Updates on Human Immunodeficiency Virus (HIV)

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Updates on Human Immunodeficiency Virus (HIV)

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Objectives

- Provide an overview on HIV/AIDS
- Review current antiretroviral treatment strategies
- Recognize recently approved and emerging pipeline agents for the treatment of HIV
- Summarize the most recent guideline updates for the treatment of HIV/AIDS
- Discuss the role of the pharmacist in the treatment of HIV
Abbreviations

- **AIDS** – Acquired Immune Deficiency Syndrome
- **ART** – Anti-Retroviral Therapy
- **CD4** – Cluster of Differentiation 4
- **CDC** – Centers for Disease Control and Prevention
- **CCR5** – CC Chemokine Receptor 5
- **GP120** – Glycoprotein 120
- **HIV** – Human Immunodeficiency Virus
- **INSTI** – Integrase Strand Transfer Inhibitor
- **MOA** – Mechanism of Action
- **MSM** – Men who have Sex with Men
- **NNRTI** – Non-Nucleoside Reverse Transcriptase Inhibitor
- **NRTI** – Nucleoside Reverse Transcriptase Inhibitor
- **PEP** – Post-Exposure Prophylaxis
- **PI** – Protease Inhibitor
- **PrEP** – Pre-Exposure Prophylaxis
- **STD** – Sexually Transmitted Disease
- **STR** – Single Tablet Regimen
- **VL** – Viral Load
HIV attacks the body’s immune system, specifically the CD4 cells (T cells).

HIV interferes with the body's ability to fight infection, making a person more vulnerable to other diseases.

The outlook for people living with HIV has significantly improved over the past two decades.

Without treatment, HIV infection is likely to develop into AIDS as the immune system gradually wears down.
Course of HIV

- **Initial Infection**
  - Asymptomatic
  - 4th generation assay (-)

- **Acute Antiretroviral Syndrome**
  - 1-4 weeks post-exposure, Lymphadenopathy, fever, rash, fatigue, myalgias, pharyngitis
  - High VL, drop CD4
  - HIV antigen (+); 4th generation assay (+)

- **Clinical Latency**
  - Begins ~ 6 wks. post infection
  - HIV sets up viral reservoirs, seroconversion has occurred
  - HIV antibody (+)

- **Clinically apparent disease**
  - AIDS symptoms may not appear for a decade or more

Source: Centers for Disease Control and Prevention
Risk of Exposure

Portal of entry + Contaminated body fluid = Risk of HIV Transmission

HIV is NOT transmitted by...

- Insect bites
- Toilet seats
- Kissing
- Sharing cutlery
- Touching

Source: Centers for Disease Control and Prevention. https://cghealth.com/topics/hiv-testing/
Transmission

Source: Centers for Disease Control and Prevention
HIV Testing:
- 4th generation antigen/antibody combination test
  - Highly infectious acute stage
- p24
  - Newly infected individuals

AIDS Diagnosis:
- A positive test for HIV antibodies or antigen and one or more of the following:
  - CD4 T cells <200 (or CD4 percentage <14%),
  - Any of the 25 “AIDS defining conditions”

Source: US DHHS. Guidelines for Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents. 2019
Diagnosis

OraQuick HIV Test

- In-vitro diagnostic home-use test
- Pain-free testing with oral fluid
- Detects HIV infection if used 3 months after a risk event

Source: US DHHS. Guidelines for Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents. 2019
Approximately 1.1 million people in the U.S. are living with HIV today.

About 15% of them are unaware they are infected.

An estimated 39,000 Americans became newly infected with HIV in 2016.

Gay, bisexual, and other MSM bear the greatest burden by risk group.
- 26,000 of new HIV infections per year.

Source: Centers for Disease Control and Prevention
In 2017, 38,739 people received an HIV diagnosis in the U.S.

New HIV Infections by Race and Transmission Group, U.S. 2010 vs. 2016:

- African American gay and bisexual men: 9,800 (2010), 9,800 (2016)
- Latino gay and bisexual men: 6,400 (2010), 8,300 (2016)
- White gay and bisexual men: 6,700 (2010), 8,000 (2016)
- African American heterosexual women: 4,700 (2010), 4,000 (2016)
- People who inject drugs: 2,700 (2010), 1,900 (2016)
- African American heterosexual men: 2,300 (2010), 1,800 (2016)
- White heterosexual women: 1,200 (2010), 1,000 (2016)
- Latino heterosexual women: 1,000 (2010), 980 (2016)

HIV in the U.S.

Source: cdc.gov/HIV/statistics/overview/geographic distribution
HIV in Florida

HIV Diagnoses by Year of Diagnosis, 2009–2018, Florida
10 year % change (2009–2018) = 5% decrease

Persons Living with HIV (PLWH) in Florida along the HIV Care Continuum in 2018

Source: cdc.gov/nchhstp/stateprofiles/pdf/florida_profile
End the HIV Epidemic: A Plan for America

Key strategies:

- **Diagnosing** all individuals with HIV as early as possible after infection.
- **Treating** HIV rapidly and effectively after diagnosis to achieve sustained viral suppression.
- **Protecting** individuals at risk for HIV using proven prevention approaches.
- **Responding** rapidly to detect and respond to growing HIV clusters and prevent new infections.

Source: https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview
**A Plan for America**

**GOAL:**
- 75% reduction in new HIV infections in 5 years
- and at least 90% reduction in 10 years.

- **Diagnose** all people with HIV as early as possible after infection.
- **Treat** the infection rapidly and effectively to achieve sustained viral suppression.
- **Protect** people at risk for HIV using potent and proven prevention interventions, including PrEP, a medication that can prevent HIV infections.
- **Respond** rapidly to detect and respond to growing HIV clusters and prevent new HIV infections.
- **HIV HealthForce** will establish local teams committed to the success of the Initiative in each jurisdiction.

Source: https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview
True or False

Antiretroviral therapy is recommended for all HIV positive patients regardless of CD4 count to reduce morbidity, mortality, and transmission.
Antiretroviral therapy is recommended for all HIV positive patients regardless of CD4 count to reduce morbidity, mortality, and transmission.
Rapid ART initiation, including starting ART on the same day as HIV diagnosis, can lead to improved clinical outcomes.

Transmission of HIV Infection in 2016

<table>
<thead>
<tr>
<th>Percentage of People with HIV</th>
<th>Status of Care</th>
<th>Accounted for x% of New Transmissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>15%</td>
<td>Didn’t know they had HIV</td>
<td>38%</td>
</tr>
<tr>
<td>23%</td>
<td>Knew they had HIV but weren’t in care</td>
<td>43%</td>
</tr>
<tr>
<td>11%</td>
<td>In care but not virally suppressed</td>
<td>20%</td>
</tr>
<tr>
<td>51%</td>
<td>On medications for HIV and virally suppressed</td>
<td>0%</td>
</tr>
</tbody>
</table>

Source: Centers for Disease Control and Prevention
**HIV Life Cycle**

1. **Binding (also called Attachment):** HIV binds (attaches itself) to receptors on the surface of a CD4 cell.
   - CCR5 Antagonist
   - Post-attachment inhibitors

2. **Fusion:** The HIV envelope and the CD4 cell membrane fuse (join together), which allows HIV to enter the CD4 cell.
   - Fusion inhibitors

3. **Reverse Transcription:** Inside the CD4 cell, HIV releases and uses reverse transcriptase (an HIV enzyme) to convert its genetic material—HIV RNA—into HIV DNA. The conversion of HIV RNA to HIV DNA allows HIV to enter the CD4 cell nucleus and combine with the cell's genetic material—cell DNA.
   - Non-nucleoside reverse transcriptase inhibitors (NNRTIs)
   - Nucleoside reverse transcriptase inhibitors (NRTIs)

4. **Integration:** Inside the CD4 cell nucleus, HIV releases integrase (an HIV enzyme). HIV uses integrase to insert (integrate) its viral DNA into the DNA of the CD4 cell.
   - Integrase inhibitors

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.

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.
   - Protease inhibitors (PIs)

Source: [https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/19/73/the-hiv-life-cycle](https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/19/73/the-hiv-life-cycle)
True or False

The initiation of a regimen containing two non-nucleoside reverse transcriptase inhibitors (NNRTIs) is common and recommended in HIV patients.
The initiation of a regimen containing two non-nucleoside reverse transcriptase inhibitors (NNRTIs) is common and recommended in HIV patients.
Therapy

NNRTI
- Efavirenz (EFV) - SUSTIVA
- Rilpivirine (RPV) - EDURANT
- Etravirine (ETR) - Intelen
- Doravirine (DOR) - Pifeltro

INSTI
- Dolutegravir (DTG) - TIVICAY
- Raltegravir (RAL) - ISENTRESS
- Elvitegravir(EVG) - VITEKTA
- Bictegravir (BIC)

2 NRTIS
- Abacavir (ABC)/Lamivudine (3TC) - EPZICOM
- Tenofovir Disoproxil fumarate (TDF)/Emtricitabine (FTC) - TRUVADA
- Tenofovir alafenamide (TAF)/Emtricitabine (FTC) - DESCOVY

BOOSTED PI
- Darunavir with Ritonavir (DRV/r) - PREZISTA/NORVIR
- Atazanavir with Ritonavir (ATV/r) - REYATAZ/NORVIR
- DRV/COBI - PREZCOBIX
- ATV/COBI - EVOTAZ
Therapy

- Integrase inhibitor based regimens are recommended for most patients.

<table>
<thead>
<tr>
<th>Agent</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dolutegravir</td>
<td>• Few drug interactions</td>
<td>• Co-formulated with abacavir and lamivudine</td>
</tr>
<tr>
<td></td>
<td>• Single-tablet formulation</td>
<td>• Risk of neural tube defects</td>
</tr>
<tr>
<td></td>
<td>• Higher barrier to resistance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• May be use during pregnancy</td>
<td></td>
</tr>
<tr>
<td>Bictegravir</td>
<td>• Few drug interactions</td>
<td>• Lack of data in pregnancy</td>
</tr>
<tr>
<td></td>
<td>• Single-tablet formulation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Higher barrier to resistance</td>
<td></td>
</tr>
<tr>
<td>Raltegravir</td>
<td>• Few drug interactions</td>
<td>• Not available as a single-tablet formulation</td>
</tr>
<tr>
<td></td>
<td>• Preferred ARV in pregnancy</td>
<td>• Lower barrier to resistance</td>
</tr>
<tr>
<td>Elvitegravir</td>
<td>• Single-tablet formulation</td>
<td>• Lower barrier to resistance</td>
</tr>
<tr>
<td></td>
<td>• Can be used for rapid ART start</td>
<td>• Avoid in pregnancy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• (inadequate drug levels in the 2nd/3rd trimesters)</td>
</tr>
</tbody>
</table>

Single Tablet Regimen

- **Biktarvy** - bictegravir/emtricitabine/TAF (INSTI + 2 NRTIs)
- **Triumeq** - abacavir/dolutegravir/lamivudine (INSTI + 2 NRTIs)
- **Atripla** - efavirenz/tenofovir/TDF (NNRTI + 2 NRTIs)
- **Stribild** - elvitegravir/cobicistat/emtricitabine/TDF (boosted INSTI + 2 NRTIs)
- **Genvoya** - elvitegravir/cobicistat/emtricitabine/TAF (boosted INSTI + 2 NRTIs)
- **Complera** - emtricitabine/ rilpivirine/ TDF (NNRTI + 2 NRTIs)
- **Odefsey** - emtricitabine/ rilpivirine/ TAF (NNRTI + 2 NRTIs)
- **Symfi** - efavirenz/lamivudine/TDF (NNRTI + 2 NRTIs)
- **Symtuza** - darunavir/cobicistat/emtricitabine/ TAF (boosted PI + 2 NRTIs)
Among a sample of HIV patients, incidence of comorbidities increased (2003 to 2013):

- Hypertension rose from 11.6% to 25%
- Hyperlipidemia rose from 9.5% to 21.9%
- Diabetes rose from 6.4% to 9.4%

Must consider the patient’s entire medical history when recommending or prescribing ART.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Consider Avoiding</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dementia</td>
<td>Efavirenz</td>
<td>Potential overlap of symptoms</td>
</tr>
<tr>
<td>Opioid dependence</td>
<td>Efavirenz</td>
<td>May precipitate withdrawal</td>
</tr>
<tr>
<td>Cardiovascular (CV) Risk</td>
<td>Abacavir, lopinavir/ritonavir</td>
<td>Increased CV risk</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>Boosted protease inhibitors, efavirenz, elvitegravir/cobicistat, tenofovir disoproxil fumarate (TDF)</td>
<td>Increased lipids</td>
</tr>
</tbody>
</table>

Source: Insights and Developments in HIV Treatment Strategies. Presentation. Las Vegas 2019
### Individualized Treatment

<table>
<thead>
<tr>
<th>Condition</th>
<th>Consider Avoiding</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic kidney disease (CrCl ≤ 60 mL/min)</td>
<td>Tenofovir disoproxil fumarate (TDF) unless end stage renal disease (ESRD)</td>
<td>Risk of proximal renal tubulopathy</td>
</tr>
<tr>
<td>Cirrhotic liver disease</td>
<td>Abacavir, Symfi®(efavirenz/lamivudine/TDF), atazanavir, darunavir, elvitegravir</td>
<td>Not recommended in severe liver disease</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>Tenofovir disoproxil fumarate (TDF)</td>
<td>Risk of decreasing bone mineral density</td>
</tr>
<tr>
<td>Psychiatric illness</td>
<td>Efavirenz, rilpivirine</td>
<td>Possible exacerbation of symptoms / suicidal risk</td>
</tr>
</tbody>
</table>

Source: Insights and Developments in HIV Treatment Strategies. Presentation. Las Vegas 2019
New Agents

Recently approved ART and agents in the pipeline:

- Doravirine
- Cabotegravir/rilpivirine
- Broadly neutralizing antibodies
- Ibalizumab
- Fostemsavir
Doravirine

MOA:
- Non-nucleoside reverse transcriptase inhibitor

Dose:
- 100 mg orally daily

Adverse Effects:
- Fatigue, nausea, headache

Points to consider:
- Concern with neuropsychic and lipid abnormalities
- STR: Delstrigo (TDF + 3TC + DOR)

Ibalizumab

MOA:
- Binds to CD4 and interferes with post-attachment

Dose:
- 2000 mg intravenous (IV) loading dose
- 800 mg IV every 14 days

Adverse Effects:
- Infusion reactions, rash, dizziness, diarrhea

Points to consider:
- Monoclonal antibody
- For use in salvage therapy
- Miss dose > 3 days, restart cycle with loading dose

Body Neutralizing Antibodies (BNAbs)

- Passive immunity
- Use alone or a combination
- Instant protection
- Must be regularly “re-dosed” to maintain protection

BNAbs trials could be an important step toward designing an HIV vaccine.
Lerinomab (PRO140)

MOA:
- Humanized monoclonal antibody that blocks entry via CCR5 binding

Likely place in therapy:
- Salvage, switch after oral

Points to consider:
- Weekly subcutaneous (subQ) injections
- High viral rebound at various doses
**Pipeline Agents**

**UB-421**

**MOA**
- Broadly neutralizing monoclonal antibody targeting CD4 binding

**Likely place in therapy:**
- Treatment failure

**Points to consider:**
- Weekly or 2 times weekly subQ injections
Pipeline Agents

Fostemsavir

MOA:
- Attachment inhibitor binds to GP 120

Dose:
- 600 mg orally twice daily

Adverse effects:
- Nausea, diarrhea, immune reconstitution inflammatory syndrome (IRIS), fatigue

Likely place in therapy:
- Salvage

Source: DHHS AIDSInfo https://aidsinfo.nih.gov/drugs/508/fostemsavir/0/professional

<table>
<thead>
<tr>
<th>Randomized cohort (n=272)</th>
<th>Non-randomized cohort (n=99)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 1 fully active ARV agent but cannot construct viable regimen w/remaining agents</td>
<td>No remaining ARV classes and no fully active approved ARV agents</td>
</tr>
<tr>
<td>Failing regimen + fostemsavir versus</td>
<td>Fostemsavir added to optimized background; investigational drugs ok</td>
</tr>
<tr>
<td>Failing regimen + placebo</td>
<td></td>
</tr>
<tr>
<td>HIV &lt; 40 copies/mL: 60%</td>
<td>HIV &lt; 40 copies/mL: 37%</td>
</tr>
</tbody>
</table>
Cabotegravir/rilpivirine

MOA:
- Integrase strand transfer inhibitor + non-nucleoside reverse transcriptase inhibitor

Dose:
- 30 mg/25 mg orally daily for 4 weeks, then 400/600 mg intramuscularly (IM) monthly

Adverse effects:
- Nausea, injection site reaction, fatigue, pyrexia

Likely place in therapy:
- Under study for treatment naïve patients and PrEP

Pipeline Agents

**Cabotegravir/rilpivirine**

<table>
<thead>
<tr>
<th>Population</th>
<th>Criteria</th>
<th>48 week outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FLAIR</strong></td>
<td><strong>Treatment naïve</strong> &lt;br&gt; - HIV RNA &gt; 1000 c/mL  &lt;br&gt; - HBSAg (-)</td>
<td>All started abacavir/lamivudine/</td>
</tr>
<tr>
<td></td>
<td>- No NNRTI mutations</td>
<td>dolutegravir first, then randomized to continue (n=283) versus switch to CAB/RPV (n=283)</td>
</tr>
<tr>
<td><strong>ATLAS</strong></td>
<td><strong>Treatment experienced</strong> &lt;br&gt; - PI, NNRTI, or INSTI based regimen with 2 NRTIs</td>
<td>Randomized 1:1 to continue (n=308) versus switch to CAB/RPV (n=308)</td>
</tr>
</tbody>
</table>

PrEP vs. PEP

**What’s it called?**

**PrEP** stands for pre-exposure prophylaxis.

**PEP** stands for post-exposure prophylaxis.

**Before HIV exposure.**

PrEP is taken every day, before possible exposure.

**When is it taken?**

After HIV exposure.

In emergency situations, PEP is taken within 72 hours (3 days) after possible exposure.

**Who’s it for?**

**PrEP** is for people who don’t have HIV and:
- have a sex partner with HIV
- have sex with people whose HIV status is unknown
- share injection drug equipment

**PEP** is for people who don’t have HIV but may have been exposed:
- during sex
- at work through a needlestick or other injury
- by sharing injection drug equipment
- during a sexual assault

**PrEP:** STD in the past 6 months

PrEP vs. PEP

➢ **Pre-Exposure Prophylaxis (PrEP)**
  - *Truvada* - TDF / emtricitabine
  - *Descovy* - TAF / emtricitabine

➢ **Post-Exposure Prophylaxis (PEP)**
  - *Truvada* - TDF / emtricitabine *plus* Raltegravir

Pre-Exposure Prophylaxis

Over 1 million Americans are at substantial risk for HIV, but only 90,000 PrEP prescriptions were filled in 2015

The number of PrEP users grew by 30% from 2017 to 2018

However...

- 94% of all PrEP users are men (16x more PrEP users are men than women)
- 25-34 year olds account for most new infections, but only 60% of PrEP use
- The South accounts for 50% of all new infections, but only 30% of PrEP use

Overcoming these disparities and expanding PrEP use is essential
The new Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV suggest screening for substance abuse disorders as routine part of clinical care.
True or False

The new Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV suggest screening for substance abuse disorders as routine part of clinical care.
Updates (Dec 18th)

DHHS. Guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents.
Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf
Treatment as prevention (TasP), commonly known as Undetectable = Untransmittable or $U = U$.

- Using effective ART to consistently suppress plasma HIV RNA levels to <200 copies/mL.
- Use another form of prevention with sexual partners for at least the first 6 months of treatment and until HIV RNA <200 copies/mL.

DHHS. Guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents. Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf
Dolutegravir Recommendations for Individuals of Childbearing Potential

- Prevalence of neural tube defects is lower than initially reported (the rate has been reduced from 0.9% to 0.3%).
- DTG may be used as an alternative ART for individuals who are of childbearing potential and trying to conceive.

DHHS. Guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents. Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf
Laboratory Testing for Initial Assessment and Monitoring of People with HIV Receiving Antiretroviral Therapy

- The panel previously recommended monitoring fasting lipid profile and fasting glucose before and after initiation of ART.
- The new recommendation allows for random (non-fasting) tests.
DTG/3TC was added to the list of Recommended Initial Regimens for Most People with HIV, except for individuals:

- With pre-treatment HIV RNA > 500,000 copies/mL
- Who are known to have active hepatitis B virus (HBV) co-infection

DHHS. Guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents.
Tables

- Common and/or Severe Adverse Effects Associated with Antiretroviral Therapy
- Antiretroviral Therapy-Associated Adverse Events That Can Be Managed with Substitution of Alternative Antiretroviral Agent

Source: aidsinfo.nih.gov/guidelines.
Pharmacist’s Role

- Empower patients to get tested.
- Identify opportunities to increase compliance.
- Recommend strategies to protect high risk individuals.
- Get involved !!!!

Breakthroughs notwithstanding, HIV/AIDS research has not slowed.

Despite the progress achieved in the last few decades, HIV incidence remains high throughout the US.

Science has provided us the tools to target a goal of reducing new HIV diagnosis by more than 90% in 10 years.

Pharmacists are uniquely positioned to contribute to this goal.


Siegfried NL, Uthman OA, Rutherford GW. Optimal time for initiation of antiretroviral therapy for asymptomatic, HIV-infected, treatment-naive adults. Cochrane Database of Systematic Reviews. 2010;2010
Updates on HIV

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