

## HIV Today: Examining the Latest Treatment Advances, Barriers to Care, and Pharmacists' Implications

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## Disclosures

Humberto R. Jimenez, PharmD, BCPS, AAHIVP, has Participated in a speakers bureau for Bristol-Myers Squibb

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## Learning Objectives

- Review the latest trends in epidemiology and pathophysiology of HIV
- Discuss appropriate antiretroviral regimens for treatment-naïve and treatment-experienced patients, based on updated guidelines
- Explore new and emerging antiretroviral regimens and therapeutic strategies
- Examine barriers in HIV management, including suboptimal adherence, medication errors, and adverse effects/interactions

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## Outline

- Management of HIV-infected patients
  - Epidemiology
  - Pathophysiology
  - Guidelines
  - Future
- Barriers to treatment success
  - Adherence
  - Side effects
  - Medication errors
  - Drug interactions
- Pharmacists' implications

## Epidemiology

- 1.2 million infected with HIV in US<sup>1</sup>
  - One-fifth unaware of serostatus
  - Approximately 56,000 new infections per year
  - 14,561 deaths from people with AIDS
- Patients living longer
  - Most patients to be over 50 years old by 2015<sup>2</sup>
- Antiretroviral therapy started earlier than ever

1. cdc.gov  
2. Effros, et al. *CID* 2008;47:542-53.

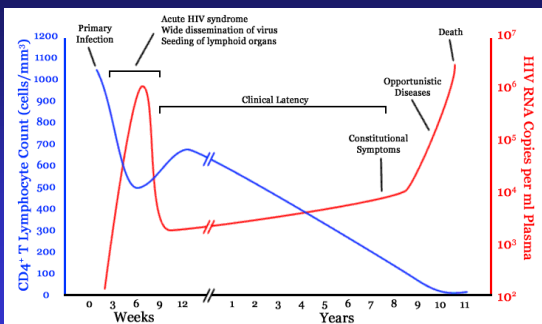
## Introduction

- Acquired immune deficiency syndrome (AIDS)
  - Condition that presents with immunosuppression, predisposing the infected subject to opportunistic infections and AIDS-related malignancies
  - CD4 cell count < 200 cells/mm<sup>3</sup> and/or an “AIDS-defining illness”
  - Caused by human immunodeficiency virus (HIV)
- Lab parameter
  - CD4 cell count
    - Most recent CD4 count is best predictor of disease progression
  - Plasma HIV RNA level (viral load, VL)
    - Critical in determining response to ART
    - May also be expressed as log value (i.e. 4 log = 10,000)

## AIDS-Defining Illnesses

Candidiasis (except oral thrush)	Cervical cancer (invasive)
Coccidioidomycosis	Cryptococcosis (extrapulmonary)
Cryptosporidiosis (w/ diarrhea > 1 mo.)	Cytomegalovirus in any organ other than liver, spleen, or lymph nodes
Herpes simplex w/ ulcer > 1 mo. or bronchitis, pneumonia, esophagitis	Histoplasmosis (extrapulmonary)
HIV encephalopathy	Isosporiasis w/ diarrhea > 1 mo.
Kaposi's sarcoma	Lymphoma (Burkitt's, immunoblastic, or primary CNS)
<i>Mycobacterium avium</i> or <i>M. Kansalii</i> (disseminated)	<i>Mycobacterium tuberculosis</i>
<i>Pneumocystis jiroveci</i> pneumonia (PCP)	Pneumonia (≥ 2 episodes in 1 yr.)
Progressive multifocal leukoencephalopathy (PML)	<i>Salmonella</i> bacteremia (recurrent)
Toxoplasmosis (cerebral)	Wasting syndrome due to HIV

## Natural History of Untreated HIV Infection



[http://www.thenakedscientists.com/HTML/uploads/tx\\_nakscilimages/Hiv-timecourse.png](http://www.thenakedscientists.com/HTML/uploads/tx_nakscilimages/Hiv-timecourse.png)

## Goals of Treatment

- Reduce HIV-related morbidity; prolong duration and quality of survival
- Restore and/or preserve immunologic function
- Maximally and durably suppress HIV viral load
- Prevent HIV transmission

<http://aidsinfo.nih.gov>

## DHHS Guidelines, 2012: When to Start

- ART recommended for **ALL** HIV-infected patients; **strength** of recommendation varies according to CD4+ cell count

CD4+ Cell Count	Recommendation
< 350 cells/mm <sup>3</sup>	Start ART (A1)
350-500 cells/mm <sup>3</sup>	Start ART (AII)
> 500 cells/mm <sup>3</sup>	Start ART (BIII)

### Clinical Conditions Favoring Initiation of Therapy Regardless of CD4+ Cell Count

- History of AIDS-defining illness (A1)
- Pregnancy (A1)
- HIV-associated nephropathy (AII)
- HBV coinfection (AII)
- Patients at risk of transmitting HIV to sexual partners (A1, heterosexuals; AII, others)
- HCV coinfection\* (BII)
- Patients > 50 years of age (BIII)

\*Including those with high CD4+ cell count and/or with cirrhosis. Some pts with CD4+ counts > 500 cells/mm<sup>3</sup> may elect to defer ART until after HCV therapy is completed.

<http://aidsinfo.nih.gov>

## Consequence of HIV Replication

- Prevention of AIDS-related illnesses still a major objective of treating HIV infection
- Collateral damage from HIV replication
  - Inflammation, oxidant stress, endothelial dysfunction, immune activation<sup>1</sup>
  - Exacerbates non-AIDS related conditions, such as cardiovascular, liver, and renal disease<sup>2</sup>

1. Boger et al. 17<sup>th</sup> International AIDS Conference, 2008: Abstract WEAB0105.  
2. El-Sadr et al. *N Engl J Med*. 2006;355(5):2283-2296.

## Association of CD4+ Cell Count Nadir With Clinical Outcomes

- Low CD4+ count nadir associated with
  - Increased rates of HIV-associated neurocognitive disorders<sup>[1]</sup>
  - Arterial stiffness contributing to CV risk<sup>[2]</sup>
  - Coronary heart disease<sup>[3]</sup>
  - Increased risk of fracture<sup>[4]</sup>

1. Ellis R et al. *AIDS*. 2011;25:1747-1751.  
2. Ho J et al. *AIDS*. 2010 ;24:1897-1905.  
3. Klein D et al. *CROI* 2011. Abstract 810.  
4. Young B et al. *Clin Infect Dis*. 2011;52:1061-1068.

## When to Start Therapy

- Drug toxicity
- Preservation of limited Rx options
- Risk of resistance (and transmission of resistant virus)

Delayed ART

[clinicaloptions.com](http://clinicaloptions.com)

## When to Start Therapy: Balance Now Favors Earlier ART

- Drug toxicity
- Preservation of limited Rx options
- Risk of resistance (and transmission of resistant virus)
- ↑ potency, durability, simplicity, safety of current regimens
- ↓ emergence of resistance
- ↓ toxicity with earlier therapy
- ↑ subsequent therapy options
- Risk of uncontrolled viremia at all CD4+ cell count levels
- ↓ transmission

Delayed ART

Early ART

[clinicaloptions.com](http://clinicaloptions.com)

## Current Antiretroviral Medications

### NNRTI

Abacavir (Ziagen<sup>®</sup>)  
Didanosine (Videx EC<sup>®</sup>)  
Emtricitabine (Emtriva<sup>®</sup>)  
Lamivudine (Epivir<sup>®</sup>)  
Stavudine (Zerit<sup>®</sup>)  
Tenofovir (Viread<sup>®</sup>)  
Zidovudine (Retrovir<sup>®</sup>)

### NNRTI

Delavirdine (Rescriptor<sup>®</sup>)  
Efavirenz (Sustiva<sup>®</sup>)  
Etravirine (Intenceo<sup>®</sup>)  
Nevirapine (Viramune<sup>®</sup>)  
Raltegravir (Isentress<sup>®</sup>)

### PI

Atazanavir (Reyataz<sup>®</sup>)  
Darunavir (Prezista<sup>®</sup>)  
Fosamprenavir (Lexiva<sup>®</sup>)  
Indinavir (Crixivan<sup>®</sup>)  
Lopinavir/ritonavir (Kaletra<sup>®</sup>)  
Nelfinavir (Viracept<sup>®</sup>)  
Ritonavir (Norvir<sup>®</sup>)  
Saquinavir (Invirase<sup>®</sup>)  
Tipranavir (Aptivus<sup>®</sup>)

### Miscellaneous

Maraviroc (Selzentry<sup>®</sup>)  
Enfuvirtide (Fuzeon<sup>®</sup>)  
Eltivitegravir (co-form. Stribild<sup>®</sup>)  
Raltegravir (Isentress<sup>®</sup>)

## Current Antiretroviral Medications

### NRTI

Abacavir (Ziagen®)  
 Didanosine (Videx EC®)  
 Emtricitabine (Emtriva®)  
 Lamivudine (EpiVir®)  
 Stavudine (Zerit®)  
 Tenofovir (Viread®)  
 Zidovudine (Retrovir®)

### NNRTI

Delavirdine (Rescriptor®)  
 Efavirenz (Sustiva®)  
 Etravirine (Intelence®)  
 Nevirapine (Viramune®)  
 Rilpivirine (Edurant®)









### PI

Atazanavir (Reyataz®)  
 Darunavir (Prezista®)  
 Fosamprenavir (Lexiva®)  
 Indinavir (Crixivan®)  
 Lopinavir/ritonavir (Kaletra®)  
 Nelfinavir (Viracept®)  
 Ritonavir (Norvir®)  
 Saquinavir (Invirase®)  
 Tipranavir (Aptivus®)

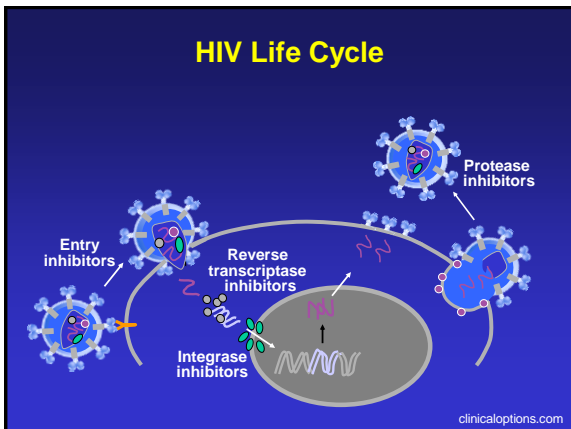
### Miscellaneous

Maraviroc (Selzentry®)  
 Enfuvirtide (Fuzeon®)  
 Elvitegravir (co-form. Stribild®)  
 Raltegravir (Isentress®)

## Combination Products

-  Combivir® (lamivudine/zidovudine)
-  Epicom® (abacavir/lamivudine)
-  Truvada® (emtricitabine/tenofovir)
-  Trizivir® (zidovudine/lamivudine/abacavir)
-  Atripla® (efavirenz/emtricitabine/tenofovir)
-  Complera® (rilpivirine/emtricitabine/tenofovir)
-  Kaletra® (lopinavir/ritonavir)
-  Stribild™ (elvitegravir/cobicistat/emtricitabine/tenofovir)

## HIV Life Cycle



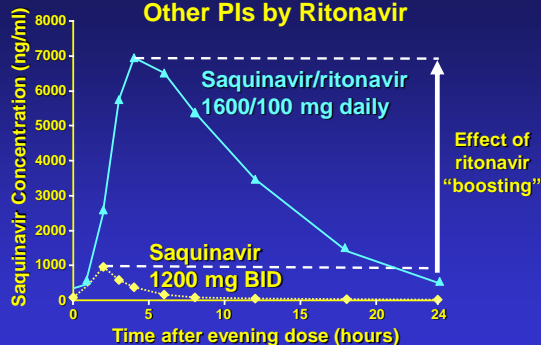
## Recommended for Treatment-Naïve Patients

Contains 2 NRTIs PLUS one other active agent

2-NRTIs	NNRTI	PI
tenofovir/emtricitabine† (Truvada®)	efavirenz	atazanavir darunavir fosamprenavir saquinavir
abacavir/lamivudine†† (Epicom®)	nevirapine	lopinavir/ritonavir
zidovudine/lamivudine† (Combivir®)	rilpivirine	
didanosine + lamivudine†		atazanavir fosamprenavir
		unboosted (no ritonavir)
	<b>Integrase Inh.</b>	<b>CCR5 Antagonist</b>
	Raltegravir	Maraviroc
	Elvitegravir*	

\*Currently only available in a four-drug combination, Stribild™ <http://aidsinfo.nih.gov>

## Pharmacokinetic Enhancement of Other PIs by Ritonavir



Kilby et al. AAC 2000; 44:2672-2678.

## Principles of Antiretroviral Therapy

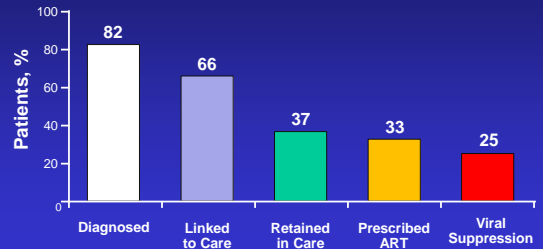
- HIV RNA (viral load)
  - Week 24: < 50 copies/mL (undetectable)
- CD4 cell count
  - Increase of ~150 cells/mL in first year
- Failure
  - Virologic: incomplete or lack of HIV RNA response (> 200 copies/mL)
  - Immunologic: CD4+ increase < 25-50 cells/mL in first year
  - Clinical progression: occurrence/recurrence of HIV-related event

<http://aidsinfo.nih.gov>

**If current treatment is so effective, then why is the eradication of HIV not yet a reality?**

### **CDC: Differences in Continuum of Care in HIV-Infected Patients**

- CDC study shows that only ~ 25% of US patients with HIV have suppressed HIV-1 RNA



Hall HI et al. AIDS 2012. Abstract FRLBx05.

### **CDC Guidelines for Screening and Testing: Adults and Adolescents**

- All persons 13-64 years of age
- All patients initiating treatment for TB
- All patients seeking treatment for STDs
- Repeat screening annually for those known to be at high risk
- Encourage testing before initiating a new sexual relationship

cdc.gov

### **Current Challenges in Fighting HIV: US**

- Patient level
  - Barriers to care
    - Not linked to care
    - Mistrust of medical community
    - Access to care issues
    - Stigmas (perceived and/or real)
    - Fragile support systems
    - Difficulty in communicating with physicians
    - Health literacy
  - Adherence
  - Side effects
  - Medication errors

### **Adherence**

- High adherence rates associated with virologic suppression, low rates of resistance, and improved survival
- 2<sup>nd</sup> best predictor of progression to AIDS & death
- Consequences of nonadherence not always equal
- Adherence is a dynamic state

www.aidsctc.org

### **Predictors of Inadequate Adherence**

- Regimen complexity and pill burden
- Low literacy level
- Active drug use or alcoholism
- Stigma
- Mental illness (especially depression)
- Cognitive impairment
- Lack of patient education
- Medication adverse effects
- Treatment fatigue

www.aidsctc.org

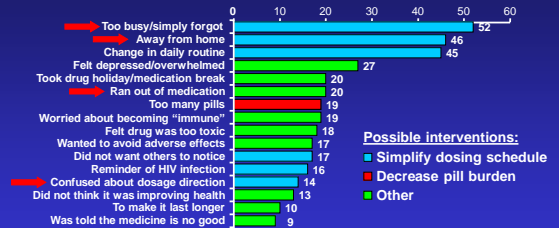
## Predictors of Inadequate Adherence

- Age, race, sex, educational level, socioeconomic status, and a past history of alcoholism or drug use do NOT reliably predict suboptimal adherence
- Higher socioeconomic status and education levels and lack of history of drug use do NOT reliably predict optimal adherence

www.aidsetc.org

## Why Do Patients Miss Doses?

Reasons Given for Missing Antiretroviral Doses (Structured Questionnaire), %



Gifford AL et al. J Acquire Immune Defic Syndr. 2000;23:386-395.

clinicaloptions.com

## Managing Adverse Effects

- About 25% of patients stop therapy within the first year on HAART because of side effects<sup>1</sup>
- Toxicity still a challenge in the management of HIV-infected patients
  - Long- and short-term safety
- Identification of drug-specific adverse effects may be difficult
- Appropriate measures may not always be clear

Their management must be individualized

1. D'Ammino Monforte A, et al. *AIDS* 2000; 14:499-507.

## Common Adverse Effects

- Gastrointestinal
  - Diarrhea
  - Nausea/vomiting
- Dermatologic
- Neurologic Symptoms
  - Dizziness
  - Headache
  - Fatigue

## Incidence of Medication Errors

- Incidence difficult to determine
  - Underreported
  - Unidentified
- Hospital setting
  - 25.8% of patients on ART had an error<sup>1</sup>
  - 86% of patients on ART had  $\geq 1$  drug-related issues<sup>2</sup>
  - 52% ART had an error at 48 hrs of admission<sup>3</sup>
- Retail setting

1. Rastegar DA et al. *CID* 2006;43:933-8.

2. Mok S et al. *AJHP* 2008;65:55-9.

3. Corrigan MA et al. *Ann Pharmacother* 2010;44:222-3.








## Common Medication Errors

- Inappropriate dose
- Incorrect frequency
- Therapeutic duplication
- Wrong drug
- Incomplete antiretroviral regimen
- Drug interactions
- Inappropriate opportunistic infection prophylaxis

## Reasons Errors Occur

- Lack of familiarity with dosing, adverse effects, and drug-drug interactions
- Drug information and best practices in HIV management always evolving
  - Resources/references not all equal
- Pharmacists need to remain updated
  - Continuing education, FDA alerts, email updates, scripts
- Patients
  - Different levels of knowledge/understanding

## Inappropriate Dose

- Daily instead of BID
    - Isentress® 1 tab daily  

  - Wrong tablet dose
    - Intelence® 200 mg PO BID
    - 100 mg tablets available  
 
  - PI
    - Boosted
    - Unboosted
      - Prezista® 1 tab daily  

      - Norvir® 1 tab daily  

    - Lexiva® 1 tab BID  
 
- In chronic kidney disease, NRTI dose

## Therapeutic Duplication

### • Coformulations



Epzicom® 1 tab PO daily



EpiVir® 150 mg 1 tab PO BID



Ziagen® 300 mg 1 tab PO BID

## Wrong Drug

- Do not accept prescriptions with potentially confusing abbreviations
  - ddl, d4T, NFV, NVP, ATV, AZT
- Close names - poor handwriting
  - Ritonavir or Retrovir
  - Nevirapine or Nelfinavir
  - Viramune® or Viracept® or Viread®
  - Intelence® or Isentress®
  - Complera® or Combivir®

## Incomplete Antiretroviral Regimen

- Monotherapy not recommended
  - Except zidovudine in pregnancy
  - Boosted PI monotherapy being evaluated (study setting only)
- Dual NRTI therapy not recommended
- Need  $\geq 2$  fully active agents for ART success
- Ensure ritonavir (Norvir®) prescribed when indicated for boosting
  - Low-dose ritonavir doesn't count as active agent
  - Remember, following **MUSI** be boosted:
    - Prezista®, Invirase®, Aptivus®
  - Boost following if:
    - Reyataz® (300 mg cap), Lexiva® (if 2 tabs/day)

## Drug Interactions

- Most ARVs have significant drug interactions with other ARVs and with other medications
- Interactions often complex and difficult to predict
- Interaction: dose adjustment, "use with caution" or contraindicated
  - Pharmacokinetics
  - Therapeutic window
- Check for interactions before prescribing

## Drug Interactions

- NNRTIs - CYP3A4 substrates
  - 2B6 as well for efavirenz and 2C9/19 for etravirine
  - CYP3A4 inducers (except rilpivirine)
    - Efavirenz also inhibits 3A4, 2C9 & 2C19
    - Etravirine is also 2C9 & 2C19 inhibitor
- PIs - CYP3A4 substrates & inhibitors
  - Ritonavir one of most potent 3A4 inhibitors
    - Inhibits: 2D6, 2C9, 2C19, 1A2, 2E1, P-gp, transporters
    - Induces: 3A4, 2C9, 2C19, 1A2, glucuronyl transferase
- Other antiretrovirals
  - Maraviroc & elvitegravir are 3A4 substrate
  - Raltegravir exposure reduced by rifampin

## Notable Interactions: One Directional (Major 3A4 Substrates)

- Benzodiazepines
  - Diazepam, midazolam, triazolam
- Statins
  - Simvastatin, lovastatin – contraindicated w/ PIs
  - Atorvastatin, rosuvastatin – caution w/ PIs; use low dose
  - Pravastatin – Prezista® (darunavir) can increase; caution
  - May need to increase with NNRTI coadministration
- Phosphodiesterase inhibitors
  - All three major substrates; use w/ caution
- Corticosteroids
  - Fluticasone is a major 3A4 substrate

## Notable Interactions: Bidirectional

- Anticonvulsants
  - Phenytoin, phenobarbital & carbamazepime induce P450
- Rifamycins (enzyme inducers)
  - Rifampin should NOT be given with PI therapy
  - Rifabutin is an alternative (major 3A4 substrate)
    - Must adjust dose with NNRTI or PI coadministration
- Azoles
  - Major 3A4 substrates (except fluconazole)
  - 3A4 inhibition (itraconazole ≥ voriconazole > fluconazole)
  - 2C9/19 inhibition (voriconazole > fluconazole)

## Notable Interactions: Complex Relationships

- Warfarin
  - Substrate of CYP3A4, 2C9/19 & 1A2
- Methadone
  - Concentration lowered by NNRTI & PI therapy; may require dose adjustment
- Hormonal contraceptives
  - Ethinyl estradiol & norethindrone levels may be lowered by NNRTI & PI therapy (except atazanavir)
- Alprazolam-ritonavir interaction
  - Alprazolam half-life ↑ to 30 hrs by short-term ritonavir<sup>1</sup>
  - Alprazolam AUC ↓ 12% if taken after 12 days of ritonavir<sup>2</sup>

1. Greenblatt et al. *J Clin Psychopharmacol*. 1999;19:293-296.  
2. Frye et al. *ICAAC* 1997: Abstract A59.

## Drug Interactions: Atazanavir

- If coadministered w/ tenofovir, must be RTV-boosted
- Atazanavir: 2 hours before or 1 hour after antacids
- H<sub>2</sub>-blockers or PPIs not recommended if unboosted
- Treatment-naïve patients on atazanavir/ritonavir (ATV/RTV) 300/100 mg:
  - Famotidine **40 mg** BID if taken ≥ 10 hours prior to ATV/RTV
  - Omeprazole **20 mg** if taken ≥ 12 hours prior to ATV/RTV
- Treatment-experienced patients:
  - Famotidine **20 mg** BID if taken ≥ 10 hours prior to ATV/RTV 300/100 mg
  - ATV/RTV **400/100 mg** daily if taken w/ tenofovir + H2-blocker

## Other Notable Interactions

- Complera® (emtricitabine/tenofovir/rilpivirine)
  - Do NOT coadminister PPIs
  - Can take antacid ≥ 2 hours before or ≥ 4 hours after Complera®
  - Can take H2-Blocker ≥ 12 hours before or ≥ 4 hours after Complera®
- Stribild® (emtricitabine/tenofovir/elvitegravir/cobicistat)
  - Absorption affected by antacids containing aluminum, magnesium hydroxide, or calcium carbonate
  - Take antacids ≥ 2 hours before or after you take Stribild®

## Pharmacists' Implications

- Pharmacists can play an important role in treatment success:
  - Educate patients
  - Reinforce adherence
  - Highlight common side effects
  - Identify potential medication errors
  - Search for and evaluate potential drug interactions
- Develop an open, trusting, nonjudgmental relationship:
  - Minimizes barriers, stigma
  - Ensures strict confidentiality

## Retail Setting

- New vs existing patient
  - Does patient have scripts filled elsewhere?
- New prescription(s) vs refills
  - New Script
    - HIV med – change in regimen or added?
  - Keep track of refill dates
    - Ensure all HIV meds filled; if not, ask why?
- Run daily/weekly report of scheduled refills

## Future Options and Strategies

## Potential New Agents

- Cobicistat (COBI)
  - PI booster, including possible coformulations coming
- Tenofovir Alafenamide – prodrug
  - 7-fold ↑ in intracellular tenofovir diphosphate levels
  - Circulating plasma tenofovir ↓ approximately 90%
  - Lower tenofovir levels in bone, kidney
- Dolutegravir
  - Once a day; no boosting required
  - To be coformulated with abacavir/lamivudine
  - Less risk of resistance

## Potential New Agents

- Cenicriviroc (formerly TBR-652)
  - CCR5 antagonist and CCR2 antagonist
  - CCR2 involved in diseases linked to inflammation
- BMS-663068
  - Inhibits attachment to CD4+ receptor; needs boosting
- Ibalizumab (formerly TNX-355)
  - Experimental anti-CD4+ monoclonal antibody
  - Inject every 2 weeks

## HIV Prevention

- Male circumcision shown to decrease HIV acquisition
- PrEP
  - CAPRISA 004 study demonstrates efficacy of 1% tenofovir vaginal gel in preventing HIV infection<sup>1</sup>
  - iPrEx study shows efficacy of pre-exposure prophylaxis with tenofovir in preventing HIV infection in men who have sex with men<sup>2</sup>
  - Some studies have shown no benefit of PrEP: FEM-PrEP, VOICE
- Treatment as Prevention
  - HPTN 052 shows 96% reduction in HIV transmission within serodiscordant couples (nearly all heterosexual) with early initiation of ART<sup>3</sup>

1. Q Abdool Karim et al. *Science*. 2010;329:1168-1174.  
2. Grant R et al. *N Engl J Med*. 2010;363:2587-99.  
3. Cohen M et al. *N Engl J Med*. 2011;365:493-505.

## Current Cure Research

- Clearing out reservoirs of infection
  - Vaccine + raltegravir + maraviroc
  - Antiviral 6 (AV6)
  - Auranofin (Ridaura): gold compound
- Therapeutic vaccines
- Making cells resistant to HIV
  - “Zinc fingers”: induce mutations in CCR5 gene, ↓ CCR5 expression on T cell surface

## Other Advances in HIV

- Berlin Patient
- “Functional cure” in HIV-Infected Child
- “Functional cure” in 14 patients with ART started after primary infection
- “Traditional” vaccines

## Summary

- HIV is a chronic disease
- Great strides still needed
- Pharmacists are critical

**Thank You!**