose). The wavy medication line starts off with a normal peak and trough, but when a dose is missed, the body enters the blue zone. This blue zone below the IC represents the development of medication resistance, and replication of resistant HIV. Resistance begins to develop after a missed dose of ART. A person needs to adhere to their medication at least 95% of the time, meaning there should be very few missed doses, or else medication will no longer work.

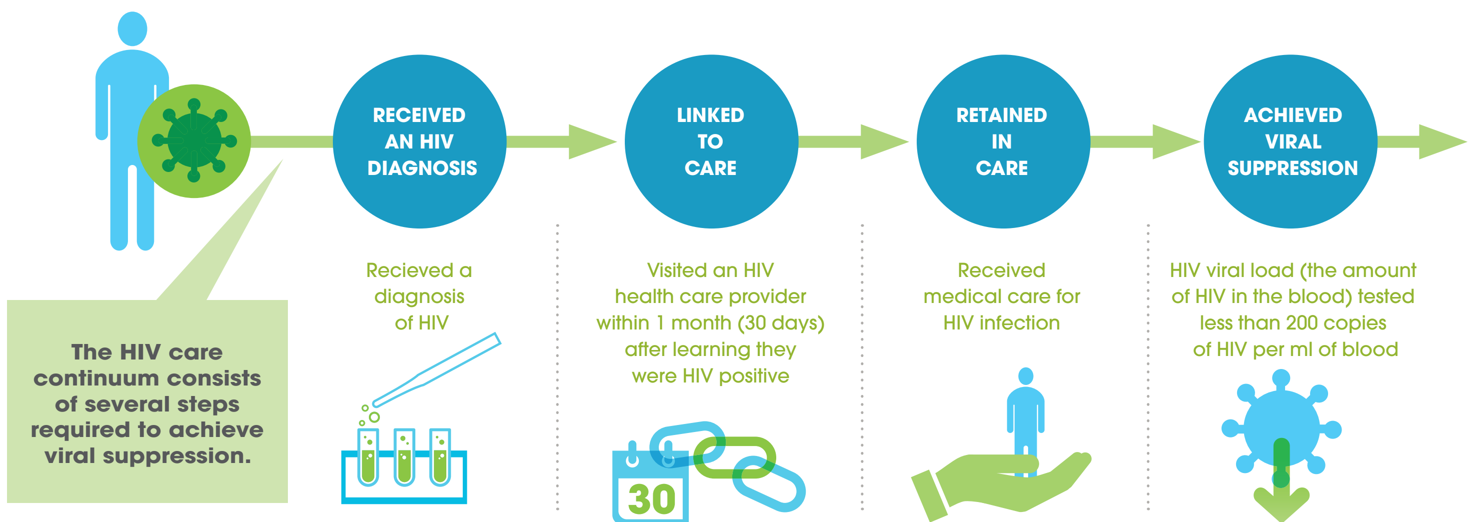
FIG 11.2



THE HIV CARE CONTINUUM

The HIV care continuum is a model that shows the process that occurs along the continuum from receiving an HIV diagnosis to achieving viral suppression.

The HIV care continuum is often shown in the form of a diagram and is sometimes referred to as the "HIV treatment cascade." This is how the HIV care continuum illustrates the process:



Upon receiving an HIV diagnosis, clients should be linked to care as soon as possible. Some clinics are able to link clients to care on the same day they receive an HIV diagnosis, others aim to link people to care within 30 days. Being linked to care is defined as having received ≥1 CD4 or viral load test after being diagnosed with HIV. After being linked to care, being retained in care is defined as having received continuous medical care and ≥2 CD4 or viral load tests 3 months apart. Viral suppression is achieved when there are less than 200 copies of HIV per ml of blood.[3] This should be assessed every 6 months.

U=U

Undetectable = Untransmittable

A person who has achieved viral suppression is not able to transmit HIV to another person sexually. Being virally suppressed means there is so little HIV in the blood that it is undetectable on a viral load test. The only way to know if a person is undetectable is by visiting a provider regularly to take viral load tests. Adhering to ART is important in order to maintain undetectable status.

UNDETECTABLE: Little HIV in the blood, cannot be detected on a viral load test

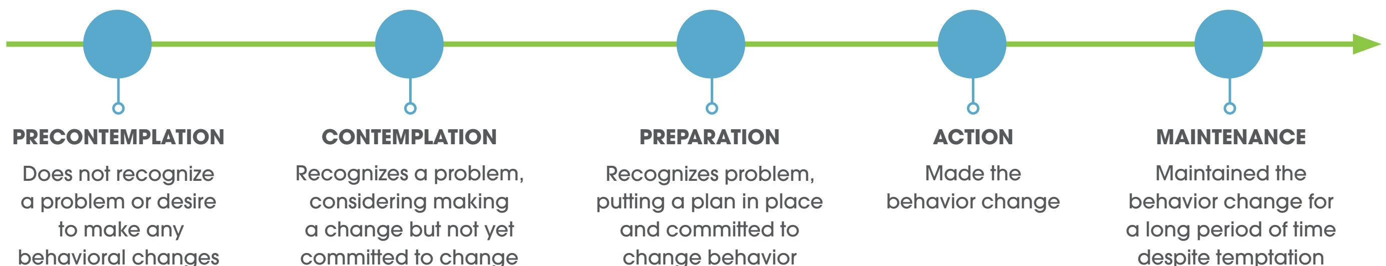
UNTRANSMITTABLE: HIV can no longer be transmitted to another person sexually

There have been multiple studies showing that there is zero risk of HIV transmission when a person is adherent to ART and undetectable. Most public health experts have adopted the U=U message as a transformative revelation which works to dismantle HIV stigma. This anti-stigma tool serves as an incentive for those who are HIV negative to get tested for HIV, and for those living with HIV to start and stay on treatment.

ASSESSING READINESS: STAGES + PROCESSES OF CHANGE

The Department of Health and Human Services (DHHS) guidelines encourage providers to assess patient readiness before offering the first prescription. Before ART is initiated, patient and clinician should discuss the likelihood of adherence. There are instances where ART may be delayed, especially when the patient is unable to commit to an adherence plan.

One way to assess readiness is by using a staging model like the transtheoretical model (also known as the stages of change). This is a social science behavioral model of intentional change that focuses on individual level decision making. The five core stages in the transtheoretical model defining where people are along a continuum of behavior change can be defined as:



There is also a "relapse/recycle" stage that refers to times when a person may be in one stage, relapse to a previous stage, then continue to work towards maintenance. It is important to know what stage a person is in to devise a plan to assist them in moving across the continuum. There are processes of change which can be used at different stages of the transtheoretical model.

If a person is in precontemplation, not recognizing a problem or desiring to make any changes, consciousness raising may help them move along the continuum toward contemplation. Consciousness raising is providing new information about the issue they may not have been aware of. A person recently diagnosed with HIV who does not understand why it is important to take ART may not be inclined to do so. Training or a health messaging campaign can help the newly diagnosed understand both the benefits of achieving viral suppression and the challenges associated with developing a resistant virus, to help them consider making behavior changes.

ASSESSING READINESS: STAGES + PROCESSES OF CHANGE

The transtheoretical model offers ten processes of change to help people move across the continuum toward maintaining a behavior change. The first five of these processes are experiential or cognitive processes that go on internally, the rest are behavioral processes that involve an external action. People need to change their thoughts and feelings about the behavior before taking action. The processes of change include the following:

PROCESSES OF CHANGE

Cognitive/ Affective Processes

Behavioral Processes

PROCESSES OF CHAGE

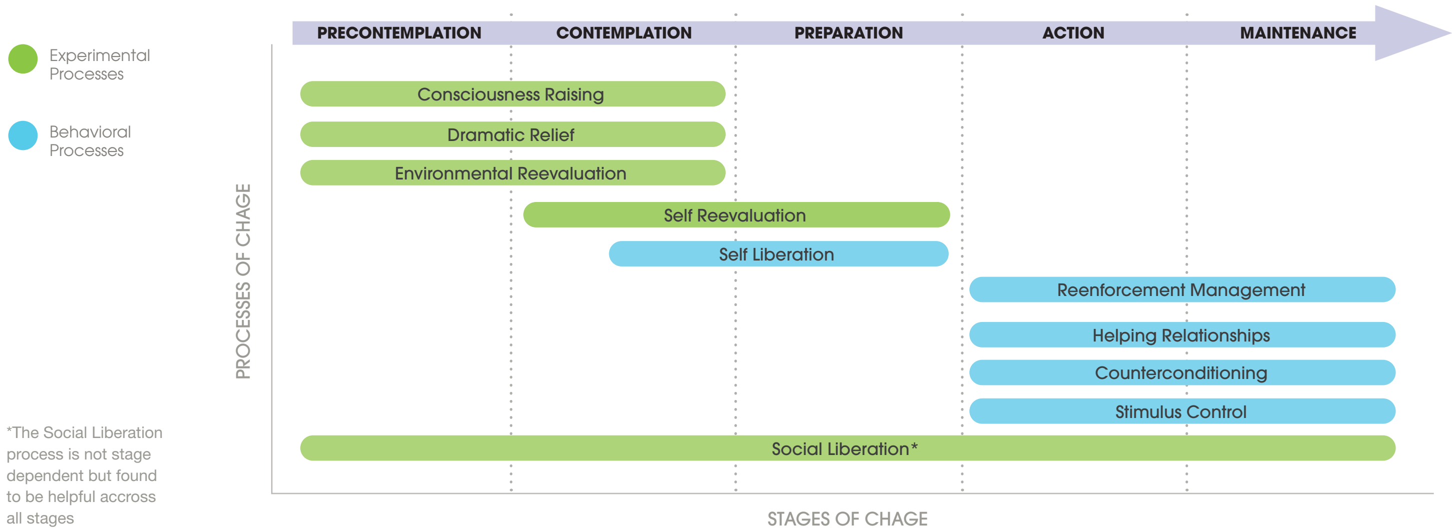
PROCESS	DEFINITION
Consciousness Raising	Increasing awareness about problem behavior (causes, effects, solution)
Dramatic Relief	Being moved emotionally with regards to the problem
Environmental Reevaluation	Assessing how one's behavior affects social/physical environment
Self Reevaluation	Assessing how one thinks and feels about oneself with regard to problem behavior
Self Liberation	Belief one can change and commitmen to do so
Reenforcement Management	Instating consequences for behavior - costs and/or rewards
Helping Relationships	Open, trusting relationships with others who support behavior change
Counterconditioning	Learning and substituting alternatives for problem behavior
Stimulus Control	Removing cues for undesired habits; adding prompts for desired ones
Social Liberation*	Increase opportunities available in society/ alternatives to problem behavior

*The Social Liberation process is not stage dependent but found to be helpful accross all stages

Source: Based on information from Prochaska and Velicer (1997), with sustainability-specific examples in author italics.
†Carbon Conversations: six meeting about climate change and carbon reduction (Randall, 2009)

ASSESSING READINESS: STAGES + PROCESSES OF CHANGE

The diagram below illustrates the point at which each process of change is recommended to be used across the transtheoretical model. These are adaptable and should be tailored to fit the needs of each individual.



There are many factors which influence behavior change, like a person's level of confidence to make the change, whether or not they feel susceptible to the issue, their skill level, social norms, and any environmental barriers that may exist.

Before working with a client to create an adherence plan, it is important to talk through these factors and to better understand how taking ART daily (in addition to any other medications they may be taking) can fit into their lifestyle effectively. What will they do when their schedule changes (i.e. a weekend away from home or a vacation)? What steps can they take to ensure they continue to take their medication? Are there any barriers that have not been considered? It is important to assess a person's understanding of their regimen, which will be discussed in the next section. Before beginning any ART regimen, it is key to simplify regimens as much as possible (is there a single pill option?) Determining if there is a single pill option, and having practice runs using jelly beans or the client's favorite candy can be keys to success in beginning any ART regimen.

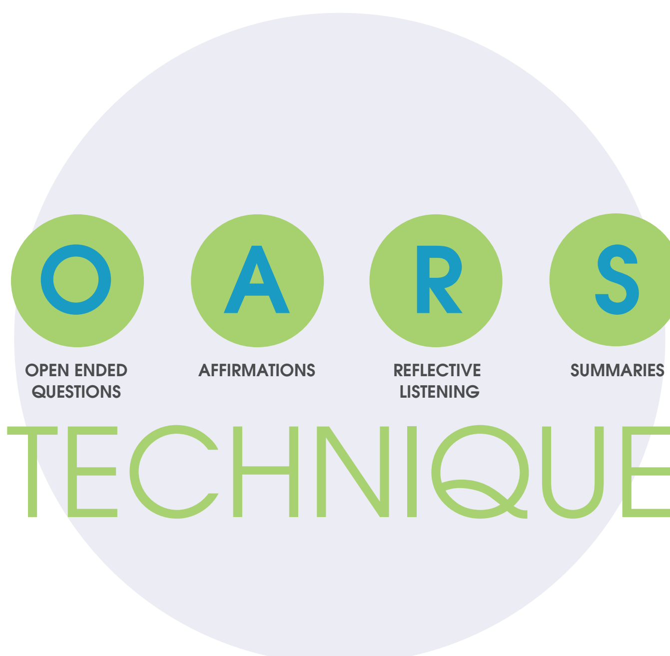
CREATING AN ADHERENCE PLAN

A multidisciplinary approach involving clients, healthcare professionals, family and friends may optimize adherence.

It is very important to remember that there are NO one size fits all adherence plans! Each client is different and their adherence plan should reflect their lifestyle and account for any challenges they may face along the way. Providers should approach creating an adherence plan through client-centered care. The adherence plan is based on the goals of the individual, not simply the provider telling the individual what to do.

Developing an adherence plan should include shared goals and shared decision making between the client and their provider.[8] Providers can help clients to understand that they have choices and provide treatment options. Providers should talk through the options, weigh the pros and cons, and describe both the benefits and risks associated with each option. Individuals should be included in the decision making process, including exploring challenges and identifying what matters most to them as they are ultimately responsible for their own daily adherence.

It is important to assess an individual's understanding of their regimen. Asking whether they understand the regimen is not enough. It is important to use methods such as OARS to learn the true level of an individual's understanding. **OARS stands for: open ended questions, affirmations, reflective listening, and summaries.**



CREATING AN ADHERENCE PLAN

Open ended questions

Open ended questions cannot be answered with a "yes" or "no." These questions often help gather a full understanding of thought processes and ideas.

Affirmations

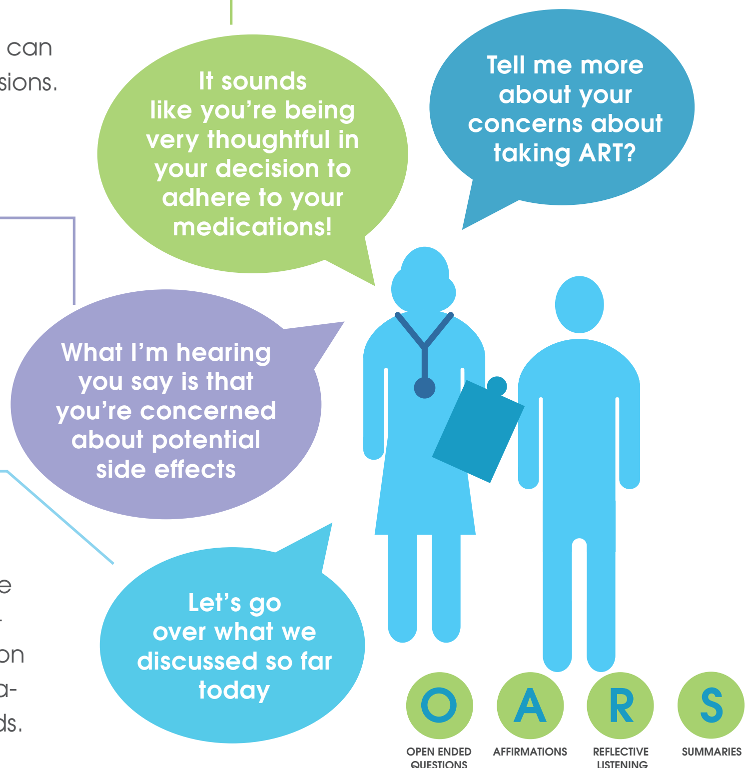
Affirmations are great rapport builders and can help those who are ambivalent make decisions. They must be genuine to be well received.

Reflective listening

Reflective listening involves rephrasing part of what the client said and then stating your understanding of what they said.

Summaries

When creating an adherence plan, it is better if the individual reflects their understanding back to the provider. This gives the provider an opportunity to assess misunderstandings and provide additional information in a summary form. The provider will summarize what the client said in his/her own words.



There are several factors that help improve adherence:

- A client's belief in the efficacy of the medication
- How the client views the associated risks and benefits
- Client skills
- Decreased depression
- Reduced recreational drug use
- Social support[10]

Studies have shown that clients' and providers' views on reasons for medication non-adherence tend to differ.[9] It is important that the provider get a thorough understanding directly from the client since reasons for non-adherence can vary depending on lifestyle, housing situations and substance use, among others.

It's imperative to take time to discuss these individual level and environmental barriers as they relate to your client. This is in addition to providing education around ART, resistance, side effects, and any other concerns the client may have.

ADHERENCE PLAN TEMPLATE

The following template is a helpful guide for creating a client-centered non-judgemental adherence plan for clients who may be facing challenges with adherence:

Questions	Client Response
Acknowledge they have a right to choose NOT to use any medication	
How often do you take your medication?	
How often do you skip or forget your medication?	
What challenges are you facing when taking your medication?	
If you've chosen not to take your medication, what are the reasons?	
Does your schedule change a lot?	
What times do you typically eat each day?	
Are you taking any other medication?	
Do you have a hard time swallowing pills?	
What side effects can you tolerate?	
What happens if ou miss a dose?	

HIV MEDICATION ADHERENCE ASSESSMENT TOOL

It is also helpful to assess clients' beliefs using the constructs of the health belief model: perceived severity of disease, perceived susceptibility, perceived risks, perceived benefits, and self-efficacy. Client responses are key in developing a plan moving forward. The following questionnaire was adapted from the MedDQ tool[11]:

Please circle your answer	Strongly Agree	Agree	Unsure	Disagree	Strongly Disagree
1. My HIV is serious					
2. I am at risk of having health problems related to my HIV					
3. Taking medication helps me avoid health problems related to my HIV					
4. I am confident I can take all my medications.					
5. I know the reason for each of my HIV medications.					
6. I know how and when to take my medications.					
7. I worry about side effects of my medications.					
8. I am afraid to take too many medications.					

9. In the past month, how often did you forget to take one or more of your prescribed medications? (please circle your answer)

	Never	Once in the past month	2 to 3 times in the past month	Once per week	Several times per week	Nearly every day

11. If you missed a dose of any of your medications, it was because …
(check as many as apply; Interviewer: please ask about each item individually)

- ○ Forgot to take it
- ○ Too many medications
- ○ Too confusing
- ○ Costs too much
- ○ Insurance co-pay is too high
- ○ Could not get my medications
- ○ Had unwanted side effects
- ○ Began feeling worse
- ○ Began feeling better
- ○ Scared about the medications
- ○ Want natural remedies
- ○ Other – please describe: ____________________

ART BASICS KNOWLEDGE CHECK

1. **HIV is considered a Retrovirus.**
   a. True (correct answer)
   b. False

2. **One of the goals of HIV Treatment is to:**
   a. Increase viral load as much as possible
   b. Eliminate immune system function
   c. Decrease CD4 cell count as much as possible
   d. Achieve undetectable viral load (correct answer)

3. **The preferred terminology regarding consistency in taking HIV medications is:**
   a. Compliance
   b. Persistence
   c. Adherence (correct answer)
   d. None of the above

4. **Patient and provider views on reasons for not taking HIV medications tend to be closely aligned.**
   a. True
   b. False (correct answer)

5. **According to the guidelines, ART is recommended for all people living with HIV.**
   a. True (correct answer)
   b. False

6. **Undetectable = Untransmittable (U=U) refers to research showing that there is _____ (level) risk associated with unprotected sex with someone with an undetectable viral load.**
   a. Statistically significant
   b. Small
   c. High
   d. Zero (correct answer)

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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.

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