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Guest Editors: Kaylee Carlson and Shaikh Nayab Samin, Pharm.D. Candidates 2023; Wesley T. Lindsey, Pharm.D.; Bernie R. Olin, Pharm.D.,

Key Inforbits

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What is HIV?

HIV is an infection caused by human immunodeficiency virus (HIV). By attacking a certain type of white blood cell (WBC) called CD4 helper T-cells, this virus impairs the body's immune system.[1] The immune system's ability to fight against opportunistic infections, which can be bacterial or fungal, is weakened when these CD4 cells are destroyed. Currently, there is no cure for HIV however, the disease can be controlled with appropriate treatment.

https://www.cdc.gov/hiv/basics/syndication-

https://www.cdc.gov/hiv/basics/syndication-test.html

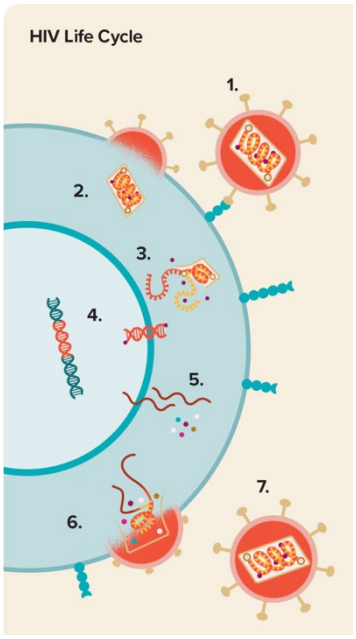
From whence came HIV?

HIV infection was first spread to humans from chimpanzee in Central Africa.[2] According to research, HIV may have spread from chimpanzees to people as far back as the late 1800s. HIV spread slowly across Africa and then into other areas of the world over decades. The virus has been known to exist in the United States since the mid to late 1970s.

HIV pathophysiology[3]

HIV is a single-stranded RNA retrovirus which causes the host's CD-4 helper T-cell (aka CD4 T lymphocyte) of the immune system to multiply and spread throughout the body. CD4 T-cell is a type of white blood cell

(WBC) which helps to protect the body against infection. The viral copies of HIV burst through the CD4 cell membrane and destroys the CD4 helper T-cell decreasing CD4 count and increasing viral load.

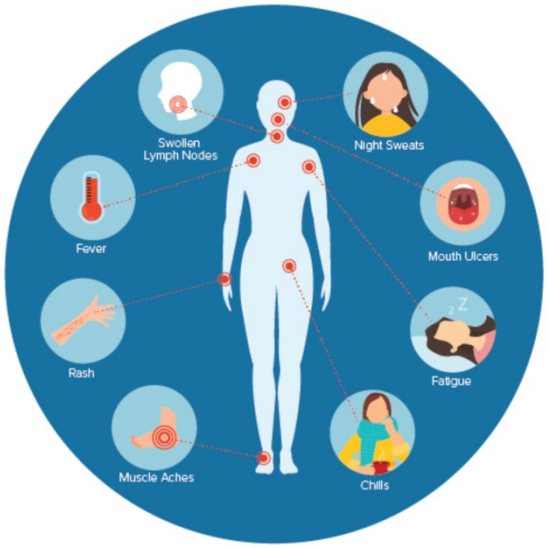


https://www.healthline.com/health/hiv-life-cycle

There are seven stages of the HIV life cycle: **1) Binding** (HIV binds to the receptor of CD4 cell), **2) Fusion** (HIV envelope and CD4 cell membrane join allowing HIV to enter the CD4 cell), **3) Reverse transcription** [HIV releases and uses reverse transcriptase (an HIV enzyme) to convert its genetic material known as HIV RNA to HIV DNA. This conversion allows HIV to enter the CD4 cell nucleus and combine with the cell's genetic material], **4) Integration** [HIV releases integrase (an HIV enzyme) inside the CD4 nucleus]. HIV uses integrase to insert its viral DNA into the DNA of the CD4 cell], **5) Replication** (Once integrated into the CD4 cell DNA, HIV begins to use the machinery of the CD4 cell to make long chains of HIV proteins. The protein chains are the building blocks for more HIV), **6) Assembly** [New HIV proteins and HIV RNA move to the surface of the cell and assemble into immature (noninfectious) HIV], and **7) Budding** [Newly formed immature (noninfectious) HIV pushes itself out of the host CD4 cell. The new HIV releases protease (an HIV enzyme). Protease breaks up the long protein chains in the immature virus, creating the mature (infectious) virus].

HIV Transmission

The virus is spread by direct contact with blood, semen, vaginal secretions, rectal secretions, and breast milk. Most infections are caused by unprotected vaginal and rectal sex, and sharing injection drug equipment, including needles. Infection can spread from a woman with HIV to her child during pregnancy, childbirth, or breastfeeding. This is called mother-to-child or vertical transmission.



https://www.cdc.gov/hiv/basics/syndication-test.html

Stages of HIV:

There are three stages of HIV.[3]

1. **Acute:** Earliest stage of HIV infection which generally develops within 2 to 4 weeks after infection. Some people have flu-like symptoms, such as fever, headache, and rash. In this stage, HIV multiplies rapidly and spreads throughout the body. The virus attacks and destroys the infection-fighting CD4 cells (CD4 T lymphocyte) of the immune system. The level of HIV in the blood is very high increasing the risk of HIV transmission. A person may experience significant health benefits if they start Antiretroviral Therapy (ART) during this stage.

2. **Chronic:** This is the second stage of HIV infection (also called asymptomatic HIV infection or clinical latency). Between 14 to 28 days after exposure, by around day 14, the virus will begin to stop multiplying rapidly and multiplies at very low levels. Although some people can experience Acute Retroviral Syndrome (ARS) symptoms for up to three months, most people will start feeling better within two weeks, as the immune system gradually brings the infection under control with the exception of lymphadenopathy which may continue for months or even longer. The chronic stage of infection occurs once the immune system brings the virus under control. During this phase, HIV will go into hiding, where it resides in various cells and tissues throughout the body in a dormant state known as latency. HIV latency can persist without symptoms for 10 years or more, although some people may experience signs within a year or two.[4] Patients may not have any HIV-related symptoms. Without ART, chronic HIV infection usually advances to AIDS in 10 years or longer, and in some people it may advance faster. People who are taking ART may be in this stage for several decades. While it is still possible to transmit HIV to others during this stage, people who take ART exactly as prescribed and maintain an undetectable viral load have effectively no risk of transmitting HIV to an HIV-negative partner through sex.
3. **AIDS:** If HIV is not treated appropriately, it can advance to the final and most severe stage of infection known as AIDS (acquired immunodeficiency syndrome). Because HIV has severely damaged the immune system, the body cannot fight off opportunistic infections. Opportunistic infections are more common in people with weakened immune systems. People with HIV are diagnosed with AIDS if they have a CD4 count of less than 200 cells/mm^3 or if they have certain opportunistic infections. In AIDS, patients have high viral load and are able to transmit HIV to others very easily. Without treatment, people with AIDS typically survive about 3 years.

Diagnosis:[5]

1. Antibody tests: Checks for HIV antibodies in blood or oral fluid. HIV antibodies are disease-fighting proteins that the body produces in response to HIV infection. Most rapid tests and home use tests are antibody tests.
2. Antigen/antibody tests: Detects both HIV antibodies and HIV antigens (a part of the virus) in the blood.
3. Nucleic Acid Tests (NATs): Checks for HIV in the blood.

AIDS-Defining Conditions[6]

Opportunistic infections that are more common or more severe due to immunosuppression are known as AIDS-defining conditions. These mostly comprise opportunistic infections, but they also include certain cancers and diseases with no known alternative causes that are believed to be linked to uncontrolled HIV infection itself, such wasting or encephalopathy. Examples of AIDS-defining conditions are represented in table 1.

Table 1: Acquired immune deficiency syndrome (AIDS)-defining conditions[6]

Recurrent Bacterial infections	Pneumocystis carinii pneumonia (PCP)	Chronic Intestinal	Wasting syndrome attributed to HIV	Mycobacterium tuberculosis

Extrapulmonary cryptococcus	Toxoplasmosis of brain	Isosporiasis	Invasive cervical cancer	Progressive multifocal leukoencephalopathy
HIV related encephalopathy	Candidiasis of bronchi, trachea, or lungs	Mycobacterium Avium Complex (MAC)	Chronic Intestinal cryptosporidiosis	Extrapulmonary coccidioidomycosis
Primary lymphoma of the brain	Candidiasis of esophagus	Recurrent pneumonia	Kaposi Sarcoma	Cytomegalovirus disease
Cytomegalovirus retinitis	Disseminated or extrapulmonary	Recurrent Salmonella septicemia		

Opportunistic Infections (OI)[7,8]

Opportunistic Infections typically only occur in patient who are immunosuppressed for variety of different reasons. The main culprit here is due to HIV and progression to AIDS. These opportunistic infections are some of the main causes of mortality in patients with AIDS.

Table 2: Bacterial Opportunistic Infections

Opportunistic Infection	Clinical Presentation:	Treatment:
Pneumocystis jirovecii pneumonia (CD4<200)	Progressive dyspnea, fever, non-productive cough, chest discomfort	**Mild-Mod:** TMP-SMX 2 DS tab PO TID x 21 days **Mod-Sev:** TMP-SMX TMP (15-20 mg and SMX 75-100 mg)/ kg/day IV Q6-8h x 21 days
	Prophylaxis:	
	CD4<200 or CD4% <14%: TMP-SMX 1 DS tablet PO daily or three times weekly	
Mycobacterium avium complex (CD4<50)	**Clinical Presentation:** Fever, abdominal pain, weight loss, diarrhea, night sweats, fatigue, multi-organ, disseminated infection	Clarithromycin 500 mg BID + Ethambutol 15 mg/kg/day -Add a 3rd or 4th drug as an alternative regimen: Rifabutin or Aminoglycoside or Fluoroquinolone [if CD4 count < 50 cells/mm3, high mycobacterial loads (>2 log CFU/mL), absence of effective ART] **Treatment duration: 1 year**
	Prophylaxis:	
	CD4<50 and not on fully suppressive ART: Azithromycin 1,200 mg PO weekly OR 600 mg PO twice weekly OR Clarithromycin 500 mg PO BID	

TMP-SMX: trimethoprim-sulfamethoxazole

Table 3: Fungal Opportunistic Infections

Opportunistic Infection	Clinical Presentation:	Treatment
Coccidioidomycosis (CD4<250):	Focal pneumonia, diffuse pneumonia, extrathoracic involvement (meningitis, osteoarticular infection), or asymptomatic **Prophylaxis:** (-) serologic test: Not recommended (+) serologic test: Fluconazole 400mg daily	**Mild-Mod pulmonary:** Itraconazole 200 mg PO TID x3 days then 200 mg BID OR fluconazole 400 mg PO daily **Severe pulmonary:** Liposomal amphotericin B 3-5 mg/kg IV daily and Amphotericin B 0.7 to 1.0 mg/kg IV daily **Meningitis:** Fluconazole 400mg to 800 mg IV/PO daily
Histoplasmosis (CD4<150)	**Clinical Presentation:** Fever, fatigue, weight loss, hepatosplenomegaly; 50% of patients: cough, chest pain, and dyspnea **Prophylaxis:** If CD4 <150: Itraconazole 200 mg PO daily	**Mild to moderate:** Itraconazole 200 mg PO TID X 3 days then 200 mg PO BID X 12 months **Moderate to severe/progressive disseminated:** Liposomal amphotericin B 3 mg/kg/day X 2 weeks (or until clinically improved) followed by Itraconazole 200 mg PO TID X 3 days then 200 mg PO BID X 12 months
Blastomycosis (CD4<150)	**Clinical Presentation:** Asymptomatic in 50% of cases; Primarily infects lungs, skin, bone & joint; Fever, chills, productive cough (similar to flu or respiratory infection) **Prophylaxis:** Not recommended	**Patients with mild to moderate infection**: Itraconazole 200 mg PO TID X 3 days then 200 mg PO BID X 12 months **Moderate to severe/CNS disease:** Liposomal amphotericin B 3-5 mg/kg/day X 1- 2 weeks followed by itraconazole 200 mg PO BID for 12 months
Toxoplasmic encephalitis (CD4<150)	**Clinical Presentation:** **Focal:** Headache, confusion, motor weakness, and fever **Non-focal:** non-specific headache and psychiatric symptoms **Prophylaxis:** **Toxoplasma IgG (-):** Not recommended	**Acute treatment (all PO):** Pyrimethamine 200 mg x1 dose followed by body weight dosing: **≤60kg:** pyrimethamine 50 mg daily + sulfadiazine 1000 mg Q6H + leucovorin 10-25 mg daily (can increase to 50 mg QD or BID) **>60kg:** pyrimethamine 75 mg daily + sulfadiazine 1500 mg Q6h + leucovorin 10-25 mg daily (can increase to 50mg QD or BID) for at

	Toxoplasma IgG (+) and CD4 <100: TMP-SMX 1 DS PO daily or three times weekly	least 6 weeks followed by maintenance. **Maintenance:** Pyrimethamine 25-50 mg daily + sulfadiazine 2000-4000 mg daily (in 2-4 divided doses) + leucovorin 10-25 mg PO daily **UNTIL** CD4>200 for 6 months on ART and remained asymptomatic
Cryptococcal meningitis or pneumonia (CD4<50)	**Clinical Presentation:** **Meningoencephalitis:** Headache, fever, N/V, altered mental status, neck stiffness, irritability, photophobia **Pneumonia:** Cough, rales, shortness of breath **Prophylaxis:** Not recommended	**Induction therapy:** Liposomal amphotericin B 3-4 mg/kg IV daily with flucytosine 25 mg/kg PO QID X at least 2 weeks, followed by PO fluconazole (maintenance therapy) **Maintenance therapy:** Fluconazole 400-800 mg PO daily X 8 weeks then 200 mg PO daily X 6-12 months

Table 4: Antiretroviral Therapy (ART)[9]

Medication Class	Mechanism of Action	Medication Names
Nucleoside Reverse Transcriptase Inhibitors (NRTI) **Prodrugs**	-Competitively inhibits binding of natural nucleotides and inserts into DNA chain resulting in premature chain termination -Inhibits RNA and DNA dependent DNA polymerase activities of reverse transcriptase	Tenofovir Alafenamide (TAF) Tenofovir disoproxil fumarate (TDF) (Viread) Emtricitabine (Emtriva) Lamivudine (Epivir) Abacavir (Ziagen) Zidovudine (Retrovir)
Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)	-Binds to reverse transcriptase and creates a hydrophobic pocket proximal to the active site. This pocket creates a new spatial configuration of the substrate-binding site to reduce the overall polymerase activity and slow DNA synthesis. -Not effective for HIV-2.	Rilpivirine (Edurant) Etravirine (Intelence) Doravirine (Pifeltro) Efavirenz (Sustiva) Nevirapine (Viramune)
Integrase Strand Inhibitors (INSTI)	-Prevents HIV integrase from incorporating pro-viral DNA into the human host cell, thus inhibiting the HIV-catalyzed strand transfer step.	Dolutegravir (Tivicay) Bictegravir Cabotegravir (Vocabria) Elvitegravir (Vitekta) Raltegravir (Isentress)
Protease Inhibitors (PI)	-Prevents the cleavage of Gag and Gag-Pol polyprotein yielding immature, noninfectious virus formation	Darunavir (Prezista) Atazanavir (Reyataz)

		Lopinavir/Ritonavir (Kaletra)
Pharmacokinetic Enhancers	**Cobicistat**: an inhibitor of CYP3A which increases the systemic exposure of CYP3A substrates in order to boost concentration levels. **Ritonavir:** a CYP3A4 inhibitor used to increases the plasma concentrations of other 3A4 substrates to increase ART efficacy.	Cobicistat (Tybost) Ritonavir (Norvir)
Entry Inhibitors	**Fostemsavir (prodrug):** binds directly to the gp120 subunit within the HIV-1 envelope glycoprotein gp160 and selectively inhibits the interaction between the virus and cellular CD4 receptors, thereby preventing attachment. Additionally, temsavir, the active metabolite of Fostemsavir, can inhibit gp120-dependent post-attachment steps required for viral entry into host cells. **Maraviroc:** a chemokine receptor antagonist that blocks the CCR5 receptor. The antiviral mechanism of action of maraviroc is exclusively CCR5-mediated by preventing the interaction of HIV-1 glycoprotein (gp) 120 and CCR5 necessary for CCR5-tropic HIV-1 to enter cells. It is inactive against the CXCR4 receptor and does not inhibit dual-tropic HIV-1 entry **Ibalizumab:** a recombinant monoclonal antibody directed to domain 2 of CD4 T-cells, blocking HIV-1 from entering the cell by interfering with post-attachment steps; it also prevents viral transmission via cell-to-cell fusion.	Fostemsavir (Rukobia) Maraviroc (Selzentry) Ibalizumab (Trogarzo)

Table 5: Pre-exposure and Post-exposure prophylaxis

Pre-exposure prophylaxis (PrEP)[10]	**Who is at risk of acquiring HIV:**	**Treatment:**
	Sexually active adults and adolescents who have had anal or vaginal sex in the past 6 months and: -HIV positive partner -Bacterial STI in past 6 months -History of inconsistent or no condom use **Persons who inject drugs and:** -HIV positive injecting partner -Sharing injection equipment	-Truvada (TDF/emtricitabine) OR Descovy (TAF/emtricitabine) daily for at least 3 months -Patients should continue PrEP for as long as the risk continue
Post exposure prophylaxis (PEP)[11]	**Should only be used as an emergency for patients within 72 hours of a possible exposure to HIV:** -Possible exposure to HIV during sex -Shared drug needles or other equipment -Sexually assaulted -Possible exposure to HIV at work	TDF/emtricitabine once daily PLUS raltegravir twice daily or dolutegravir once daily Take for 28 days

Table 6: Guideline Recommended Treatment[12]

Group	Treatment Recommendations	Key:
Most people with HIV	**INSTI + 2 NRTIs:** -BIC/TAF/FTC -DTG/ABG/3TC [if HLA-B*5701 (-)] -DTG + TAF or TDF + FTC or 3TC	**INSTI:** Integrase Inhibitors **BIC:** bictegravir **DTG:** dolutegravir **EVG:** elvitegravir **RAL:** raltegravir **NRTI:** nucleoside reverse transcriptase inhibitors **TAF:** tenofovir alafenamide **TDF:** tenofovir disoproxil fumarate **FTC:** emtricitabine **3TC:** lamivudine **PI:** Protease inhibitors **DRV:** darunavir **ATV:** atazanavir **c:** cobicistat **r:** ritonavir **NNRTI:** non-nucleoside reverse transcriptase inhibitors **DOR:** doravirine **EFV:** efavirenz **RPV:** rilpivirine
Most people with HIV if VL <500,000, HBV negative, resistance testing completed	**INSTI + NRTI:** -DTG/3TC	
Certain clinical situations	**INSTI + 2 NRTIs:** -EVG/c/(TAF or TDF)/FTC -RAL/(TAF or TDF)/(FTC or 3TC) **Boosted PI + 2 NRTIs:** -DRV/(r or c)/(TAF or TDF)/(FTC or 3TC) -ATV/(r or c)/(TAF or TDF)/(FTC or 3TC) -DRV/(r or c)/ABC/3TC **NNRTI + 2 NRTIs:** DOR/TDF/3TC or DOR/TAF/FTC EFV/(TAF or TDF)/(FTC or 3TC)	
Certain clinical situations if VL <100,000 and CD4 >200	**NNRTI + 2 NRTIs:** RPV/(TAF or TDF)/FTC	
Regimens when ABC, TAF, TDF should not be used if VL <500,000, HBV negative, resistance testing completed	DTG/3TC	
Regimens when ABC, TAF, TDF should not be used if VL <100,000 and CD4 >200	DRV/r +RAL twice a day	
Regimens when ABC, TAF, TDF should not be used	DRV/r daily + 3TC	

Goals of Therapy:

1. Prevent HIV transmission
2. Suppress HIV viral load (<200 copies/mL)
3. Restore and maintain immunologic function (CD4 >200 cells/mm^3)
4. Reduce morbidity and mortality

Key Counseling Points

- All-or-None: Ensure patients are taking their full regimen at all times. Never take a partial regimen, in order to prevent resistance.
- Always tell patients to inform their doctors about their HIV and medication in order to prevent drug interactions and treatment failure.
- Patients taking an INSTI should avoid cation containing products such as iron-containing multivitamins, calcium carbonate or other antacids, iron supplements, or dairy products.
- Patients taking a PI or pharmacokinetic enhancer should take their medications with food.
- Patients must adhere to their regimens and avoid missing more than 2 doses a month.

Vaccine Recommendations in HIV patients[13]

Patients with HIV are at an increased risk of diseases due to chronic immunosuppression from the HIV virus. Due to this immunosuppression, patient with HIV are indicated for vaccinations earlier in life than patients without HIV. However, live vaccinations pose too high of a risk and should be avoided in patients with HIV.

All CD4 counts:

Quadrivalent Inactivated Influenza Vaccine (IIV4) or Recombinant Inactive Influenza Vaccine (RIV4) (Ages ≥ 6 months)

- 1 dose annually

Tetanus-diphtheria (Td) or Tetanus-diphtheria-pertussis (Tdap) (11 and older)/ **Diphtheria-Tetanus-Pertussis (DTap)** (Ages 2 months to < 7 years)

- DTaP: 5 doses of DTaP. One dose at each of these ages: 2, 4, 6 months, 15-18 months, and 4-6 years. Td or Tdap: 1 dose every 10 years. At least one Tdap.

Hepatitis A (Ages ≥ 12 months)

- 2-dose series Hep A 6 months apart

Hepatitis B (All ages)

- Adults: 2-dose (Heplisav-B) or 3-dose (Engerix-B, Recombivax HB) series or 3-dose series HepA-HepB (Twinrix)
- Pediatrics: 3-dose series at age 0, 1–2, 6–18 months (monovalent Hep B vaccine recommended for doses administered before age 6 weeks)

Recombinant Zoster Vaccine (RZV) (Ages ≥ 19 years)

- 2 doses 2-6 months apart

Human Papillomavirus (HPV) (Ages 9-26)

- 3-dose series, even for those who initiate vaccination at age 9 through 14 years

Meningococcal (MenACWY) (Ages 2 months and older)

- 2-dose series at least 8 weeks apart every 5 years

Haemophilus Influenzae Type b (Hib) (Ages 12 months and older)

- Pediatrics: Age 12–59 months unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart; 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose; Unvaccinated [less than routine series (through age 14 months) or no doses (age 15 months or older)] persons age 5–18 years: 1 dose

Pneumococcal conjugate or polysaccharide (≥ 2 months)

- Adults: 1-dose PCV20 or PCV15 followed by PPSV23 1 year later.
- Pediatrics: 2 doses of a pneumococcal conjugate vaccine (either PCV13 or PCV15) if unvaccinated or received an incomplete pneumococcal conjugate vaccine series with <3 doses before 24 months of age. 2nd dose at least 8 weeks after the first.; OR 1 dose of PCV13 or PCV15 if they received 3 doses of a pneumococcal conjugate vaccine before 12 months but have not received their fourth booster dose; OR 2 doses of PPSV23 after the pneumococcal conjugate vaccine series is complete. 1st dose at least 8 weeks after any prior pneumococcal conjugate vaccine dose, then 2nd dose of PPSV23 at least 5 years after the first PPSV23 dose.

Inactivated Poliovirus Vaccine (IPV) (Ages ≥ 2 months)

- Pediatrics: 4 doses of polio vaccine. One dose at each of the following ages: 2 months, 4 months, 6 through 18 months, 4 through 6 years.

Only patients with HIV and CD4 >15% or >200 mm^3

Measles-Mumps-Rubella (MMR) (Ages ≥ 12 months)

- 2 dose series at least 4 weeks apart

Varicella (Ages ≥ 12 months)

- 2 dose series at least 3 months apart

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What's New?

These are some highlights of the new therapies that have been recently approved and some that are still investigational, undergoing studies for their approval.

- **Cabenuva (cabotegravir and rilpivirine)[14]**
  - First and only long-acting injectable treatment for HIV-1
  - Approved for patients 12 years and older who are virally suppressed (VL <50 copies/mL)
  - Dose: Cabotegravir 200 mg/mL and rilpivirine 300 mg/mL 2 3mL IM injections monthly or every 2 months

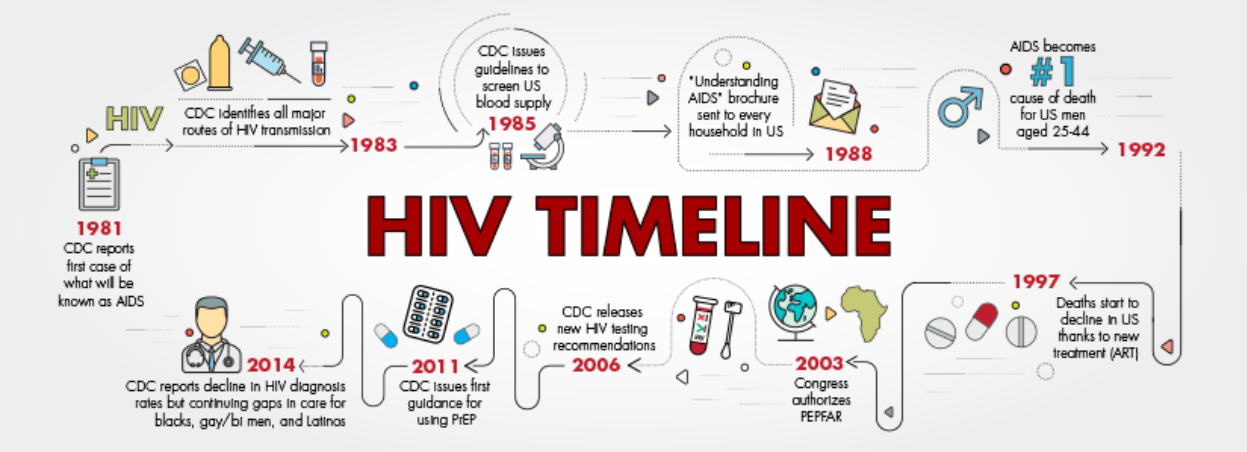
- **HIVACAT T-cell immunogen (HTI) for Patients with HIV[15]**
  - Currently being studied (not FDA approved)
  - Used to treat HIV rather than preventing it.
  - It strengthens the immune system of the host by teaching the T-cells of the host to attack a specific part of the HIV that allows it to make copies of itself.

- In one small study of 45 patients, 40% of those who received it were able to stay off of ART for 22 weeks.

- **Lenacapavir**[15]
  - Investigational injectable HIV medication
  - Administered every 6 months
  - Viral capsid inhibitor prevents HIV from multiplying

- **Islatravir**[15]
  - Investigational drug under clinical trial
  - A NRTTI (nucleoside reverse transcriptase translocation inhibitor)
  - A weekly pill that prevents HIV from multiplying

- **HIV Vaccines Trials**
  - eOD-GT8 60mer (mRNA-1644)[16]
    - A germline-targeting priming vaccine candidate
    - Broadly neutralizing antibodies (bnAbs) which can protect against HIV inducing VRC01-class immunoglobulin G (IgG) B cell responses
    - Underwent Phase 1 clinical trial (IAVI G001), randomized placebo-controlled trial with 48 HIV-uninfected, healthy adult volunteers
    - Primary end points were the occurrence of adverse events, and the secondary endpoint was induction of eOD-GT8 60mer-specific, eOD-GT8 monomer-specific and CD4-binding-site (CD4bs)-specific serum binding antibody responses



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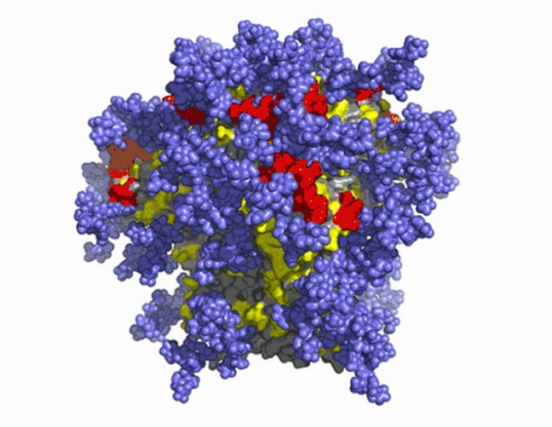
The last "dose" …

"AIDS today is not a death sentence. It can be treated as a chronic illness or a chronic disease."

-Yusuf Hamied [Chairman of Cipla (a generic pharmaceuticals company), 1936-Present]

Health Professional with a Question? Drugs – Therapeutics – Pharmacy Practice?
Please contact us. We can help resolve your issue.
Please call **344-844-4400** Monday-Friday 8:00 to 5:00 pm (some holidays excepted)
or visit our website, 24/7 at: http://pharmacy.auburn.edu/di/



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