Adherence, Labs, and Medication Resistance

**OBJECTIVES**

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

- Define what adherence means
- Identify common reasons for adherence challenges
- Brainstorm questions to ask to assess adherence
- List behaviors and/or activities that may indicate non-adherence
- Identify some of the barriers that providers, agencies, and the community at large have built that make it difficult to adhere
- Recognize the types of laboratory tests used to monitor a person’s HIV care and treatment
- Understand why laboratory tests are important in monitoring health and how they can be used to manage care
- Understand the concept of drug resistance
- Understand what types of drug resistance testing are available and when they are used

**INSTRUCTIONS**

1. This section is divided into three topics to be taught in one session with an estimated time of 120 minutes. The facilitator should provide a break for participants.
2. Welcome participants.
3. Review the unit objectives.
4. Play the video “The ART Wall: Antiretroviral Therapy,” which provides an overview of all of the topics to be covered in the session. [https://www.youtube.com/watch?v=1PEisyVjHsl&sns=em](https://www.youtube.com/watch?v=1PEisyVjHsl&sns=em)
5. **Adherence:** Begin by facilitating a group conversation, as detailed in the slides. Review slides about the definition of adherence and factors affecting it. Review handouts and tools.
6. Take a 10-minute break.
7. **Resistance:** Play the video “Stop the Virus—HIV: Avoiding Resistance,” [https://www.youtube.com/watch?v=_H1zLCjZxeE](https://www.youtube.com/watch?v=_H1zLCjZxeE)
8. Review slides about drug resistance testing.
9. **Labs:** Ask participants about the importance of lab visits and review slides. Facilitate lab test activity (in pairs) and then case scenario activity (divide participants into three groups). Slides 33 through 38 are optional.
10. Wrap up. Thank participants for their work. As CHWs educating clients about their lab values is an important step to promoting adherence as part of the HIV care team.

**Related C3 Roles**

Care coordination, case management and system navigation, providing coaching and social support, providing direct service

**Related C3 Skills**

Communication skills, interpersonal and relationship-building skills, knowledge base

**Method(s) of Instruction**

Lecture, brainstorm, pairing, video, group discussion

**Estimated time**

120 minutes

**Key Concepts**

Adherence, viral load, resistance, CD4

**Materials**

All sections
- Computer with internet access and projector
- PowerPoint slides
- Flip chart for case scenario activity

Adherence
- Video: ART Wall [https://www.youtube.com/watch?v=1PEisyVjHsl&sns=em](https://www.youtube.com/watch?v=1PEisyVjHsl&sns=em)
- Adherence tools (e.g., pill boxes, medication watch, pill bottles)
- Sample (unidentified client) lab reports

Handouts
- Ten Questions to Ask Yourself Before You Begin HIV Treatment
- Assessing Adherence: Ten Questions You Should Ask
- Adherence Fact Sheet #405 at [http://www.aidsinfonet.org](http://www.aidsinfonet.org)
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Materials (continued)

Resistance
- Video: Stop the Virus—HIV: Avoiding Resistance at https://www.youtube.com/watch?v=_H1zLcJZxeE

Handouts
- HIV Resistance Testing Fact Sheet #126 at http://www.aidsinfonet.org
- Genosure Sample Test www.monogrambio.com/hiv-tests/genotypic-assays/genosure-prime (click on sample report to obtain copy)

Labs

Handouts
- Lab Worksheet
- Lab Worksheet—Answers
- Normal Laboratory Values, Fact Sheet 120 A/B page 1, at http://www.aidsinfonet.org
- Adherence Case Scenarios
This session will cover three topics—it’s a longer session, so we will take a break.

Review objectives.

First we’ll watch a video, called the ART Wall: Antiretroviral Therapy (ART). [https://www.youtube.com/watch?v=1PEisyVJHsl&sns=em](https://www.youtube.com/watch?v=1PEisyVJHsl&sns=em)

It does a good job of explaining all three topics.

Ask, “How do you define adherence?”
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SLIDE 5

Review the slide.

Engage participants in discussion. Ask, “Has anyone missed or stopped taking a prescribed antibiotic? If so, what were some of the barriers that kept you from finishing the antibiotic? People with HIV are told by providers, family, and friends that they have to take HIV medications every day; however, there are sometimes barriers to doing so. What are they?”

Taking medication daily is often a skill that is learned, especially if you are a person who does not have a history of taking meds. If you don’t take HIV medications every day, HIV might multiply out of control. For the best viral load results, it is recommended that people with HIV should take over 90% of their pills correctly.

Doctors start patients on a preferred regimen from the HHS Guideline Recommendations; provide participants with a current copy (https://aidsinfo.nih.gov).

SLIDE 6

There are many factors that affect adherence. Review the slide. Some barriers to adherence are pictured here.

Ask, “What behaviors may signal non-adherence?”

SLIDE 7

Ask, how do you gauge if a patient is adherent?

Review the slide.

We often don’t ask clients about their readiness to start medications, which is extremely important. It’s important to know if the person you’re working with does not have a history of taking medication, avoids taking medication, has problems swallowing, or other tendencies that would prevent adherence. Once the doctor has prescribed medication and the person is not adherent, they may develop resistance quickly. It has been said that the first regimen is the best regimen, because doctors want patients to have longevity with their first line of prescribed medication.

Let’s take a look at the handout, 10 Questions to Ask Yourself Before You Begin HIV Treatment. Ask participants to take turns reading the questions on the handout.
SLIDE 8
Review the slide and discuss with participants.

SLIDE 9
Review the slide.
Ask, “What are some of the walls or barriers that providers, agencies, and the community at large have built that make it difficult for clients to adhere?”

Some barriers created by organizations can include:
- Clinic hours—time flexibility
- Clinic personnel that do not return calls
- What about enrolling in insurance plans such as Ryan White HIV/AIDS Program (RWHAP), AIDS Drug Assistance Program (ADAP), or ACA (Affordable Care Act)?
- Fear of a clinic employee breaching confidentiality or meeting someone you know.
- Finances—paying for HIV medications
- Transportation—in the case of meds, could a CHW or specialty pharmacy provide help by pick up or mailing?
- Do providers know or refer clients to practical resources they need (e.g. support groups, hot meals, etc.)?
- Can you think of any thing else that providers or agencies can do to help clients be successful in improving adherence?

SLIDE 10
Non-adherence can take many forms. These are more personal causes of non-adherence.

Review the slide.
Optional resource: Adherence Fact Sheet #405 at www.aidsunited.org.
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**SLIDE 11**
This chart shows a high viral load when a person is not taking medication.
Review the legend on the chart:
White—shows drug-susceptible virus
Blue—shows drug-resistant virus
Pink—shows that medication is not being taken properly
Light blue—shows that medications are being taken properly

As you look to the left, there are drug susceptible viruses that can be controlled by taking medication; there are fewer blue resistant virus strains. However, to the right there are a lot of blue drug-resistant viruses in the absence of not taking medication.

**SLIDE 12**
Ask, “What questions would you ask a client if you wanted to assess how adherent they are to their medication regimen?” Refer to handout, Assessing Adherence: Ten Questions You Should Ask.

**SLIDE 13**
Pass around adherence tools (medication watch, calendars, pill bottles, and trays etc.) for in person training. Also review the following:

Adherence and medication go hand in hand. In the past, a huge part of non-adherence was the pill burden for clients (i.e. some taking up to 16 pills a day)—but not anymore. STR or (single-table regimens) have made taking anti-retrovirals easier; today there are so many choices, some of which cause little to no side effects.

Another advance researchers have made is a change in the formulation of one of the most prescribed medications, Truvada. The tenofovir DF (TDF) formulation of Truvada has been decreased from 300mg, which was associated with long-term decreases in bone mineral density and kidney problems in some patients. The new formulation, tenofovir alafenamide, is 25mg and in some medications 10mg; doctors are seeing fewer kidney and bone issues with the TAF formulation compared to TDF in clinical trials.

Explain the concept of **U = U** which stands for Undetectable = Untransmittable.

**Undetectable**: By taking the right HIV medicine every day, one can lower the amount of HIV in the blood to become “undetectable.” This doesn’t mean the client no longer has HIV—it means that by continuing their plan of treatment, they can still have a healthy life with HIV.

**Untransmittable**: People with HIV who take HIV medication daily as prescribed and achieve and maintain an undetectable viral load for at least six months have effectively no risk of sexually transmitting the virus to an HIV-negative partner.

SLIDE 14

Take a 10 minute break.

After the break, ask:

- “What is drug resistance?"
- “What do you think causes drug resistance?”

Allow participants to respond, then review answers on the next slide.

SLIDE 15

Review the slide.

What is drug resistance?

- HIV is “resistant” to a drug if it keeps multiplying rapidly while a person is taking the drug.
- Physical changes (or mutations) in parts of the virus that prevent the medications from working cause resistance.
- HIV mutates almost every time a new copy is made. Not every mutation causes resistance. The “wild type” virus is the most common form of HIV. Anything different from the wild type is considered a mutation. An antiretroviral drug (ARV) won’t control a virus that is resistant to it. It can “escape” from the drug.

What causes resistance?

HIV usually becomes resistant when it is not totally controlled by drugs someone is taking. In short it is caused by:

- Transmitted resistance: about 10% of people who contract HIV are already resistant to one or more ARVs. The person inherited resistance from the person they contracted the virus from
- Missed doses or non-adherence
- Re-infection—condomless sex with a person with HIV.

If a drug does not work against a mutated virus, that virus will reproduce rapidly and viral load increases. A person may then have to change drugs to get HIV under control. HIV drugs are used in combination to block reproduction in the HIV life cycle; however, drug resistance is very common.

SLIDE 16

Play a short video on resistance. https://www.youtube.com/watch?v=_H1zLcJZxeE
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SLIDE 17

Review the slide.

Provide the handout of a GenoSure sample copy of a resistance test for a patient.

Explain that some resistance tests are called GenoSure or PhonoSense tests.

Both tests show if a person has become resistant to HIV medication. In this case, a physician will need to change the patient’s medication regimen.

Tests usually show the word “resistant” or “sensitive” next to the name of the medication. **Sensitive** = patient not resistant to the drug; **Resistant** = patient is resistant to the drug; “resistant possible” means that if the patient continues on the path of not taking the drug properly they will soon develop resistance.

**Genotypic tests** are normally performed at the first lab visit to determine if the person that contracted HIV already has resistance from the person that transmitted the virus to them. Physicians may or may not tell the patient they are performing the test.

**Phenotypic test** is offered after patients have been non-adherent and gone through most HIV medications with multiple resistances to many medications. For the test, HIV medications are in a petri dish and the person’s blood sample is put into each medication slot and allowed to cure overnight. The test is costly but does show the physician which medications a patient can still take that may provide benefit and slow the progress of the disease.

SLIDE 18

Review the slide.

When should drug resistance testing be used?

Genotype tests are generally performed before therapy begins. Phenotypic tests are performed when treatment has failed due to non-adherence.

Being adherent is the best way to prevent drug resistance.

SLIDE 19

Ask, “What are the benefits of keeping lab appointments?”

Allow for participants to answer, then review the slides.
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SLIDE 20

Explain that lab tests are some of the most important ways that clients and their healthcare provider can monitor their health. There are a variety of monitoring tests to help gauge HIV disease progression and the state of overall health for people with HIV.

SLIDE 21

Review the slide.

SLIDE 22

Review the slide.

SLIDE 23

HIV medication helps control HIV by reducing the growth of new virus. HIV medications can be very effective at lowering viral load, which is the amount of HIV in the blood. HIV medications do not cure HIV infection or AIDS.
SLIDE 24
A client’s healthcare provider will order a number of lab tests to help monitor treatment and disease progression. These may include HIV viral load, CD4 cell count, complete blood count (CBC), lipids, glucose, liver and kidney function, and HIV drug resistance.

SLIDE 25
Review the slide.

SLIDE 26
A healthcare provider will order a number of lab tests when a patient is first diagnosed with HIV to determine baseline values; every time they start or switch to new medicines; and to help monitor ongoing treatment.

Most of these tests should be performed regularly, usually every three to six months or whenever the healthcare provider feels it’s appropriate.

SLIDE 27
Ask participants to pair up for a lab practice activity.
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SLIDE 28
Using the Lab Worksheet handout, we will discuss specific monitoring lab tests for people with HIV and explain the significance of why each test is being monitored.

SLIDE 29
Let’s take a look at this Lab Worksheet. You also have it as a handout.

SLIDE 30
Reviewing our labs on the CD4 Test, you see 4 columns:
1. Test Name—identifies the type of procedure performed
2. Result—the patient’s actual result or percent
3. Units—how are the results measured in cells or percent
4. Reference Range—the normal or reference ranges for a person without HIV as compared to the actual result of a person with HIV. The result column will be identified as H for High or L for Low when compared to the patient’s actual result.

Using the Lab Worksheet and the following sample tests:
- CD4
- Blood Chemistry
- Viral load Sample Tests

Identify and write in the lab results for each test on the Lab Worksheet (CD4, VL, Liver, Kidney, Cholesterol, and Glucose). Compare them to the actual result of a person living with HIV. The result column will be identified as H for High or L for Low when compared to the patient’s actual result.

Guide participants as follows:
- Ask, “What is Mr. Doe’s CD4 absolute or count?”
- Answer: 232. Please write 232 on your Lab Activity Sheet beside CD4 Count.
- Is this number considered high or low compared to the reference range?
- What is Mr. Doe’s CD4 Percent?
- Answer: 8%. Please write 8% on your Lab Worksheet beside CD4 Percent.
- Is it low or high compared to the reference range?
- The CD4 Percent is the better indicator for HIV progression for Mr. Doe. The CD4 Percent is not variable; percentages are usually more stable over time than absolute counts.
- CD4 absolute or cell counts often fluctuate due to factors including time of day (levels are usually higher in the morning), fatigue, stress, vaccinations, infections such as flu, and monthly menstrual cycles in women.
Now let’s review the blood chemistry tests. The blood chemistry, or chem panel, measures many important substances in the blood. Although the chem panel does not directly measure HIV disease progression, it can help indicate how well various organs are functioning and provide valuable information about drug side effects.

Find the Glucose, BUN, Creatinine, AST and ALT.

Please write the results of all the procedures beside the name on the Lab Worksheet.

Let’s discuss one at a time:

- Glucose—sugar is carried in the blood in the form of glucose; it’s broken down by cells to provide energy. What is a normal glucose range?
- BUN—(Blood Urea Nitrogen) is a metabolic waste product that is normally filtered out by the kidneys and excreted in the urine. Elevations may indicate kidney dysfunction or a body fluid imbalance (e.g. dehydration).
- Creatinine—waste product of protein metabolism is also normally excreted by the kidneys. Elevation may indicate kidney damage.
- AST—liver muscle disease
- ALT—early detection of liver damage

Viral load test:

- Finally, the viral load test is the most significant. Viral load tests measure the amount of HIV RNA or virus in the blood. The presence of RNA indicates that the virus is actively replicating (multiplying).
- Viral load is expressed as copies of RNA per milliliter of blood (copies/mL) or in terms of logs.
- If the level of HIV is too low to be measured, viral load is said to be undetectable, or below the limit of quantification.
- However, undetectable viral load does not mean that HIV has been eradicated; people with undetectable viral load maintain a very low level of virus. Even when HIV is not detectable in the blood, it may be detectable in the semen, reproductive organs, tissues, lymph nodes, and brain.

Guide participants as follows:

- Ask, “What is this person’s viral load?”
- Answer: 32,030. Please write the results of the HIV-1 RNA, PCR or viral load on the Lab Worksheet.
- Ask, “What is the recommended viral load for patients?
- Answer: Less than 20 or 40 depending on the lab.
- Ask, “What is meant by the term viral suppression?”
- Answer: People who are virally suppressed report a viral load of 200 copies or HIV-1 RNA, PCR or virus in the blood.
- Tell participants that they should work with the client to also identify other tests that may be concerning for the client (e.g. hemoglobin or A1c, cholesterol etc.)

**U = U a new term is Undetectable = HIV Untransmittable**

In September 2017, the CDC (Centers for Disease Control and Prevention) officially supported the medically proven claim that people who are HIV+ and Undetectable and remain consistently undetectable or Virally Suppressed (20–200 copies) cannot transmit HIV to partners who do not have HIV. Nearly 20,000 cases were studied and all HIV negative persons remained HIV negative. (McCray & Mermin, 2017)
Please note: The remainder of the lab slides are optional and do not need to be covered unless further clarification is needed. The lab activity alone reviews material on the remaining PowerPoint slides.

“Normal” values or reference ranges can vary from lab to lab, depending on the equipment and/or testing method used. It is important to compare your results to the range shown on the lab report. The lab results can be low, high, or within normal range.

Test results can be affected by many factors, such as age or gender, the time of day when the sample was taken, active infections, the stage of HIV and food. For example, some test samples need to be taken after a person has fasted for several hours.

If any labs values are too high or too low, encourage your client to discuss the results with their healthcare provider.

HIV viral load is a test that measures the amount of HIV virus in the blood. When used in combination with CD4 cell count results, viral load is extremely useful in determining when to begin and change your HIV therapy.

The goal of HIV therapy is simple: to keep the amount of HIV in the blood as low as possible.

A person’s viral load can measure from less than 20 copies of HIV per milliliter of blood to more than one million copies. Although there is no cure for HIV, when your viral load is below 20 copies/mL, this is known as “undetectable” because the test is not sensitive enough to give a reliable number. Again, as we discussed previously—Undetectable does not mean that the person is cured. You may also see less than 400 copies/mL referred to as undetectable when less sensitive tests are used.

An important goal of HIV therapy is to encourage the client to get their viral load to undetectable.
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SLIDE 36
CD4 cells are an important part of the immune system. Therefore, the CD4 cell count is a key measure of the health of the immune system. The more CD4 cells, the stronger the immune system is and the better able clients are to fight off infections.

Certain factors can cause the CD4 cell count to vary. These include time of day, fatigue, and stress. It’s best to have blood drawn at the same time of day for each CD4 cell test and to use the same laboratory. When the body fights an illness, CD4 counts go up. Vaccinations can cause the same effect. Don’t check CD4 cell count until two weeks after recovering from illness, or immediately after a vaccination.

SLIDE 37
CD4 cell tests are normally reported as the number of cells in a cubic millimeter of blood. Normal counts are between 500 and 1,500. Because CD4 cell counts can vary, some healthcare providers prefer to look at what’s called the CD4 cell percentage. The CD4 cell percentage refers to the proportion of all lymphocytes that are CD4 cells. For example, if your CD4 percentage is 34%, it means that 34% of your lymphocytes were CD4 cells. The normal range is between 20% and 40%.

Anyone who has fewer than 200 CD4 cells or a CD4 percentage of less than 14% is considered to have AIDS.

In closing, understanding labs enables clients to:
- Play an active role in their health care
- Use new knowledge of lab tests and lab values to be a partner with their doctor
- Live a healthier life

SLIDE 38
CASE SCENARIO ACTIVITY: ADHERENCE AND RESISTANCE

(Approximately 20 minutes; 10 for group discussion and 10 for presenting feedback to the larger group).

Divide participants into three groups. There are three scenarios: A, B, and C. Give each group an adherence scenario to read, have them brainstorm as a group and answer the following questions in the assigned group. Write the four questions below on a flip chart. Each group will select a spokesperson who will report the groups’ answers to the class.

1. What questions can the CHW ask the client?
2. Are there barriers or factors that would affect the client’s adherence?
3. What strategies could the CHW suggest?
4. Are there any concerns regarding adherence or resistance?

To close the session, review the following points:
- 90% adherence is the goal and is key to living a long healthy life with HIV.
- Resistance can happen at any time when the virus is not totally controlled by HIV medications; it’s important to keep medical appointments.
- Trends are important; however labs should be viewed over time, not just once to determine medical outcomes.
- Always make sure the lab report you are reading belongs to the correct client.
- Every lab is different, so what may be out of range for one lab may not be for another.
- Encourage clients to use portals or sources like MyChart, if available, so they can review their own labs and request copies prior to or at doctor visits so they can ask questions.
Ten Questions to Ask Yourself Before You Begin HIV Treatment

1. Why do I want to start treatment?
2. Am I ready?
3. Which regimen will still let me live my life?
4. Have I surrendered to the truth that I have HIV?
5. Who will I tell about my regimen?
6. Why this regimen?
7. What side effects am I willing to tolerate?
8. How can I expect to feel on this regimen?
9. What if it doesn’t work?
10. Can I stop?
Assessing Adherence: Ten Questions You Should Ask

1. Which meds are you currently taking?

2. How frequently do you have to take each of your meds?

3. What are the food restrictions for each of your meds (i.e. with or without food)?

4. Why do you think some meds need to be taken with food and some on an empty stomach?

5. Why do you think some meds are taken once a day and others twice a day?

6. What helps you remember to take your meds?

7. What do you do when you miss a dose?

8. What problems have you encountered from taking meds?

9. How soon before you run out of meds do you order refills?

10. Do you believe that the meds are helping you and, if so, how?
Adherence Case Scenarios

Scenario A

Joe is a 32-year-old who started medication 3 weeks ago. The Community Health Worker (CHW) gives Joe a call to see how he has adjusted to his new medication regimen. Joe tells the CHW that he was prescribed Triumeq. He reports that he is taking his medications faithfully, however, Joe said he was worried because he has been experiencing side effects since starting the medication. Joe reports that he has mild stomach cramps, headaches, and diarrhea. He hasn't missed a dose but he switches from morning to night depending on how he feels and if friends are around since he has not disclosed.

1. What questions could the Community Health Workers ask Joe?
2. Are there barriers or factors that would affect the client’s adherence?
3. What strategies could the CHW suggest?
4. Are there any concerns regarding adherence or resistance?

Scenario B

Carmen was diagnosed with HIV in July 1992. Before starting HIV treatment, her T cells were 868 and she was in great shape, but was angry at herself for trusting her partner and not asking him to wear a condom when they had sex. Soon after her diagnosis she told her partner, who blamed her for transmitting HIV; he broke up with her. She felt dirty, thought she was going to die, and insisted on starting her meds. She fell into a depression and began to drink, and soon could not remember when or how to take her meds. She didn't keep her medical appointments and began to feel really sick, coughing uncontrollably and losing weight. Her doctor recently introduced her to a CHW.

1. What questions could the CHW have asked Carmen before she started her meds?
2. Are there barriers or factors that would affect the client’s adherence?
3. What strategies could the CHW suggest?
4. Are there any concerns regarding adherence or resistance?
**Scenario C**

Desiree, a 31-year-old transgender woman living in California, has been HIV positive for 10 years and has yet to take a single HIV medication. Though she has had several conversations with her doctors about the possibility of starting treatment, she has a history of non-adherence and is afraid it will continue if she begins taking HIV meds.

Though Desiree has never been on HIV medications, she has been prescribed both antidepressants and hormones on a long-term basis. Desiree has always had trouble adhering to both of her pill regimens. "I always end up forgetting," she explained. More than merely forgetting, Desiree hates the taste of her pills and feels overwhelmed by the prospect of having to take her medications every day.

"I usually end up thinking how much I don't want to do it. I get concerned that, if I take this now, am I going to feel OK in a few hours to do whatever else I need to do?" she said. With a child to raise and a job to perform, Desiree is fearful every time she takes her meds.

1. What questions can the CHW ask Desiree before she starts a new regimen?
2. Are there barriers or factors that would affect the client’s adherence?
3. What strategies could the CHW suggest?
4. Are there any concerns regarding adherence or resistance?
# Lab Worksheet

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<td>% of CD4’s working</td>
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<td>virus-enemy</td>
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<tr>
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*Lipid test taken less often for clients.
Acknowledgments

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