A Training Curriculum for Community Health Workers | HIV Fundamentals

Medication and Treatment Adherence



OBJECTIVES

At the end of this unit, participants will be able to:

- Educate clients about the benefits of antiretroviral therapy and address strategies to optimize adherence
- Discuss the goals of treatment
- Discuss new HIV drugs and the importance of single-tablet regimens
- Discuss the future of HIV medications
- Educate clients about HIV pre-exposure prophylaxis and Undetectable = Untransmittable (U = U)

- 1. Welcome participants.
- 2. Review the unit objectives.
- **3.** Ask participants to complete the worksheet, Medications and Treatment II—Understanding Medicine Options and Treatment individually or in groups. Review correct answers.
- **4.** Review slides on treatment, drug regimens, new drugs, and PrEP (pre-exposure prophylaxis). Slides 3–15.
- 5. Facilitate group quiz activity slides 16–17.
- **6.** Optional: Distribute the Case Scenario handout. Ask for volunteers to read the scenario and discuss case scenario as a group.
- 7. Wrap up. Tell the group we have numerous medications that help people with HIV live longer and HIV is now a chronic disease. As CHWs, helping to inform and educate our clients about the latest treatments is important and encourage them to ask their health care providers about new treatments that could be appropriate for them.



Related C3 Roles

Providing coaching and social support, providing culturally appropriate health education and information, advocating for individuals and communities

Related C3 Skills

Interpersonal and relationship-building skills, communication skills, advocacy skills, education and facilitation skills

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Method(s) of Instruction

Lecture, group activity—worksheet and quiz, case scenario



Estimated time

1.25 hours



Key Concepts

Medication, treatment, antiretroviral therapy (ART), single-tablet regimen (STR), adherence, resistance, undetectable = untransmittable (U = U)

Materials

- Computer with internet access and projector
- PowerPoint slides

Handouts

- Worksheet: Medications and Treatment II—Understanding Medicine Options and Treatment
- Medication and Treatment Case Scenario
- Medications and Treatment II— Understanding Medicine Options and Treatment (Answer Key)

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.... Objectives

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- Strategies to oplinize advective oplinize advectory and address strategies to oplinize advectory and address Discuss the goals of treatment Discuss the HIV drugs and the importance of single-tablet regimens Discuss the future of HIV medications Discuss the future of HIV medications Educate clients about HIV pre-exposure prophylaxis and U=U



Treatment

- Standard Practice DHHS Treatment Guidelines (U.S. Department of Health and Human Services).

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- Antiretroviral therapy (ART) is recommended for ALL individuals with HIV, regardless of CD4 count to reduce morbidity and mortality.
- ART is also recommended for individuals to prevent HIV transmission. It is important to educate clients on: benefits, strategies to increase adherence when starting ART.

SLIDE 1

This session will build upon your knowledge of HIV medication and treatment.

SLIDE 2

Review objectives.

Ask participants to complete the worksheet "Medications and Treatment II— Understanding Medicine Options and Treatment." The worksheet can be completed individually or in small groups. Ask participants for answers; facilitator can review the correct answers if necessary.

SLIDE 3

Review the slide.

There are now more than 25 antiretroviral (ARV) drugs that are FDA approved for the treatment of HIV. Without antiretroviral therapy (ART), most individuals with HIV will progress to AIDS-defining illnesses and premature death. The primary goal of ART is to prevent HIV-associated morbidity and mortality.

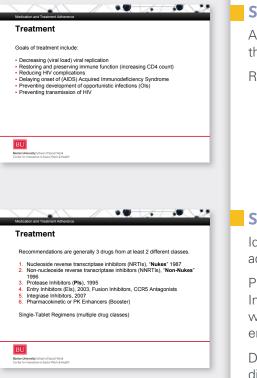
When starting ART, it is important to educate patients about the benefits and considerations of ART, and to address strategies to optimize adherence. On a case-bycase basis, therapy may be deferred because of clinical and/or psychosocial factors, but therapy should be initiated as soon as possible.

Doctors rely on Department of Health and Human Services (DHHS) guidelines that tell them what prescriptions will be most effective. There is an advisory group that determines what medications are most effective to use for first time HIV therapy.

When you look at the preferred regimen on some drug charts you may see A,B,C and roman numerals I, II, III. These symbols identify the rating of recommendations: for example

Rating of Recommendations: A = Strong; B = Moderate; C = OptionalRating 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. Rated based on how the evidence was proven for the drug.

This is useful information because regimens should be individualized based on comorbid conditions, drug-to-drug interactions, pill burden, and dosing frequency (which can be challenging for people who are homeless or who have substance use disorder).



SLIDE 4

Ask participants: "What are the goals of treatment?" Ask participants to share their ideas.

Review the slide by asking for volunteers to read each point.

SLIDE 5

Identify all HIV drug classes along with previous standard recommendations and new advancements in single-table regimens (STRs).

Provide some examples. For instance, Selzentry (maraviroc) is categorized as an Entry Inhibitor. It works by blocking the CCR5 receptor on the surface of the CD4-T cell, which HIV must attach to infect cells in the first place. It stops HIV infection before it enters the cell.

Depending on the drug chart and who publishes it, it may categorize a medication differently.

For example, Fuzeon (enfuvirtide) injection is rarely prescribed, but it may be listed under entry inhibitors or it may be in it's own category. Norvir was first approved as a protease inhibitor, but is often used as a booster.

Antiretroviral drugs have a trade or brand name, generic name and an abbreviation; the drugs all start with a scientific name given during research. For example:

Trade name or brand name: Truvada Generic name: emtricitabine/tenofovir Abbreviation : FTC/TDF (3 character abbreviation)

Trade name or brand name: Tivicay Generic name: dolutegravir Abbreviation: 3 character abbreviation DTG

A Fixed dose IS 2 or more drugs in one tablet, such as Prezcobix.

Single table regimens contain different drug classes—a complete regimen in one pill, such as Triumeq.

Recommendations are generally for 3 drugs from at least 2 different classes; however, a new STR, Juluca has changed the paradigm.



New Ten	ofovir Formulation
	roxal Fumarate (DF) is an NRTI. effects: low bone density, kidney complications rember, 2011.
 Tenofovir Ala 	afenamide (AF) is an NRTI.
	on with fewer bone density and kidney complications
 Approved Nov Game change reformulated. 	rember, 2016. r! Many formulations that contain tenofovir DF have been
 Examples: Co 	mplera, Odefsey, Stribild, Genvoya, Truvada, Descovy

Drug	Dosing Considerations	Side Effects
Atripla	-Must be taken on empty stomach at bedtime -Must consider psychiatric history	Headache, dizziness, fatigue, depression, abnormal dreams, anxiety
Complera	-Must be taken with a 400 calorie meal	Lipid abnormalities, diarrhea, nausea, fatigue
Genvoya	-Must be taken with food -Avoid with poor kidney or liver function	Nausea, diarrhea
Odefsey	-Must be taken with a 400 calorie meal	Lipid abnormalities, diarrhea, nausea, fatigue
Stribild	-Must be taken with food -Avoid with poor kidney or liver function	Nausea, diarrhea, protein in urine, increase in serum creatinine
Triumeq	-Can be taken with or without food -Abacavir: HLA-B 5701 testing required -Avoid with poor kidney or liver function	Headache, insomnia, fatigue

SLIDE 6

This list shows all 3 drug regimens, known as single dose regimens, and their approval dates.

Several of these drugs have been re-formulated and we'll talk about what that means in more detail.

Atripla was the first single table regimen (STR) for awhile before Complera was approved, and now we have quite a few choices.

Preferred HIV medication lists can be found on websites such as AIDSInfo or thebody.com

Single-Tablet Regimens have been successful in extending many lives well beyond 50 years of age; the life span for people with HIV in many cases is the same as the general population; however, with this success other issues exist for those over 50 years of age who have been on these medications long-term.

SLIDE 7

Let's discuss the new tenofovir formulation—tenofovir alafenamide, also known as TAF.

TAF reaches higher levels in cells, meaning lower concentrations in the blood. This allows for less drug exposure to the kidneys, bones, and other organs and tissues. Studies have shown that it is just as effective as the old tenofovir formulation.

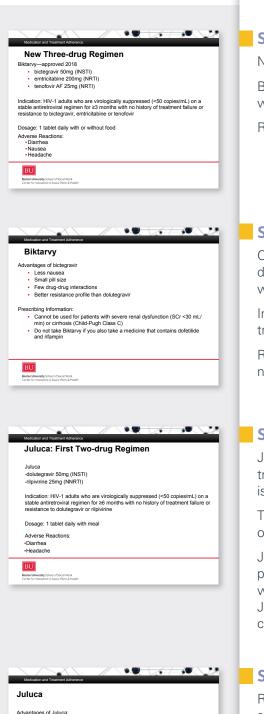
TDF—the old formulation has 300 mg of tenofovir as compared to TAF—the new formulation, with 25 mg of tenofovir

While many of the newer agents are tolerable, long-term side effects (e.g. metabolic and cardiovascular) and drug-drug interactions remain a concern. Young patients faced with the need to be on life-long therapy for upwards of fifty years require agents with safer long-term side effects. The approval of TAF will likely reduce the incidence of bone and renal toxicity; however, long-term data over a lifetime is needed to guide therapy. Many older combinations have been replaced with the new TAF.

SLIDE 8

Let's take a look at some of the single table regimens (STR) regimens.

- Atripla has been known to cause vivid dreams, which is caused by the efavirenz component. Most adverse effects from efavirenz are related to the central nervous system (CNS), such as hallucinations, dizziness, drowsiness, and unusual dreams. This is enhanced with food, so it should be taken on an empty stomach.
- Odefsey and Complera must be taken with high-calorie meals because of the rilpivirine component, which requires a basic environment for absorption.
- If one tests positive for the genetic variation HLA-B 5701, there's a risk of hypersensitivity to abacavir. This reaction affects 5-8% of patients and can be observed during the first 6 weeks of therapy. Symptoms of an abacavir hypersensitivity reaction include skin rash, fever, malaise, gastrointestinal symptoms, and respiratory symptoms. If a person with HIV has a reaction to abacavir, they should not take it again.



Juluca
Advantages of vluca:
 Simplified regimen
 Well tokerated
 Some state tokerated
 Monitor for hepatoloxicity and depressive disorders.
 Co-administration where significant decreases in rilpivirine plasma
 concentrations may occur.

SLIDE 9

Now we will discuss a couple of new drugs that were recently approved by the FDA.

Biktarvy, which was approved in 2018, is composed of two NRTIs as the backbone, with a new integrase inhibitor, bictegravir.

Review the slide.

SLIDE 10

Clinical data show that the regimen's antiviral efficacy, tolerability profile and limited drug interactions offer an effective new treatment option for a range of people with HIV.

In clinical trials through 48 weeks, no patients taking Biktarvy developed what is called treatment-emergent resistance.

Review STR dosing considerations and side effects of the older regimens and the newer agents.

SLIDE 11

Juluca is the first two-drug regimen (integrase and non-nucleoside reverse transcriptase inhibitor) to be approved. Studies have proven that the two-drug regimen is just as effective as the previous standard of care with a three-drug regimen.

The most common side effects are headache and diarrhea, occurring in 2% of patients.

Juluca's safety and efficacy in adults were evaluated in two clinical trials of 1,024 participants whose virus was suppressed on their current anti-HIV drugs. Participants were randomly assigned to continue their current anti-HIV drugs or to switch to Juluca. Results showed Juluca was effective in keeping the virus suppressed and comparable to those who continued their current anti-HIV drugs.

SLIDE 12

Review slide. A simplified regimen provides the option to reduce the number of anti-retrovirals a patient takes, while maintaining the efficacy of a traditional three-drug regimen.

Hepatotoxicity comes from the dolutegravir component and depressive disorder comes from the rilpivirine component.

As mentioned before, rilpivirine requires a basic environment for maximal absorption. It's important for patients to avoid acid-reducing drugs such as proton pump inhibitors and H2 blockers.



The Future of HIV Therapy

- Do clinical trials play a role?
- Cabotegravir and rilpivirine as long-acting injectables
- Dapivirine within a vaginal ring Tenofovir alafenamide as a subdermal implant Studies for use as pre-exposure prophylaxis (F Cimduo* contains lamivudine and tenofovir is (PrEP)

keted as a similar medication to Truvada however, research has not bee tion for use as a PrEP drug. It is also important to know that it is not an e a. An over-the-counter HIV medication online may prove heneficial for a

hool of Social Work

SLIDE 13

It is difficult to determine with the high efficacy, safety, tolerability and the convenience of STRs where and to what extent improvements can be made. However, considering the vast advancements in treatment that have already occurred, it may be naïve to think that the current approach to HIV treatment is the best and only way.

HIV therapy has evolved considerably since the disease was first discovered. Initially, treatment consisted of multiple tablets per day then changed to three-drug single tablet regimens. Now, a recent two-drug regimen has been approved and injectable medications are being studied.

Cabotegravir, an integrase inhibitor, is currently in phase 3 trials. Clinical trials have shown two long-acting injectable antiretrovirals, cabotegravir and rilpivirine, administered once every 4 or 8 weeks, maintained viral suppression in about 90% of people who started therapy with an undetectable viral load. In the study, patients were given injectable ART as a maintenance therapy over 96 weeks once they had achieved viral suppression after 20 weeks of daily oral medication. The potential for a long-acting injectable ART could ease the burden faced by people with HIV of having to take daily oral medication lifelong to manage the disease. Phase 3 trials are ongoing and are needed to confirm the results, and further trials will be needed in wider groups of patients to generalize the findings.

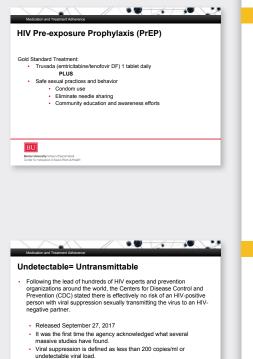
Long-acting cabotegravir and rilpivirine are also being studied for HIV prevention. Cabotegravir injections given every 8 weeks produced high enough drug levels in both men and women to offer protection against HIV, although a larger dose every 12 weeks fell short of this threshold. Rilpivirine did not fare so well as a solo PrEP candidate, failing to consistently reach high levels enough to offer protection against HIV in a phase 1 study. Development of injectable rilpivirine was therefore stopped. Adherence to an HIV regimen gives HIV medicines the chance to do their job: to prevent HIV from multiplying and destroying the immune system.

Taking HIV medication every day prevents HIV from multiplying, which reduces the risk that HIV will mutate and produce drug-resistant HIV.

Tips to help maintain adherence:

- 7-day pill box
- Setting daily pill reminders on a smartphone
- Set up automatic refills at your pharmacy; your medicine will be ready when you need it, and you won't run out

Cimduo, is the first over-the-counter medication and is being marketed to be similar to Truvada, however, research has not been done on this medication for use as a PrEP drug. It is also important to know that it is not an exact formulation of Truvada. An over the counter option may prove beneficial for some.



Medication and Treatment Part 2
Research among people with HIV has shown that Descovy is less toxic to the andthan Truvada. User, Rones Heart, Liver Kidney, Heart
 Which drug is the first two-drug regimen available to the market? a) Biktarvy b) Juluca
Which drug is FDA approved for HIV PrEP? a) Truvada b) Descovy
 True or False. Having an undetectable viral load means the virus is cleared from your system.
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5.	Which drug class is considered the backbone of HiV therapy?
a)	NNRTIs
b)	NRTIs-NUKES
c)	INSTIs
d)	PIs
a)	Which single-tablet regimen must be taken on an empty stomach?
b)	Artipla
c)	Complera
d)	Schibid
7.	Which single tablet regimen must you test for the HLA-B 5701 allele?
a)	Complera
b)	Codefeay
c) d)	Stribild Triumeq U and Usering food 1904 and Usering food 1904

SLIDE 14

Review the slide.

Truvada is FDA approved for adults at high risk for infection. Descovy, which is an updated take on Truvada, is not approved for PrEP. Researchers estimate that many years of clinical trials are yet required before Descovy could be approved as PrEP. The estimated approval date is September of 2020.

To take PrEP, one must be HIV negative upon initiation and get tested every three months.

Take one pill once a day, and if you are exposed, it will prevent HIV. Often used in situations where one person in a couple is living with HIV and the other is not.

SLIDE 15

Undetectable = Untransmittable.

While studies show that HIV is not transmittable even without the use of condoms and PrEP, many doctors still encourage undetectable patients to practice safe sex.

Per Dr. Benjamin Young, MD. PHD Chief Medical officer of the international Association of Providers of AIDS Care, "The scientific evidence is compelling—not a single documented case of transmission by someone who is on effective ART. While it is hard to prove 'zero' risk, the risk of transmission is extraordinarily low."

Visit *www.preventionaccess.org*, or *www.thebody.com* to learn more.

SLIDE 16

End the unit with a quick "teach back" activity. Read the questions and take answers from participants. Review the correct answers.

Answers:

- 1. D
- 2. B
- 3. A
- 4. False

SLIDE 17

Answers:

- 5. B
- 6. A
- 7. D



SLIDE 18

Optional case scenario activity. (Medication and Treatment Case Scenario handout).

If time allows, pass out the case scenario. It can be read by the facilitator or participants. Discuss the questions as a group.

Ask participants if they have any final questions.

To close, note that the consistent need for ARV medications may be the most challenging of all to change. Will broadly neutralizing antibodies, therapeutic vaccines, latency reversing agents, or CRISPR technology ever become routine methods for inhibiting, suppressing, or eliminating HIV? Evidence for these approaches and others continue to emerge and provide optimism that the future may hold a potential cure.

Medication and treatment will always be a subject to explore and discuss until we have a cure for HIV.

SLIDE 19

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Medications and Treatment II: Understanding Medicine Options and Treatment

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Date:

Word Bank

- A. 2 drug regimenB. long-acting injectableC. undetectableD. highly active antiretroviral therapyE. single-tablet regimenF. seven or eightG. HAARTH. stigmaI. undetectableJ. viral loadK. disclose
- Directions: Match terms to the correct letter using the Word Bank.
- 1. _____ What is HAART?*
- HIV medications are grouped into _____ classes or categories according to how they fight HIV.
- **3.** _____ STR's have made combination Antiretroviral Therapy (ART) a simple one pill, once-a-day reality.
- **4.** The goal of therapy is to suppress the virus to ______ levels.
- HAART regimens mainly consist of 3 to 4 drugs from different classes of medications; however, the FDA approved the first _____ November 2017.
- 6. One strategy for making ART simpler and more convenient would be to change the frequency anti-HIV medications need to be taken. Two investigational anti-HIV medications have been developed into ______ (into muscle) forms that maintain high enough levels in the blood to suppress HIV allowing for monthly or every two months dosing.

Medications and Treatment II: Understanding Medicine Options and Treatment - Answers

Name:	Date:

W	ord	Ban	k
			_

A. 2 drug regimenB. long-acting injectableC. undetectableD. highly active antiretroviral therapyE. single-tablet regimenF. seven or eightG. HAARTH. stigmaI. undetectableJ. viral I oadK. disclose

Directions: Match terms to the correct letter using the Word Bank.

- 1. ____D___ What is HAART?*
- HIV medications are grouped into _____F___ classes or categories according to how they fight HIV.
- E_____STR's have made combination Antiretroviral Therapy (ART) a simple one pill, once-aday reality.
- **4.** The goal of therapy is to suppress the virus to _____C or I______ levels.
- HAART regimens mainly consist of 3 to 4 drugs from different classes of medications; however, the FDA approved the first <u>A</u>_____ November 2017.
- 6. One strategy for making ART simpler and more convenient would be to change the frequency anti-HIV medications need to be taken. Two investigational anti-HIV medications have been developed into ____B___ (into muscle) forms that maintain high enough levels in the blood to suppress HIV allowing for monthly or every two months dosing.

Case Scenario

Carmen contracted HIV in March of 2016. Her first lab values indicated that her T- cell count was approximately 600. She still felt good physically; she was living with diabetics but it was also under control. She continued to work but was angry at herself for trusting a new partner and not asking him to wear a condom. Even with suspicions that he may have HIV from reading social media, she never asked him. Carmen was depressed and felt mentally broken.

To make things worse, Carmen's partner blamed her for transmitting the disease to him. Carmen tried ART, but when her 30-day prescription ran out she didn't get it refilled. She told her mother she was done with horse pills and side effects from HIV medicines. Carmen's health spiraled from good to poor: she was not getting out of bed as she was weak and it ached to stand and walk. Carmen stopped working and went on short-term disability. As Carmen's short-term disability was running out she had to seek out help from her doctor for medical care and recommendations. At Carmen's doctor visit he insisted that she meet with a CHW; he introduced her to the CHW after her exam.

- 1. What concerns would the CHW have about Carmen's physical and mental health?
- 2. What questions could the CHW ask Carmen or her doctor during the office visit?
- 3. What medications may not be good options for Carmen?
- 4. Are there barriers or factors that would affect the client's adherence?
- 5. What strategies could the CHW suggest?
- 6. Are there any concerns regarding adherence or resistance?

Acknowledgments

This curricula draws from and is adapted from other training curricula for peer educators and community health workers, such as the Building Blocks to Peer Success (https://ciswh.org/resources/HIV-peer-training-toolkit) and the Community Capacitation Center, Multnomah County Health Department (https://multco.us/health/communityhealth/community-capacitation-center)

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