

Viremia and Vulnerability: HIV, Resistance, and Options

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Overview:

The most effective way to keep HIV at an undetectable level and to increase patients' CD4 counts is to treat patients with a powerful regimen for HIV. Even with the correct antiretroviral therapy (ART) and patient adherence, HIV cannot always be suppressed to an undetectable level. Taking ART daily as directed stops HIV infection from progressing. Stopping and restarting treatment can cause drug resistance to develop, making that treatment regimen ineffective and limiting future treatment options.¹ Several factors contribute to drug resistance: viral mutations, variation in drug absorption and metabolism, nonadherence, and variability in pharmacokinetics. Drug resistance can occur as follows:

- Acquired drug resistance occurs when HIV is able to replicate in a person taking antiretroviral medication. In this setting, the virus can mutate to escape the medication.
- Transmitted HIV drug resistance occurs when a person with HIV who has never received treatment acquires a strain of HIV that is already resistant to one or more medications for HIV.

HIV drug resistance is important because it impacts the ability of HIV to multiply in the presence of drugs that usually kill the virus. HIV drug resistance affects survival and quality of life. While there are currently several medication regimens to treat individuals with HIV infection, once an individual is infected with HIV the virus begins to multiply and often mutates even while the individual is taking the regimens. Regrettably drug-resistant HIV infection can occur in these individuals.²

Some facts about HIV in the United States:

- Approximately 1.2 million people in the United States are infected with HIV today. About 14% of them are unaware they are infected and are likely transmitting HIV to others; these infected individuals require testing for HIV infection.³
- According to Centers for Disease Control and Prevention (CDC) data available in November 2019,

among the estimated 1.1 million people who were infected with HIV at the end of 2016, approximately 65% received HIV medical care, approximately 49% were retained in care, and an estimated 53% achieved the targeted clinical outcome of viral suppression.⁴ Consequently, almost half of the people in the United States are not receiving effective HIV care as evidenced by a lack of viral suppression. This finding is critical since individuals who are virally suppressed have better health outcomes and a lower risk of HIV transmission.⁴

- Vulnerable populations in the era of HIV drug resistance include infants and children, the population with the highest resistance rates; adolescents and young adults, for whom adherence has been challenging; and stigmatized and criminalized populations, which face tremendous social and structural barriers to prevention, treatment and care.⁵

HIV Treatment Options:

Antiretroviral therapy is recommended for all individuals with HIV infection, regardless of CD4 cell count, to consistently suppress viral load (the amount of HIV in the blood), maintain high CD4 cell counts, prevent AIDS, prolong survival, and reduce the risk of transmitting HIV to others.

The following are some of the most common ART medications:

- Nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs). HIV requires an enzyme called reverse transcriptase (RT) in order to convert its RNA into DNA (reverse transcription), a necessary step in replication. NRTIs block RT and prevent HIV from replicating.
- Nonnucleoside reverse transcriptase inhibitors (NNRTIs) also bind to and block HIV RT and prevent

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HIV from replicating.

- Integrase inhibitors. Once HIV has penetrated a CD4 cell, it inserts genetic material into the cell with the assistance of a protein called integrase. These inhibitors block the virus' ability to complete this crucial replication step.

- Entry inhibitors block the virus' ability to enter the cell by blocking various pathways (eg, by blocking attachment, CCR5 [cysteine-cysteine chemokine receptor 5] coreceptor attachment, or cell fusion).

The increased use of HIV therapies has been accompanied by the emergence of HIV drug resistance. HIV drug resistance is caused by changes in the genetic structure of HIV that affect the ability of drugs to block the virus' replication. When resistance occurs, there is loss of viral suppression, loss of effective treatment options, increased ability to transmit HIV, and an increased risk of mortality, thus warranting a call to action.

Patients are often the first to identify potential side effects and toxicities of their ART that may indicate HIV drug resistance. Patients with HIV drug resistance may develop, for example, flulike symptoms and may have a detectable viral load. HIV antiretroviral resistance testing is used to help select a drug regimen that will likely be effective in treating a person with an HIV infection. The blood test is used to determine whether the HIV strain infecting an individual is resistant or has developed resistance to one or more drugs used to treat HIV.

Testing for Drug Resistance

Drug-resistance testing identifies which, if any, HIV medications will not be effective. There are two types of resistance tests: genotype and phenotype. Genotype tests look for drug resistance mutations in relevant genes of the virus whereas phenotype tests measure the ability of a person's virus to replicate in different concentrations of antiretroviral drugs. HIV

Taking antiretroviral treatment daily as directed stops HIV infection from progressing. Stopping and restarting treatment can cause drug resistance to develop, making that treatment regimen ineffective and limiting future treatment options.

Drug Resistance and HIV

As noted in several research studies and programs, drug resistance is one of the markers of failure of HIV treatments. The threat, of course, is not just that an individual patient's treatment will fail clinically but that nonsuppressed patients will be able to transmit the virus.⁵

The following factors lead to HIV mutations, which create resistant virus in HIV-positive patients:

- Poor treatment adherence: Many HIV treatment regimens are complex but need to be taken exactly as directed to drive the maximum therapeutic result
- Poor absorption: Drugs for treatment of HIV infection need to be absorbed effectively into the bloodstream and some of the side effects (eg, diarrhea and vomiting) need to be monitored closely.
- Variability in pharmacokinetics: The drug-drug interaction is, for example, important not only for ARTs but also for other prescribed over-the-counter medications and nutritional supplements.

Signs and Symptoms of HIV Drug Resistance

To determine whether HIV drug resistance has occurred, it is important to consider how a patient feels.

treatment guidelines from the U.S. Department of Health and Human Services recommend testing for all HIV-positive individuals when HIV is first diagnosed, if treatment is failing, and during pregnancy.

Multidrug-resistant HIV occurs when the virus is resistant to multiple different antiretroviral medications. Importantly, patients who develop multidrug-resistant HIV-1 may eventually progress to AIDS and become increasingly susceptible to many opportunistic infections; in addition, multidrug-resistant HIV-1 may lead to disability and even death.

Adherence Considerations

HIV infection is currently treated more as a chronic condition rather than a terminal illness. With appropriate treatment, individuals can expect to live close to a normal lifespan. Therefore, no matter how effective medications might be, adherence is crucially important. Without adequate adherence, these agents are not maintained at sufficient concentrations to suppress HIV replication in infected cells and to lower the plasma viral load. Poor adherence also accelerates the development of drug-resistant HIV.

The consequences of nonadherence to HIV medication are high, and thus we need to identify

HIV-positive individuals who are most at risk for nonadherence to develop appropriate interventions and to determine how to improve their outcomes.

Some of the critical factors that influence adherence are as follows: 1. patient factors (eg, drug use, alcohol use, age, sex, or ethnicity) 2. medication regimen (eg, dosing complexity and number of pills) 3. patient-health care provider relationship; and 4. the system of care.⁶ While we might not be able to eliminate all the barriers to HIV medication adherence, we need to acknowledge their existence. The social determinants of health have impacted patients with HIV. People at risk for or living with HIV may have a different baseline of economic, housing, and insurance stability, especially in the wake of the COVID-19 pandemic. A recent National Academy of Sciences report suggests that up to 70% of health outcomes stem from socioeconomic factors, physical environment, and access to health care.⁷

Stigma Management and HIV

Few illnesses have been as stigmatized around the globe as HIV infection, and social stigma is one of the most significant factors associated with improper adherence.⁸ Several stigma-related factors contribute to improper HIV treatment adherence, including discriminatory behavior directed at the LGBTQIA+ (lesbian, gay, bisexual, transgender, queer or questioning, intersex, and asexual or allied) communities, especially when patients from these groups encounter discriminatory behavior where they receive care. Combatting stigma, discrimination, and violence against sexual and gender minorities requires action at many levels and across many sectors.⁹

U=U: Undetectable = Untransmittable

This is not just an HIV treatment and prevention campaign slogan but rather a strategic plan backed by science. The journal *Science* chose the HPTN 052 clinical trial, an international HIV prevention trial, as the 2011 Breakthrough of the Year. According to Anthony S. Fauci, MD, the Director of National Institute of Allergy and Infectious Diseases (NIAID), “The HPTN 052 study convincingly demonstrated that antiretroviral medications can not only treat but also prevent the transmission of HIV infection among heterosexual individuals.”¹⁰ Two additional studies, PARTNER and Opposites Attract, reinforced the conclusion that HIV is not transmitted sexually when the partner living with HIV has a sustained undetectable viral load. These studies also extended the finding to male-male couples.¹¹

Simply put, the main goal of treatment for patients with HIV infection is to reduce their viral load to an undetectable level. Individuals with undetectable viral loads do not transmit HIV to partners. If they can't transmit HIV, the stigma goes down and their quality of life goes up. Research supported by NIAID demonstrated that achieving and maintaining a “durably undetectable” viral load not only preserves the health of the person living with HIV infection but also prevents sexual transmission of the virus to an HIV-negative partner. Viral loads will drop to an undetectable level in ≤ 6 months for most individuals who take their HIV medication daily as prescribed.¹²

While U=U may be the gold standard in HIV treatment, undetectable does not mean that the virus does not exist. Combination ART has decreased morbidity and mortality among HIV-positive individuals. The U.S. Department of Health and Human Services HIV Guidelines recommend ART for all HIV-positive individuals with the goal of virologic suppression to improve clinical outcomes, to reduce HIV transmission, and to prevent the development of antiretroviral resistance.¹³

V=V: Viremia = Vulnerability

Low level viremia (HIV-1 RNA between 51–200 and 201–500 copies/mL) was strongly associated with virologic failure.¹⁴ These findings provide support for the current U.S. Department of Health and Human Services definition of virologic failure as persistent viremia >200 copies/mL.¹³ In addition, findings also suggest that patients with low level viremia (<200 copies/mL) are at increased risk for virologic failure and may benefit from increased clinical monitoring and intervention.¹⁴ Ongoing viral replication in patients receiving ART promotes the selection of drug-resistance mutations. As mutations accumulate, the likelihood that patients will have fewer future drug options increases, as do the risks associated with other consequences of viremia (including immunologic failure and, potentially, clinical progression). In addition, inadequate suppression of viremia compromises future treatment options, regardless of the level of ongoing viremia.¹⁴

Treatment

The main goal of HIV ART is to have a viral load that is “undetectable” (<50 copies/mL). If the viral load is increasing or genotype testing shows resistance, treatment options must be explored. Treatment options may include a different ART regimen or different doses of medications.

One treatment option is TROGARZO[®], a monoclonal antibody. In combination with other antiretrovirals, TROGARZO[®] is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection whose current ART regimen is failing. TROGARZO[®] binds to the surface of T cells to block HIV-1 from entering. In a clinical study, TROGARZO[®] was proven to have a significant and long-lasting impact on HIV-1 in the body by reducing or “lightening” the viral load. Studies also showed that patients who achieved an undetectable viral load were able to maintain an undetectable viral load over time.

TROGARZO[®] is administered intravenously as a single loading dose of 2,000 mg followed by a maintenance dose of 800 mg every 2 weeks after dilution in 250 mL of 0.9% Sodium Chloride Injection, USP. The duration of the first infusion is typically no less than 30 minutes and, if no adverse reactions

Lactation

The CDC recommends that HIV-1-infected mothers in the United States avoid breastfeeding their infants to prevent postnatal transmission of HIV-1 infection. Because of the potential for HIV-1 transmission, instruct mothers not to breastfeed if they are receiving TROGARZO[®].

Pediatric Use

The safety and effectiveness of TROGARZO[®] in pediatric patients have not been established.

Geriatric Use

No studies have been conducted with TROGARZO[®] in geriatric patients.

Clinical Studies

Trial TMB-301 was a single arm, multicenter clinical trial conducted in 40 heavily treatment-experienced HIV-1-infected subjects with multidrug resistant HIV-1. Subjects were required to have a viral load >1,000

The increased use of HIV therapies has been accompanied by the emergence of HIV drug resistance. HIV drug resistance is caused by changes in the genetic structure of HIV that affect the ability of drugs to block the virus' replication.

occur, subsequent infusions can be decreased to no less than 15 minutes.

CONTRAINDICATIONS: TROGARZO[®] is contraindicated in patients with a prior hypersensitivity reaction to TROGARZO[®] or any components of the product.

WARNINGS AND PRECAUTIONS: Immune reconstitution inflammatory syndrome has been reported in patients who were treated with combination ARTs.

ADVERSE REACTIONS: The most common adverse reactions (incidence $\geq 5\%$) were diarrhea, dizziness, nausea, and rash.

The following are considerations for use of TROGARZO[®] in specific populations:

Pregnancy:

No adequate human data are available to establish whether TROGARZO[®] poses a risk to pregnancy outcomes. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to TROGARZO[®] during pregnancy. Health care providers are encouraged to register patients by calling the Antiretroviral Pregnancy Registry at 1-800-258-4263.

copies/mL and documented resistance to at least one antiretroviral medication from each of three classes of antiretroviral medications as measured by resistance testing. Subjects had to have been treated with antiretrovirals for at least 6 months and had to be failing or had to have recently failed (ie, in the last 8 weeks) therapy.

Most subjects in the trial were male (85%), White (55%), and between 23 and 65 years old (mean [standard deviation] age: 50.5 [11.0] years). At baseline, median viral load was 35,350 copies/mL and CD4+ T cell counts were 73 cells/mm³. The subjects were heavily treatment-experienced: 53% of participants had been treated with 10 or more antiretroviral drugs before trial enrollment; 98% had been treated with NRTIs, 98% with protease inhibitors, 80% with NNRTIs, 78% with INSTIs, 30% with glycoprotein 41 fusion inhibitors, and 20% with CCR5 coreceptor antagonists.

The primary efficacy endpoint was the proportion of subjects achieving a $\geq 0.5 \log_{10}$ decrease in viral load from the beginning to the end of the “functional monotherapy period” as compared with the proportion of subjects achieving a $\geq 0.5 \log_{10}$

decrease from the beginning to the end of the “control period.”

Significant findings showed:

- TROGARZO® significantly reduced viral load within 7 days after the first dose of functional monotherapy and maintained the treatment response when combined with an optimized background regimen that included at least one other active ART for up to 24 weeks of treatment, while being safe and well tolerated.
- More than 80% of patients achieved the study’s primary endpoint—at least a 0.5 log₁₀ viral load reduction from baseline 7 days after receiving a 2,000-mg loading dose of TROGARZO® and no adjustment to the failing background regimen.
- The average viral load reduction after 24 weeks was 1.6 log₁₀, with 43% of patients achieving undetectable viral loads.
- Patients experienced a clinically significant mean increase in CD4+ T cells of 44 cells/mm³, and

management plan should be developed by the case manager in collaboration with the patient and other members of the health care team. Using the principles and guidance included in Standards of Practice from the Case Management Society of America, the process is defined as follows:

“...Case Management is a collaborative process of assessment, planning, facilitation, care coordination, evaluation and advocacy for options and services to meet an individual’s and family’s comprehensive health needs through communication and available resources to promote patient safety, quality of care, and cost-effective outcomes...”¹⁶

The case manager should ensure that clients begin medical care and develop an ongoing relationship with a physician trained to provide continuous and comprehensive HIV specialty care. With client approval, case managers should exchange information regularly with the client’s health care provider.

The case management plan should focus on edu-

In combination with other antiretrovirals, TROGARZO® is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection whose current antiretroviral therapy regimen is failing.

increases varied based on the T-cell count at baseline. Rebuilding the immune system by increasing T-cell counts is particularly important because individuals with multidrug resistant HIV-1 often have the most advanced form of HIV-1 infection.

For complete prescribing information for TROGARZO® including full patient information and patient instructions, please read the product insert.¹⁵

Case Management:

The treatment barriers and impact of HIV drug resistance underscore an urgent need for case management for individuals diagnosed with HIV infection, especially those who are exhibiting HIV drug resistance. As a case manager, it is vital to identify patients who are not virally suppressed or those who are at risk of losing viral suppression. In addition, barriers to treatment should be identified and patients should be provided with resources and solutions, including a referral to a health care provider for possible resistance testing and changes to the treatment regimen. The goals for case management need to be aligned with those expressed by the client; an in-depth assessment and development of a case

ating the client, family, and support network to recognize HIV drug resistance, improve patient adherence to their medication regimen, and educate the client about treatment options for HIV drug resistance.

In addition to assisting clients to access and maintain specific services, case management activities may include negotiation and advocacy for services, consultation with providers, navigation through the health care delivery system, psychosocial support, supportive counseling, and general client education.

Specific attention should be given to clinical laboratory monitoring of the viral load and CD4 T-cell count as well as compliance with medical appointments. Treatment adherence support is an ongoing process, which may change with client needs, goals, and identified problems. The goal of any treatment adherence intervention is to provide clients with the skills, information, and support to follow mutually agreed upon goals and objectives to achieve optimal health outcomes; these outcomes are achieved by following evidence-based treatment adherence recommendations.

Case managers should start conversations with patients during each encounter in a supportive and

nonjudgmental manner to encourage trust and facilitate opportunities for teachable moments. Patients should also be able to understand the potential negative consequences of nonadherence to HIV treatment regimens such as increased mortality, morbidity, and, of course, the risk of transmitting HIV to others.

Because of the significant barriers that patients face regarding ART adherence (eg, personal or cultural beliefs, cognitive abilities, health status including comorbidities), the following strategies are recommended:¹⁷

- When discussing patient beliefs and behaviors, explain the importance of consistent adherence to the HIV treatment regimen even when the viral load is undetectable
- When addressing cognitive barriers, provide information about available tools (eg, pill boxes, dosing alarms on phones)
- When addressing comorbid conditions, review all medications, offer to help communicate with other medical providers, and consider drug-to-drug interactions
- To assist with psychosocial barriers, offer referrals for housing, substance-abuse programs, and peer support programs¹⁷

Although there have been substantial improvements in ART, HIV drug resistance continues to be a challenge for clients and health care providers. Monitoring and education are key to managing HIV drug resistance. Case managers play an important role in educating and supporting the client and health care team. ■

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Viremia and Vulnerability: HIV, Resistance, and Options

Questions

- 1. The aim of HIV antiretroviral therapy is to keep the virus at an undetectable level.**
 - a. True
 - b. False
- 2. Factors contributing to HIV drug resistance include:**
 - a. Viral mutation
 - b. Nonadherence
 - c. Variation in drug absorption and metabolism
 - d. All of the above
- 3. According to the CDC, what percentage of individuals who were infected with HIV at the end of 2016 achieved the target outcome of viral suppression?**
 - a. approximately 53%
 - b. approximately 62%
 - c. approximately 68%
 - d. approximately 72%
- 4. Antiretroviral therapy for HIV-infected patients has the following outcomes:**
 - a. Suppresses the viral load
 - b. Maintains high CD4 cell counts
 - c. Reduces the risk of transferring HIV to others
 - d. All of the above
- 5. Viral load is the amount of HIV in the blood.**
 - a. True
 - b. False
- 6. Which of the following are signs and symptoms of HIV drug resistance?**
 - a. Flulike symptoms
 - b. Detectable viral load
 - c. A genotype test detecting drug resistance
 - d. All of the above
- 7. Factors that influence drug adherence include:**
 - a. Patient factors
 - b. Medication regimen
 - c. Patient-health care provider relationships
 - d. All of the above
- 8. Treatment options for HIV drug resistance include a different antiretroviral therapy regimen such as TROGARZO® or a different dose of medication.**
 - a. True
 - b. False
- 9. In a clinical trial with TROGARZO®, what percentage of patients achieved the study's primary endpoint 7 days after receiving a loading dose?**
 - a. >50%
 - b. >60%
 - c. >70%
 - d. >80%
- 10. The case management plan for patients with HIV drug resistance should include:**
 - a. Educating the patient about the signs and symptoms of HIV drug resistance
 - b. Encouraging HIV medication adherence
 - c. Educating the patient about options in HIV treatment
 - d. All of the above

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Objectives

January 2021

- a. State the goal of HIV antiretroviral therapy.
- b. List the signs and symptoms of HIV drug resistance.
- c. State the goals of case management for patients with HIV drug resistance.

Answers

Please indicate your answer by filling in the letter:

1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____ 7. _____ 8. _____ 9. _____ 10. _____ 11. _____ 12. _____ 13. _____

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