Florida AMCP
Mini Day of Education

Saturday, January 20th, 2024

AMCP Florida

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Please see www.amcp.org/antitrust for full statement.

AMCP Florida

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Mission

The Florida AMCP Affiliate seeks to serve the AMCP membership in the state of Florida in three primary areas; networking, education, and advocacy.

www.amcp.org/Florida-AMCP

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Optimizing medicine.
Improving lives.

Mission

To improve patient health by ensuring access to high-quality, cost-effective medications and other therapies.

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Friday Night, Happy Hour Networking Event

Artia SOLUTIONS

Saturday, Mini Day of Education:

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Lundbeck

Agenda

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- Welcome & Introductions
- Game
- Session 1: HIV/AIDS Updates
- Break: Exhibits & Networking
- Session 2: Federal & State Managed Care Policy Update
- Closing Remarks
- Lunch: Exhibits & Networking
- SeaWorld @ 1pm

Meet the Board!

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HIV/AIDS Updates

Elizabeth Sherman, PharmD, AAHIVP

Associate Professor, Nova Southeastern University

Division of Infectious Disease, Memorial Physician Group

Faculty, Southeast AIDS Education and Training Center

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Faculty, Southeast AIDS Education and Training Center

NSU Florida
NOVA SOUTHEASTERN UNIVERSITY

Disclosures

- This speaker has no conflicts of interest associated with this presentation.

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Learning Objectives

- Interpret current Florida law on HIV/AIDS
- Discuss epidemiology of HIV/AIDS
- Identify modes of HIV transmission and evidence-based prevention methods to reduce new infections
- Describe up-to-date clinical management strategies for HIV/AIDS and related complications

Law: HIV Testing and Reporting

Scope of the Problem: Burden of HIV Infection in the US

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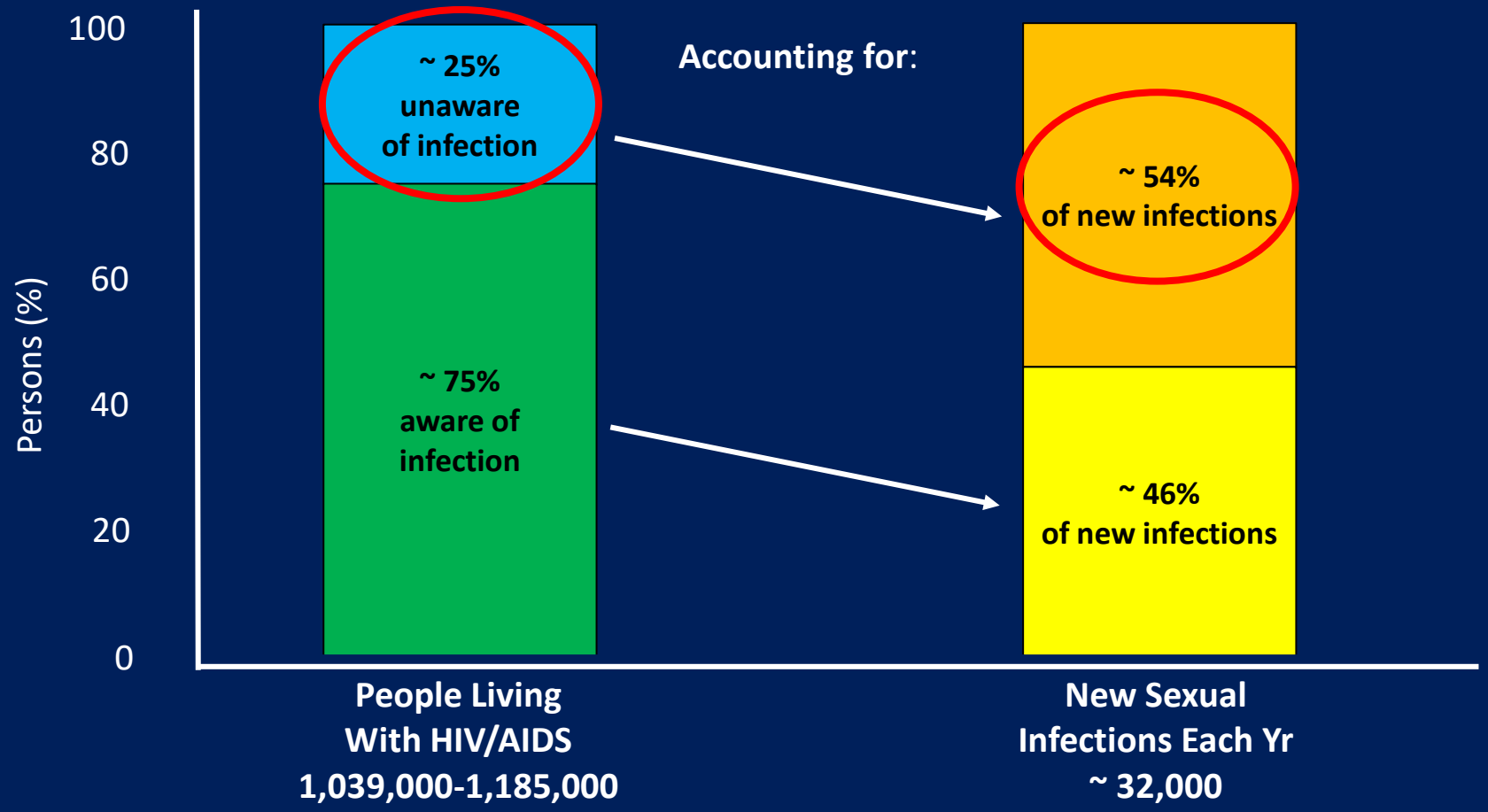

Marks G, et al. AIDS. 2006;20:1447-50.
Campsmith ML, et al. J Acquir Immune Defic Syndr. 2010;53:619-24.

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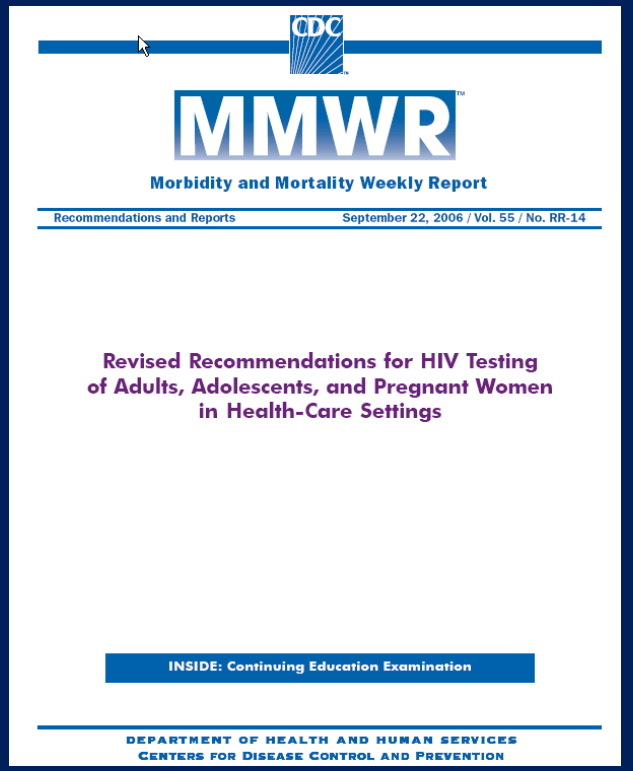
Routine HIV Testing Recommended by CDC & USPSTF

- Routine voluntary testing in healthcare settings for patients aged 13-64 years old, including pregnant women
- HIV testing **not** based on patient risk
- Repeat HIV testing at discretion of provider, based on patient risk



MMWR Recomm Rep. 2006;55(RR-14):1-17.
USPSTF. Ann Intern Med. Published online 30 April 2013.

Changes to Florida's HIV Testing Law (381.004, F.S.)

- Amends 381.004, F.S. **removing the requirement for informed consent** prior to HIV testing in health care settings

  381.004(2)(a)1. In a health care setting, a person to be tested shall be notified orally or in writing that the test is planned. A person who has signed a general consent form for medical care is not required to sign or otherwise provide a separate consent for an HIV test. If the person declines the test, it shall be documented in the medical record.

- Intent of legislation: Normalize HIV testing and address CDC recommendations published in 2006

Changes to Florida's HIV Testing Law (381.004, F.S.)

- Opt-out approach to HIV testing in health care settings
  - ***Written*** informed consent eliminated
  - Patient must be notified that they will be tested for HIV, and that they have the right to decline testing
  - Notification of HIV test can be oral or in writing
  - Refusal must be noted in patient's medical record
- No change in law for testing in non-health care settings
  - Health care settings: a setting devoted to the diagnosis and care of persons or the provision of medical services to persons (e.g., hospitals, primary care settings, clinics, blood banks)
  - Non-health care settings: no medical treatment; conducts HIV testing for sole purpose of identifying HIV infection (e.g., outreach settings, mobile vans)

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HIV Testing and Partner Notification

- Current law: Test results reporting required; requirement for notification to patient

  *Notification of a person with a positive test result shall include information on the availability of appropriate medical and support services, the importance of **notifying partners** who may have been exposed, and preventing transmission of HIV*

- After diagnosis, health-care providers should:
  - Encourage patients to disclose HIV status to partners
  - Recommend partners be tested for HIV
- Voluntary & confidential partner notification services offered by Department of Health
- Florida AIDS Hotline **(800) FLA-AIDS**

HIV Epidemiology

Global View:
33.3 Million People Living with HIV

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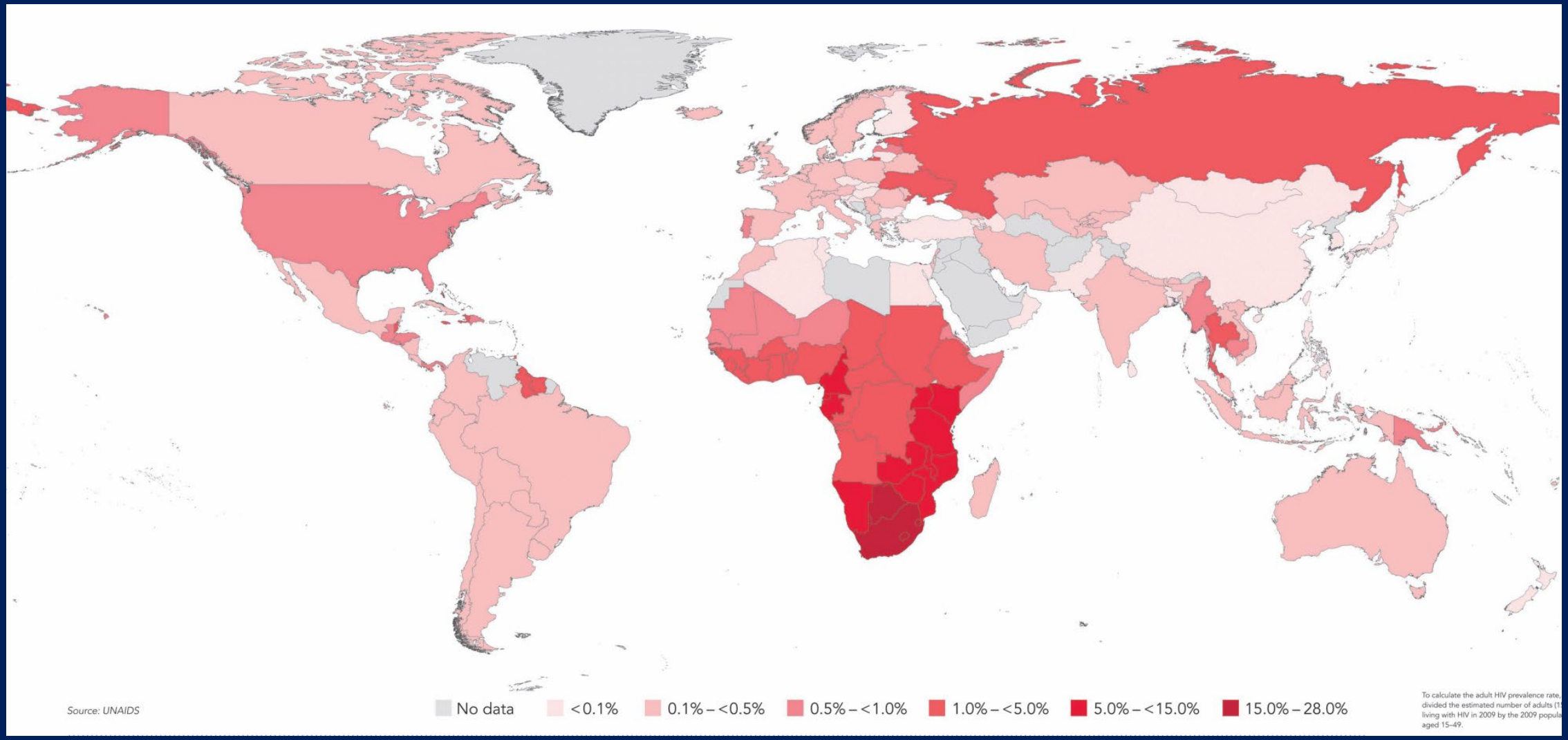

http://www.unaids.org/documents/20101123_2010_HIV_Prevalence_Map_em.pdf

HIV Prevalence in the US

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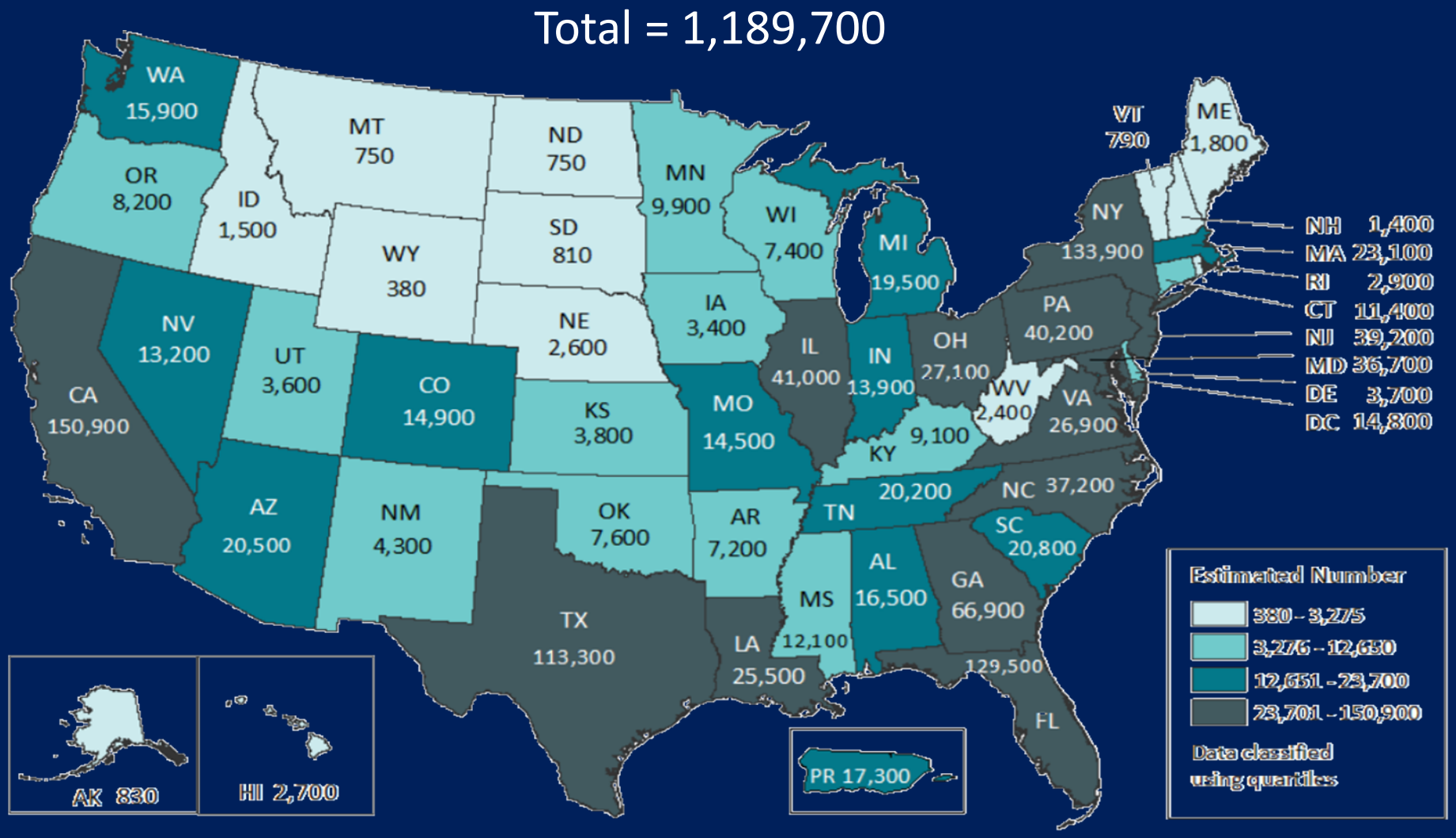

https://www.cdc.gov/hiv/library/slideSets/index.html

HIV Epidemic in FL:

1 in 157 adults known to be living with HIV

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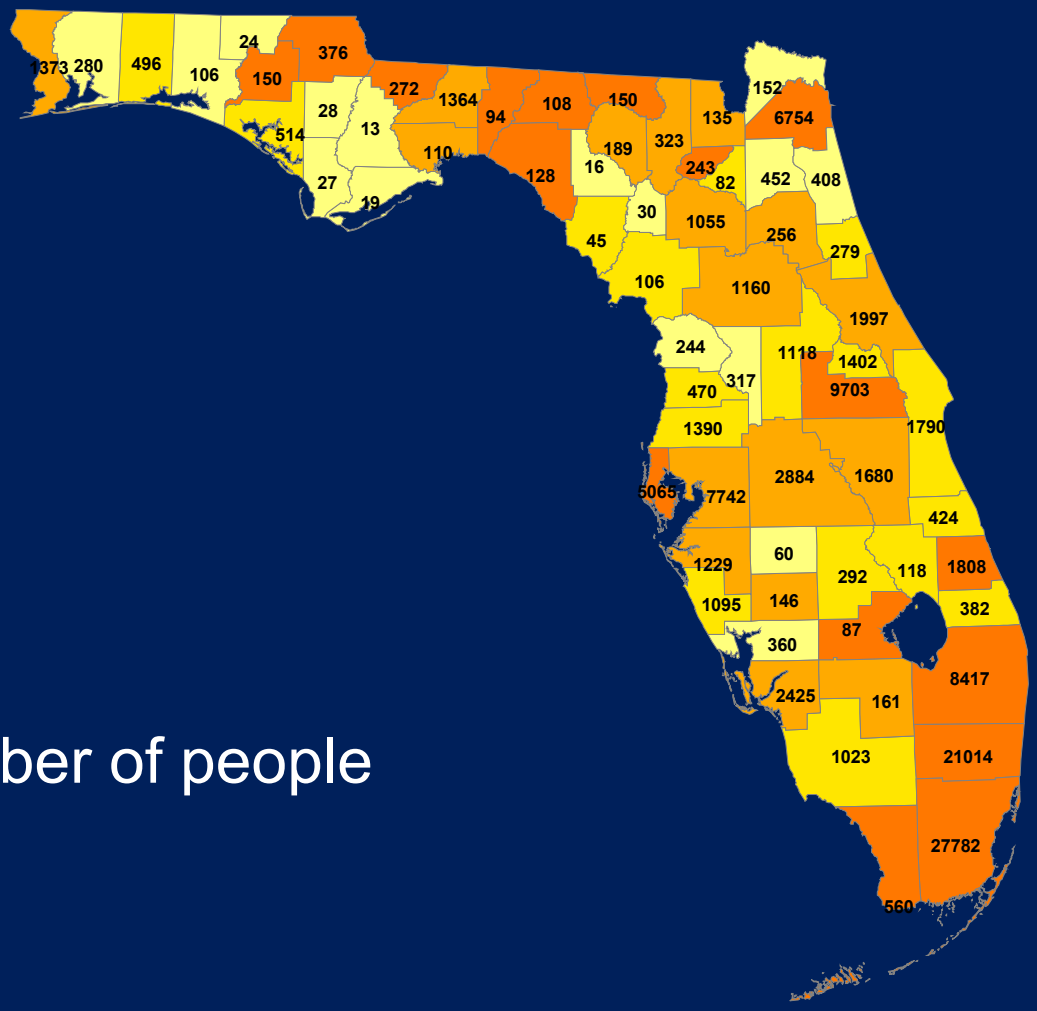
HIV Rate
per 100,000 Population

0.0
0.1–218.7
218.8–296.7
296.8–511.0
>=511.1



Numbers on map are number of people with HIV

http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/epi-slide-sets.html

Modes of HIV Transmission and Strategies to Prevent Transmission

Modes and Risk of HIV Transmission

- An exposure must meet two criteria:
  - Portal of entry
  - Contaminated body fluid

- Types of exposures:

Occupational Exposures	
Percutaneous	0.3%
Mucocutaneous	0.09%

Non-Occupational Exposures	
Vertical birth	24%
Needle-sharing IDU	0.67%
Receptive anal	0.1 – 5%
Receptive vaginal	0.1 – 0.2%
Insertive anal	0.065%
Insertive vaginal	0.05%
Receptive oral- ♂	0.01%
Insertive oral	0.005%
♀-♀ orogenital contact	Case reports

Centers for Disease Control and Prevention. MMWR 2005;54:RR-2.
Landovitz RJ. Top HIV Med 2009;17:104-8.

OSHA: Universal Precautions

- Employees who come into contact with HIV-infected materials:
  - Wear protective equipment (gloves, gowns, masks, and goggles)
  - Wash hands with antimicrobial soap before and after wearing gloves
  - Properly dispose of needles and other sharps
  - Avoid recapping needles, or use needleless devices, to prevent needle sticks

Center for Disease Control and Prevention. MMWR 2006;55(RR-14)

Spectrum of HIV Prevention Strategies

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- Behavior change
- Syringe services programs
- Circumcision
- HIV testing
- Pre-exposure prophylaxis

- Condoms
- Antiretroviral therapy for prevention of mother-to-child transmission

- Antiretroviral therapy
- Post-exposure prophylaxis

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Pre-Exposure Prophylaxis (PrEP) for HIV Prevention

- Use of antiretroviral meds by *uninfected* patients to prevent HIV infection
- Used before and during periods of risk
  - Heterosexually active men and women, men who have sex with men, people who inject drugs
- Antiretrovirals approved for PrEP are 99% effective at reducing risk of sexual transmission of HIV
  - Emtricitabine/tenofovir (Truvada® or Descovy®) PO
  - Cabotegravir (Apretude®) IM
- Additional antiretrovirals & dosage forms in clinical trials

CDC: USPHS: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf.

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Post-Exposure Prophylaxis (PEP) for HIV Prevention

- Use of antiretroviral meds by *uninfected* patients *following an HIV exposure* to prevent HIV infection
  - Needlesticks, blood splashes (occupational)
  - Injection drug use, sexual (non-occupational)
- Antiretrovirals started immediately (ideally 1-2 hrs) after HIV exposure and continued 28 days; Start not recommended beyond 72 hours
  - Preferred PEP regimen: Truvada + Isentress **or** Truvada + Tivicay
- PEPLine provides consultation 888-448-4911

Kuhar DT, et al. Infect Control Hosp Epidemiol. 2013;34:875-92
CDC. Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV – United States, 2016. April 18, 2016.

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Role of the Pharmacist: Expand PrEP/PEP Uptake

- Pharmacists with direct PrEP/PEP prescribing authority
  - 10 states have passed legislation
- Establishing collaborative practice agreements
- Facilitating PrEP awareness among sexually active persons and persons who inject drugs
  - “Do you know about PrEP/PEP and what it does?”
  - [preplocator.org]

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Role of the Pharmacist: Help Patients Pay for PrEP

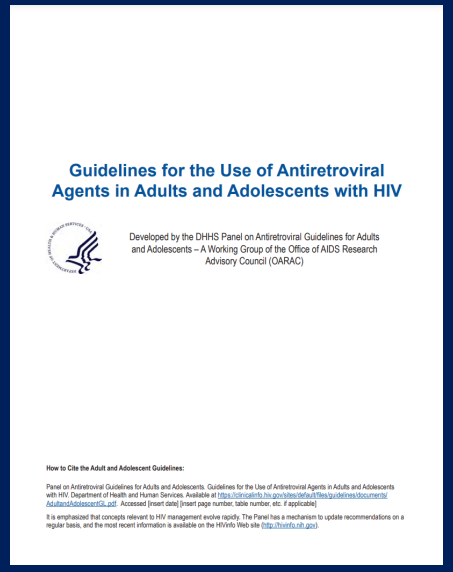
- Generic emtricitabine/tenofovir disoproxil fumarate
- Copay and manufacturer assistance programs
- Additional resources
  - Federal Ready, Set, PrEP Program
    [readysetprep.hiv.gov]
  - Patient Advocate Foundation (if < 400% FPL)
    [copays.org]
  - PAN Foundation (if <500% FPL)
    [panfoundation.org]
  - Florida's PrEP Drug Assistance Program
    [850-245-4422]

Clinical Management of HIV: Antiretroviral Therapy (ART)

Recommended HIV Treatment Resources

www.clinicalinfo.hiv.gov

- DHHS: Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. Dec 6, 2023.



Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV

Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents – A Working Group of the Office of AIDS Research Advisory Council (OARAC)

How to Cite the Adult and Adolescent Guidelines:

Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf. Accessed [insert date] [insert page number, table number, etc. if applicable]

It is emphasized that concepts relevant to HIV management evolve rapidly. The Panel has a mechanism to update recommendations on a regular basis, and the most recent information is available on the HIVinfo Web site (http://hivinfo.nih.gov).

www.hiv-druginteractions.org

- HIV Drug Interactions Checker, University of Liverpool
- HIV iChart app for iPhone and Android

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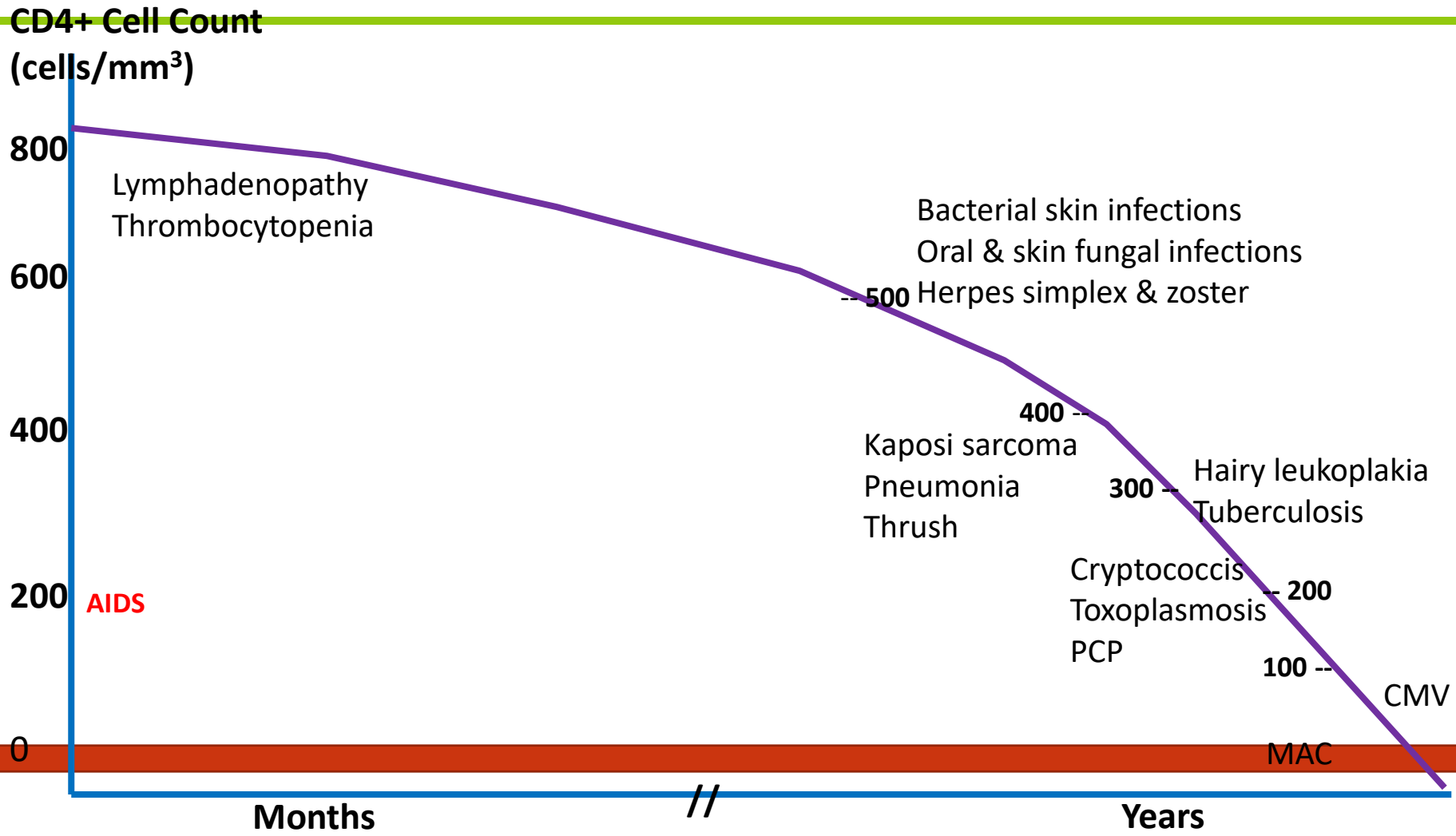
HIV Attacks CD4 T Cells

- HIV attacks immune system CD4 T cells
  - HIV uses T cell machinery to replicate
- Depletion of CD4 T cells by HIV impairs immune defenses (leaving host susceptible to opportunistic infection)
- ART suppresses viral load, allowing improvements in immune system functioning


CD4+ Cell Count
(cells/mm³)
800
600
400
200
0
AIDS
Lymphadenopathy
Thrombocytopenia
Bacterial skin infections
Oral & skin fungal infections
500
Herpes simplex & zoster
400
Kaposi sarcoma
Pneumonia
Thrush
300
Hairy leukoplakia
Tuberculosis
Cryptococcis
Toxoplasmosis
PCP
200
100
CMV
MAC
Months
//
Years

Initiation of Antiretroviral Therapy: Current Recommendations

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DHHS Panel's Recommendations for Initiating Antiretroviral Therapy in Treatment-Naïve Patients

- Antiretroviral therapy (ART) is recommended for all persons with HIV to reduce morbidity and mortality and to prevent the transmission of HIV to others. (AI)
- The Panel recommends initiating ART immediately (or as soon as possible) after HIV diagnosis in order to increase the uptake of ART and linkage to care, decrease the time to viral suppression for individual patients, and improve the rate of virologic suppression among persons with HIV. (AII)
- When initiating ART, it is important to educate patients regarding the benefits of ART and to deploy strategies to optimize care engagement and treatment adherence. (AIII)

Rating of Recommendations: A = Strong B = Moderate; C = Optional

Rating of Evidence: I = Data from randomized controlled trials; II = Data from well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

US DHHS. Guidelines for Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv.

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Overview of ART Drug Classes

- Classification based on where in the viral life cycle each drug acts
- 6 Antiretroviral Classes
  - Nucleos(t)ide reverse transcriptase inhibitors (NRTI)*
  - Integrase strand transfer inhibitors (INSTI)*
  - Protease inhibitors (PI)†
  - Non-nucleoside reverse transcriptase inhibitors (NNRTI)†
  - Entry inhibitors††
  - Capsid inhibitor††

*Recommended in initial regimens for most people with HIV
†Recommended only in certain clinical situations
†† Not recommended for initial therapy

HIV Life Cycle & ARV Drug Classes

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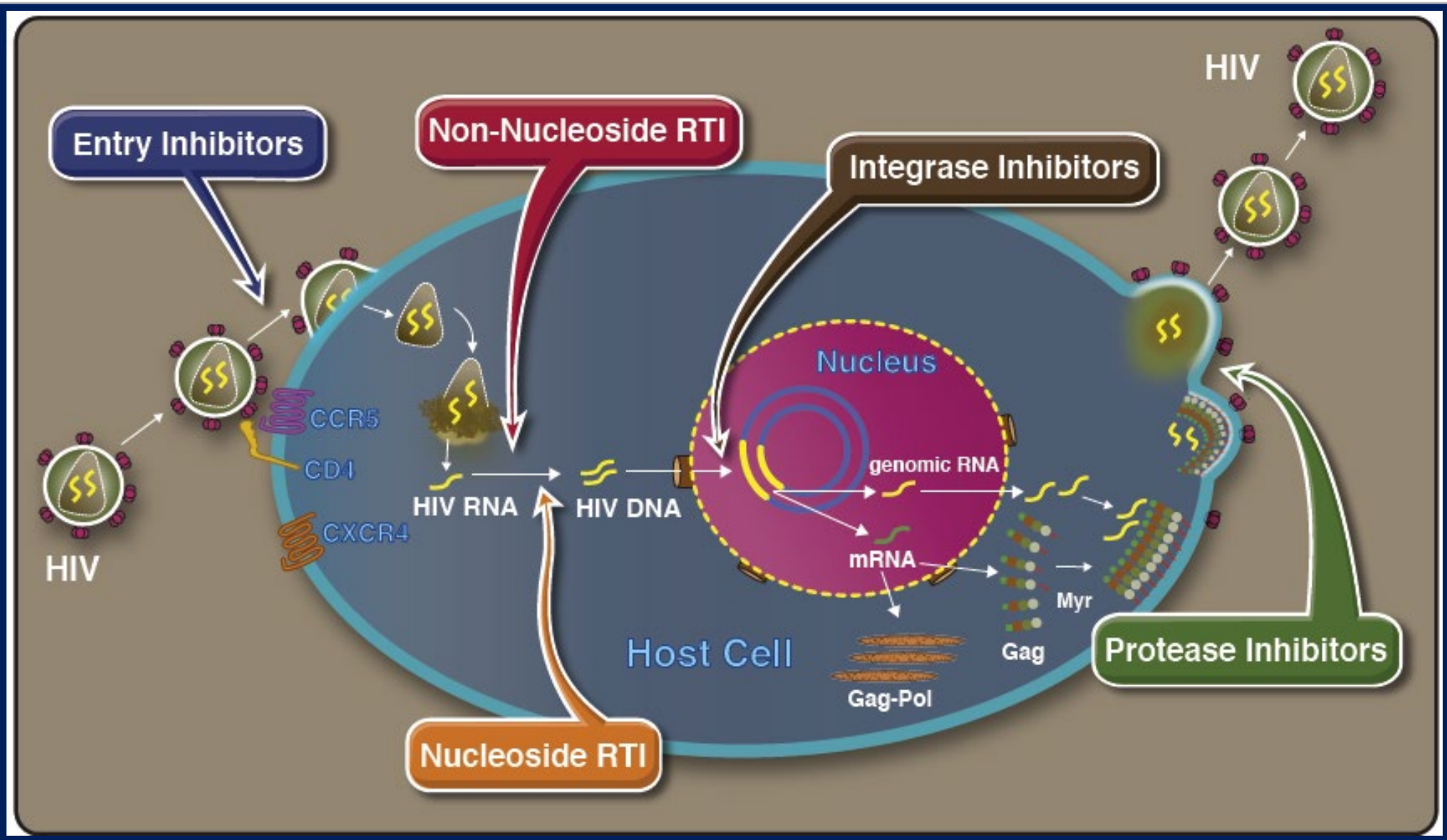

Antiretroviral Medications

Nucleoside Reverse Transcriptase Inhibitors (NRTIs)

- Abacavir (ABC) (Ziagen®)
- Didanosine (ddI) (Videx®)
- Emtricitabine (FTC) (Emtriva®)
- Lamivudine (3TC) (Epivir®)
- ~~Stavudine (d4T) (Zerit®)~~ *withdrawn 2020*
- Tenofovir (TDF or TAF) (Viread® or Vemlidy®)
- ~~Zalcitabine (ddC) (Hivid®)~~ *withdrawn 2005*
- Zidovudine (ZDV, AZT) (Retrovir®)
- 3TC/ABC (Epzicom®)
- ~~3TC/ABC/ZDV (Trizivir®)~~ *to be discontinued January 2024*
- 3TC/ZDV (Combivir®)
- 3TC/TDF (Cimduo®, Temixys®)
- FTC/TDF (Truvada®)
- FTC/TAF (Descovy®)

Non-nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

- Delavirdine (DLV) (Rescriptor®)
- Doravirine (DOR) (Pifeltro®)
- Efavirenz (EFV) (Sustiva®)
- Etravirine (ETR) (Intelence®)
- Nevirapine (NVP) (Viramune®)
- Rilpivirine (RPV) (Edurant®)

Integrase Inhibitors (INSTIs)

- Bictegravir (BIC)
- Cabotegravir (CAB) (Vocabria®)
- Dolutegravir (DTG) (Tivicay®)
- Elvitegravir (EVG)
- Raltegravir (RAL) (Isentress®)

Pharmacokinetic Enhancers "Boosters"

- Cobicistat (cobi) (Tybost®)
- Ritonavir (r) (Norvir®)

Protease Inhibitors (PIs)

- ~~Amprenavir (APV) (Agenerase®)~~ *discontinued 2004*
- Atazanavir (ATV) (Reyataz®)
- Atazanavir/cobicistat (ATV/c) (Evotaz®)
- Darunavir (DRV) (Prezista®)
- Darunavir/cobicistat (DRV/c) (Prezcobix®)
- Fosamprenavir (FPV) (Lexiva®)
- Indinavir (IDV) (Crixivan®)
- Lopinavir/ritonavir (LPV/r) (Kaletra®)
- Nelfinavir (NFV) (Viracept®)
- Ritonavir (RTV) (Norvir®)
- Saquinavir (SQV) (Invirase®)
- Tipranavir (TPV) (Aptivus®)

Entry Inhibitors

- Enfuvirtide (ENF, T20) (Fuzeon®)
- Fostemsavir (Rukobia®)
- Ibalizumab (Trogarzo®)
- Maraviroc (MVC) (Selzentry®)

Capsid Inhibitor

- Lenacapavir (LEN) (Sunlenca®)

Single Tablet Regimens

- BIC/FTC/TAF (Biktarvy®)
- DRV/cobi/FTC/TAF (Symtuza®)
- DOR/3TC/TDF (Delstrigo®)
- DTG/3TC/ABC (Triumeq®)
- DTG/RPV (Juluca®)
- DTG/3TC (Dovato®)
- EFV/FTC/TDF (Atripla®)
- EFV/3TC/TDF (Symfi® or Symfi Lo®)
- EVG/cobi/FTC/TAF (Genvoya®)
- EVG/cobi/FTC/TDF (Stribild®)
- RPV/FTC/TAF (Odefsey®)
- RPV/FTC/TDF (Complera®)

Long-Acting Injectable ART

- CAB/RPV (Cabenuva®)

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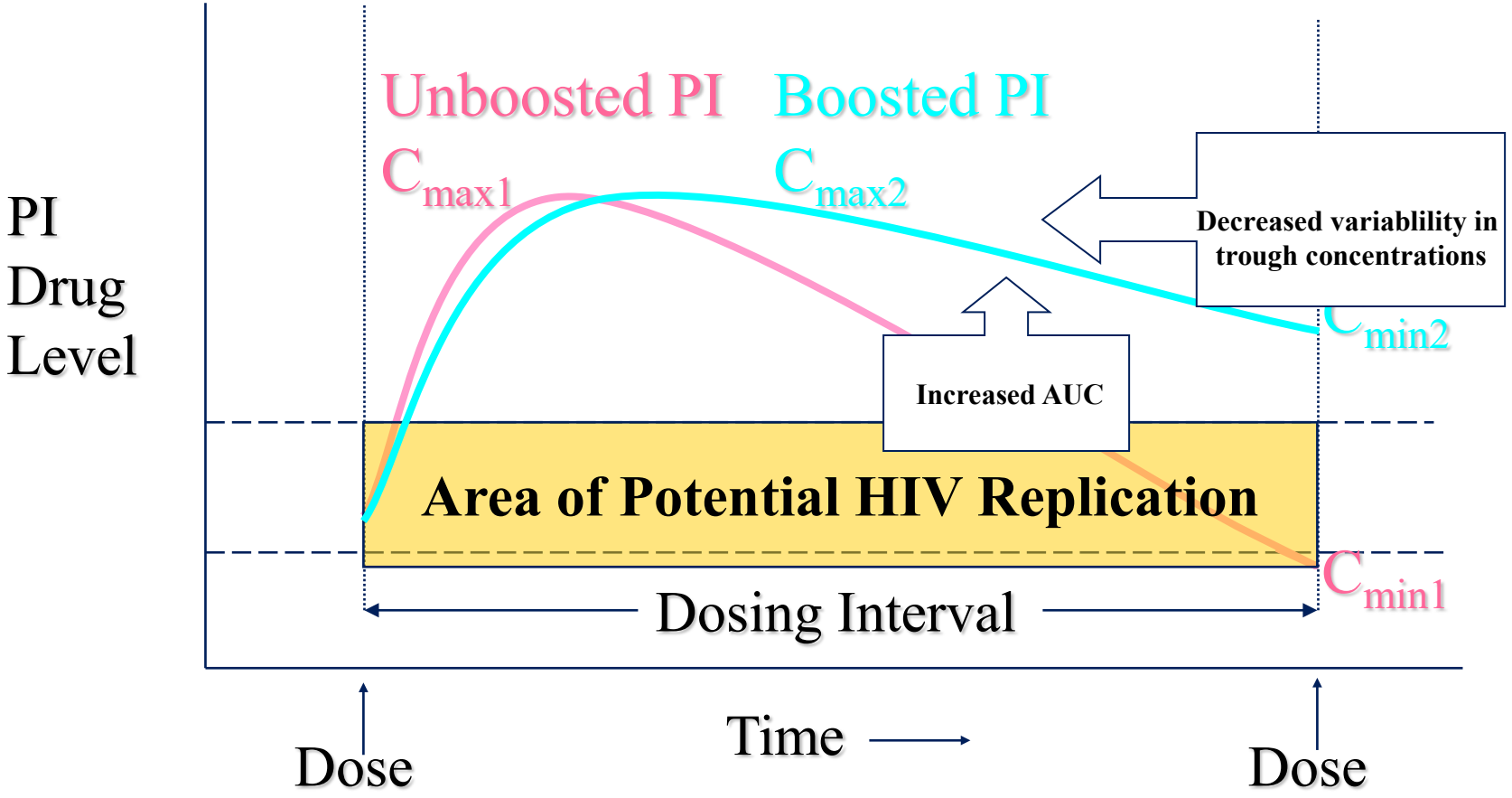
Initial HIV Management Principles

- Initiate ART with 1 of 3 types of regimens
- Most regimens should include **2 NRTIs plus 1 drug from a separate class**:
  - 1-2 NRTIs + 1 INSTI*
  - 2 NRTIs + NNRTI†
  - 2 NRTIs + 1 PI (boosted PI)†

*Recommended for most patients with HIV
†Recommended in certain clinical situations


PI
Drug
Level
Unboosted PI
Boosted PI
C_{max1}
C_{max2}
Decreased variablility in trough concentrations
C_{min2}
Increased AUC
Area of Potential HIV Replication
C_{min1}
Dosing Interval
Time
Dose
Dose

Goals of Antiretroviral Therapy

- Decrease HIV RNA
  - Goal HIV RNA or “viral load” <20-75 copies/mL or “undetectable”
- Increase CD4 count
  - 500-1500 cells/mm^3 is normal CD4 range
  - AIDS diagnosis is CD4 < 200 or CD4% < 14% (or AIDS defining illness)
- Improve quality of life and reduce HIV-related morbidity & mortality
- Prevent HIV transmission to others

DHHS panel on antiretroviral guidelines for adults and adolescents. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/

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Tools to Achieve Treatment Goals

- Performing pretreatment resistance testing
- Maximizing adherence
- Selecting individualized ART regimen

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Tools to Achieve Treatment Goals

- **Performing pretreatment resistance testing**
- Maximizing adherence
- Selecting individualized ART regimen

Use of Drug Resistance Testing to Guide Therapy Decisions

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- Drug resistance is the reduction of the sensitivity of the virus to a particular drug
- Resistance results from genetic mutation of viral enzymes & proteins leading to changes in the way drugs interact with them
- Mechanisms for ARV drug resistance
  - Transmitted resistance: Infected with a resistant strain of HIV at baseline
  - Spontaneous resistance: HIV develops mutations easily and becomes resistant
- **Obtain genotype prior to initiation of therapy to determine if resistant virus transmitted**
- Repeat resistance test if virologic failure during ART or suboptimal suppression of viral load after start of therapy to determine if spontaneous resistance occurred

Tools to Achieve Treatment Goals

- Performing pretreatment resistance testing
- **Maximizing adherence**
- Selecting individualized ART regimen

Adherence Interventions

- Provide an accessible, trustworthy, nonjudgmental multidisciplinary health care team
- Find resources to assist with treatment costs to maintain uninterrupted access to both ART and appointments
- Allow flexible appointment scheduling
- Assist with transportation
- Link patients to counseling to overcome stigma, substance use, or depression
- Change ART to simplify dosing or reduce side effects

DHHS panel on antiretroviral guidelines for adults and adolescents. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/

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Simplified ART Regimens

- Use of single tablet regimens (STRs)
- Co-formulated antiretroviral agents and once-daily dosing can reduce pill burden and simplify dosing schedules
- Simplified treatment regimens
  - Effective
  - Favored by patients and providers
  - Associated with better adherence

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Single Tablet Regimens (STRs)

Year of FDA Approval	Brand Name	Generic Name	Antiretroviral Drug Classes
2006	Atripla	Efavirenz/tenofovir DF/emtricitabine	NNRTI + dual NRTI
2011	Complera	Rilpivirine/tenofovir DF/emtricitabine	NNRTI + dual NRTI
2012	Stribild	Elvitegravir/cobicistat/tenofovir DF/emtricitabine	INSTI + booster + dual NRTI
2014	Triumeq	Dolutegravir/abacavir/lamivudine	INSTI + dual NRTI
2015	Genvoya	Elvitegravir/cobicistat/tenofovir AF/emtricitabine	INSTI + booster + dual NRTI
2016	Odefsey	Rilpivirine/tenofovir AF/emtricitabine	NNRTI + dual NRTI
2017	Juluca	Dolutegravir/rilpivirine	INSTI + NNRTI
2018	Biktarvy	Bictegravir/tenofovir AF/emtricitabine	INSTI + dual NRTI
2018	Symtuza	Darunavir/cobicistat/tenofovir AF/emtricitabine	PI + booster + dual NRTI
2018	Delstrigo	Doravirine/tenofovir DF/emtricitabine	NNRTI + dual NRTI
2019	Dovato	Dolutegravir/lamivudine	INSTI + NRTI

Key: DF = disoproxil fumarate; AF = alafenamide; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucelos(t)ide reverse transcriptase inhibitor; INSTI = integrase strand transfer inhibitor; PI = protease inhibitor

Food Considerations with STRs

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STR Brand Name	Single Tablet Regimen Generic Name	Food Considerations
Atripla	Efavirenz/tenofovir DF/emtricitabine	**Empty stomach**
Biktarvy	Bictegravir/tenofovir AF/emtricitabine	**With or without food**
Complera	Rilpivirine/tenofovir DF/emtricitabine	**With a full meal (not a protein drink)**
Delstrigo	Doravirine/tenofovir DF/emtricitabine	**With or without food**
Dovato	Dolutegravir/lamivudine	**With or without food**
Genvoya	Elvitegravir/cobicistat/tenofovir AF/emtricitabine	**With food**
Juluca	Dolutegravir/rilpivirine	**With a full meal (not a protein drink)**
Odefsey	Rilpivirine/tenofovir AF/emtricitabine	**With a full meal (not a protein drink)**
Stribild	Elvitegravir/cobicistat/tenofovir DF/emtricitabine	**With food**
Symtuza	Darunavir/cobicistat/tenofovir AF/emtricitabine	**With food**
Triumeq	Dolutegravir/abacavir/lamivudine	**With or without food**

Key: DF = disoproxil fumarate; AF = alafenamide

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What exactly does empty stomach, with food, or with a full meal mean?

- Empty stomach: 1 hour before a meal or 2 hours after a meal
- With food: Within 2 hours after eating
- With a full meal: At least 390 calories

Full meal of at least 390 calories (good examples and bad examples):

Simplified Regimen: Cabenuva (IM cabotegravir/rilpivirine)

- DHHS guidelines panel recommends LA CAB/RPV as optimization strategy for HIV+ on ART with viral suppression for ≥ 3 months, who –
  - have no baseline resistance to either medication,
  - have no prior virologic failures,
  - do not have active HBV infection (unless also receiving oral HBV treatment),
  - are not pregnant/planning on becoming pregnant, and
  - are not receiving medications with significant drug interactions
- DHHS recommends against LA CAB/RPV in people with detectable viral load due to suboptimal ART adherence and in people with ongoing challenges with retention in care

DHHS panel on antiretroviral guidelines for adults and adolescents. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/

Tools to Achieve Treatment Goals

- Performing pretreatment resistance testing
- Maximizing adherence
- **Selecting individualized ART regimen**

AMCP Florida

Process for Selecting an Initial ART Regimen

- Regimen efficacy
  - Standard therapy for HIV typically consists of 2-3+ drugs from 2+ classes (no monotherapy)
- Comorbidities
  - Potential adverse effects or drug-drug interactions
- Drug resistance
  - Presence of transmitted drug resistance or development of drug resistance on failure
- Adherence potential
  - Pill burden, dosing frequency, food restrictions

1-2 NRTIs		INTEGRASE INHIBITOR
Emtricitabine + Tenofovir **OR** Lamivudine +/- Abacavir *only w/ Dolutegravir	+	Bictegravir Dolutegravir*

Tenofovir alafenamide (TAF) and tenofovir disoproxil fumarate (TDF) are two forms of tenofovir approved by the FDA. TAF has fewer bone and kidney toxicities than TDF, while TDF is associated with lower lipid levels. Safety, cost, and access are among the factors to consider when choosing between these drugs.

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2 NRTIs

Tenofovir + Emtricitabine

OR

Abacavir + Lamivudine

+

PROTEASE INHIBITOR

(boosted with ritonavir or cobicistat)

Darunavir + RTV or Darunavir + COBI
Atazanavir + RTV or Atazanavir + COBI

OR

NNRTI

Doravirine
Efavirenz
Rilpivirine

OR

INTEGRASE INHIBITOR

Elvitegravir + cobicistat
Raltegravir

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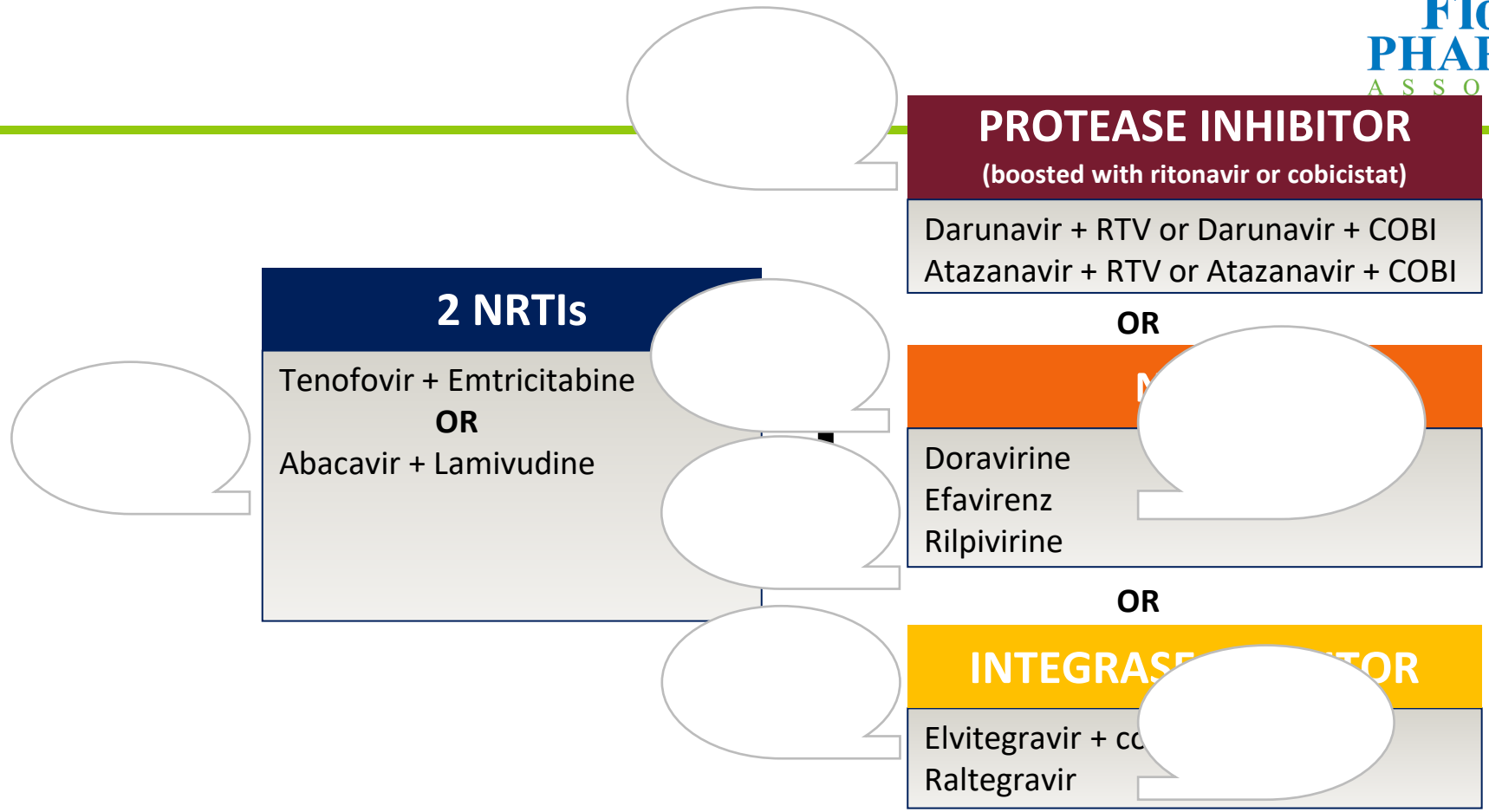

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Selecting an Initial HIV Regimen: The “Chinese Food Rule”

*Tip of the hat to Royce Lin, MD, Associate Clinical Professor of Medicine, UCSF

PROTEASE INHIBITOR
(boosted with ritonavir or cobicistat)

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Atazanavir + RTV or Atazanavir + COBI

OR

2 NRTIs

Tenofovir + Emtricitabine
OR
Abacavir + Lamivudine

+

NNRTI

Doravirine
Efavirenz
Rilpivirine

OR

INTEGRASE INHIBITOR

Elvitegravir + cobicistat
Raltegravir

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Raltegravir

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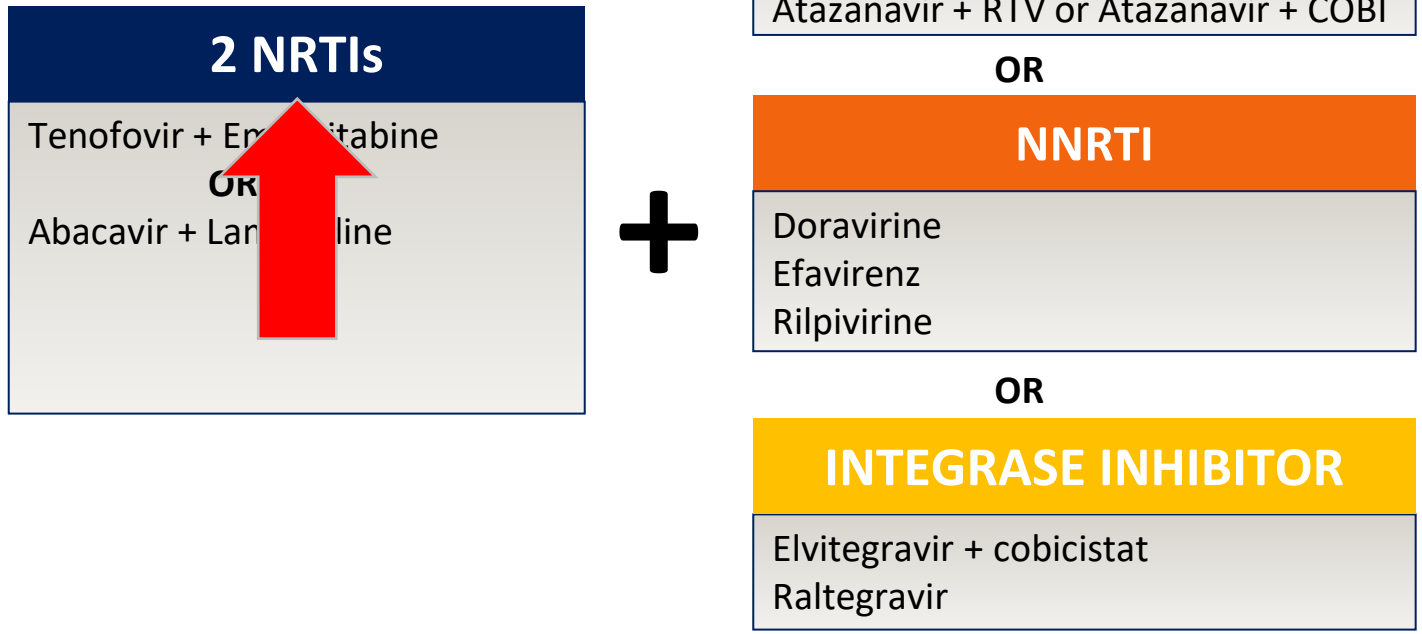

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2 SCOOPS OF RICE

Tenofovir + Em[illegible]itabine

OR

Abacavir + Lam[illegible]line

+

PROTEASE INHIBITOR
(boosted with ritonavir or cobicistat)

Darunavir + RTV or Darunavir + COBI
Atazanavir + RTV or Atazanavir + COBI

OR

NNRTI

Doravirine
Efavirenz
Rilpivirine

OR

INTEGRASE INHIBITOR

Elvitegravir + cobicistat
Raltegravir

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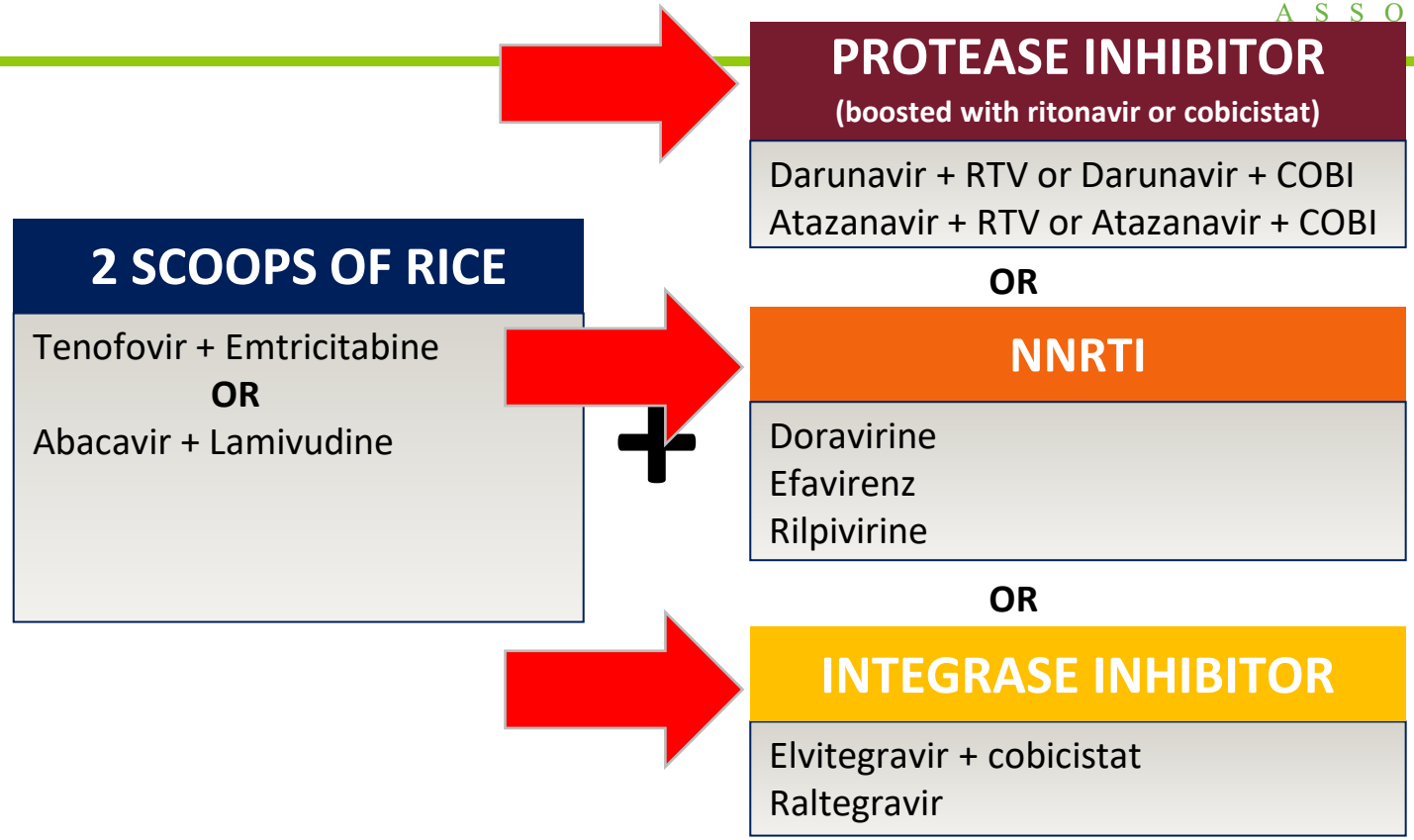

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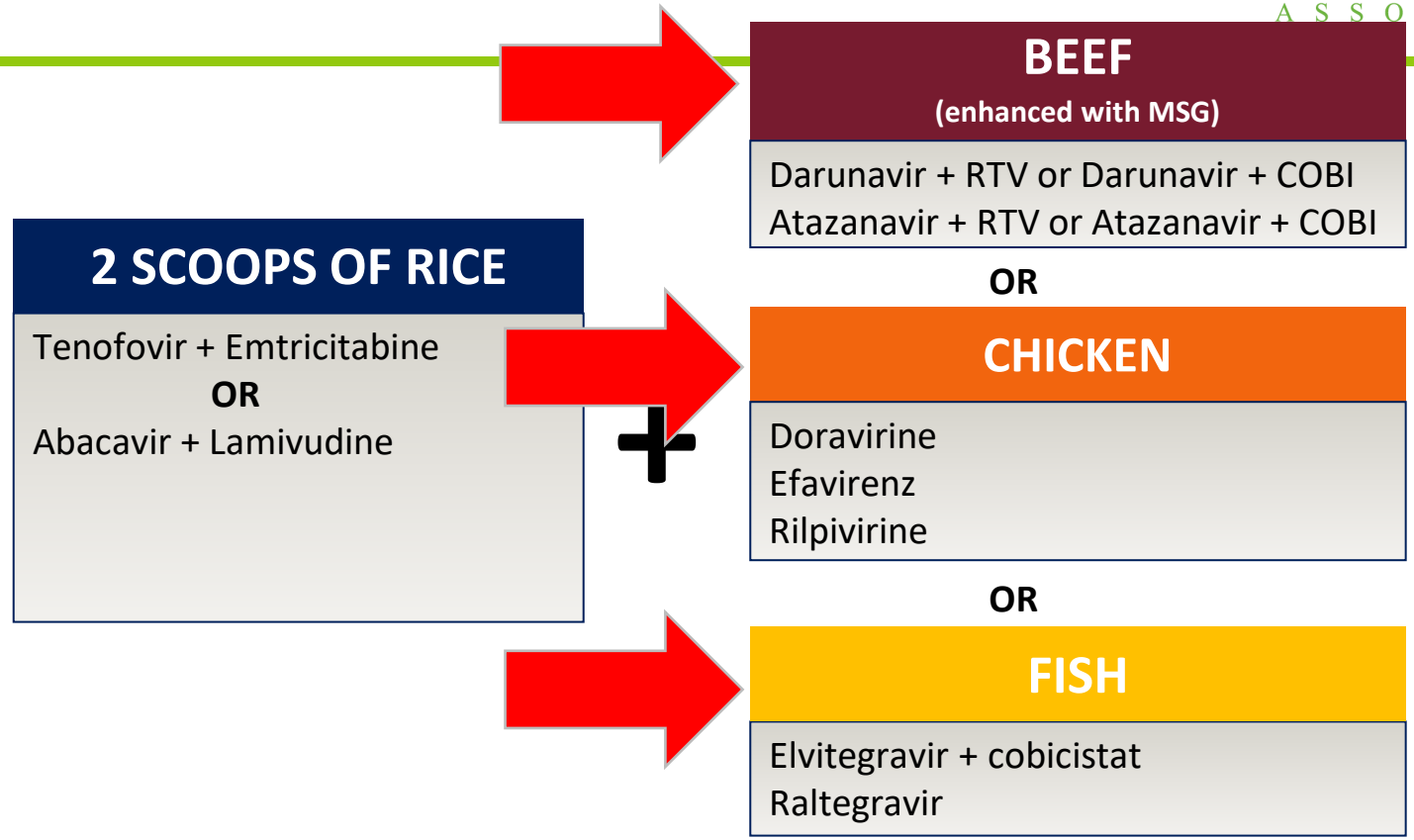

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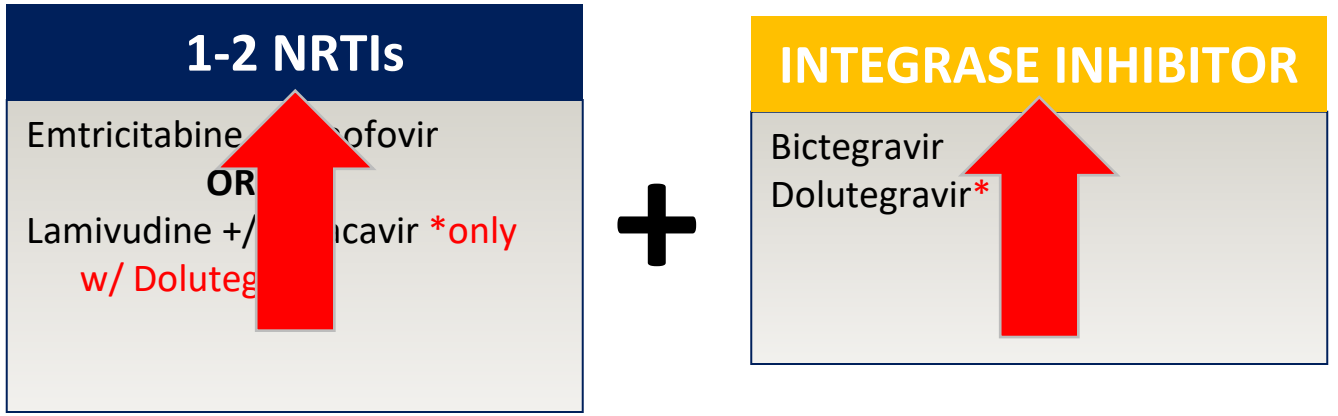

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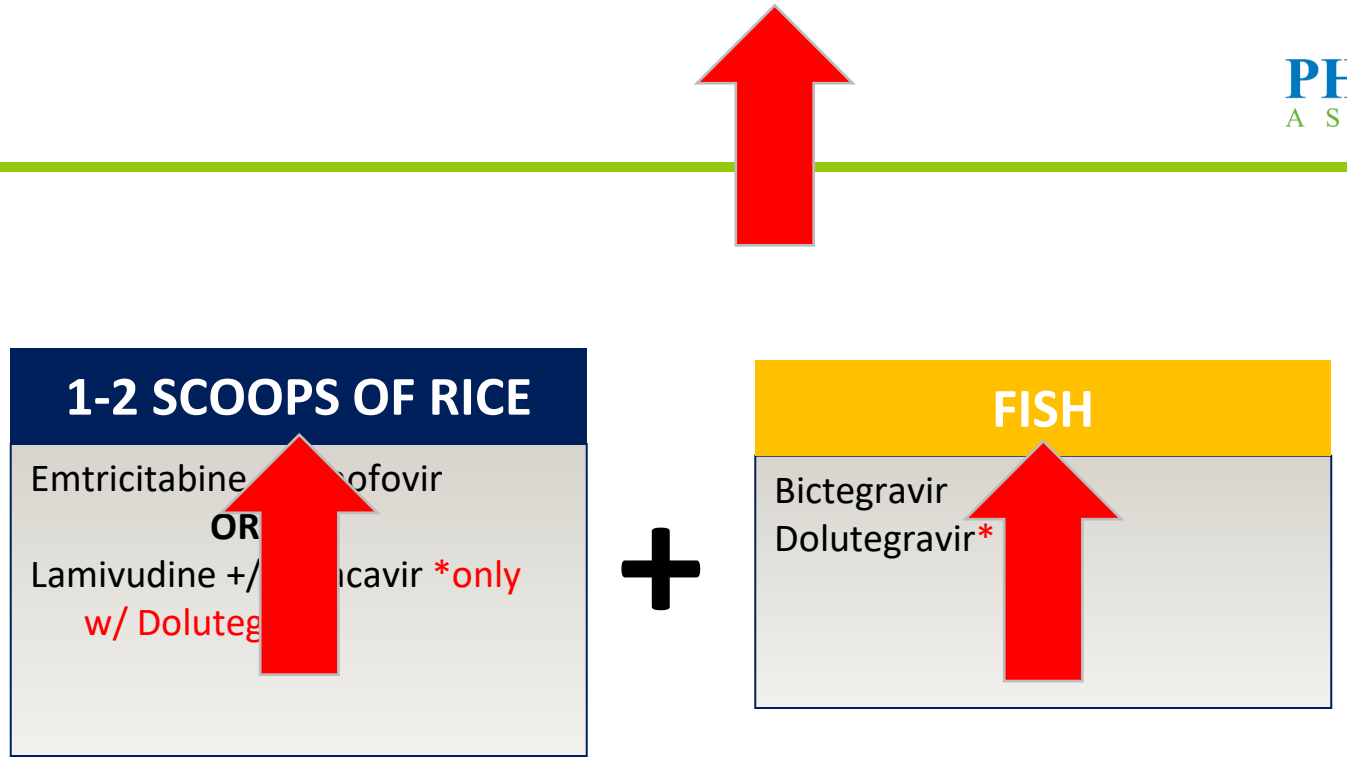

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HIV Regimen / Chinese Food Selection: A Stepwise Approach

1. Get 1-2 scoops of rice

- Choose 2 NRTIs, co-formulated when possible
  - Example: Tenofovir + emtricitabine
  - Example: Abacavir + lamivudine
- Only one regimen uses 1 NRTI (one scoop of rice): lamivudine + dolutegravir

2. Beef, fish, or chicken?

- Decide which class to use (PI, INSTI, NNRTI)
- Choose specific agent based on comorbidities, pill burden, drug interactions, resistance testing, etc.

PI + RTV or COBI (Beef + MSG)	INSTI (Fish)	NNRTI (Chicken)
PRO •Very strong, potency well established •Harder to get resistance •Best for patients with uncertain adherence or if resistance tests not available •Recommended if history of using long-acting (LA) cabotegravir for PrEP and no INSTI resistance test result	**PRO** •Highly effective for most patients •Very few side effects •Less drug interactions •Dolutegravir & bictegravir have high genetic barrier to resistance (strong, potent) •Dolutegravir or bictegravir can be used if resistance tests not available (unless prior use of LA cabotegravir for PrEP)	**PRO** •Efavirenz: minimal drug interactions w/ rifamycins •Doravirine: less drug interactions, can take with or without food •Rilpivirine is in smallest single tablet regimen
CON •Many drug interactions (P450 metabolism) •Metabolic effects (↑ cholesterol, glucose) •GI side effects •Boosting required	**CON** •Some delicate, prone to resistance (e.g., raltegravir, elvitegravir) •Weight gain (e.g., bictegravir, dolutegravir, especially when used with tenofovir alafenamide)	**CON** •Prone to resistance •Efavirenz has CNS side effects •Doravirine comes co-formulated only with TDF/3TC •Rilpivirine has lower efficacy in some patients (use only if CD4>200 and VL<100,000) and requires acidic environment for absorption

AMCP Florida

Summary

- HIV testing should be routinized
- HIV transmission risk varies widely depending on the type of exposure or behavior
- Pharmacists have a role in HIV prevention
  - Expanding PrEP and PEP uptake can limit new HIV infections
- Antiretroviral therapy recommended for all HIV+
  - Initial ART = 1-2 NRTIs + INSTI or PI or NNRTI
  - 1-2 scoops of rice + 1 main entrée

HIV/AIDS Updates

Elizabeth Sherman, PharmD, AAHIVP

Associate Professor, Nova Southeastern University

Division of Infectious Disease, Memorial Physician Group

Faculty, Southeast AIDS Education and Training Center

Federal & State Managed Care Policy Update

Policy & Government Relations Manager at AMCP

Financial Relationship Disclosures

Faculty/Reviewer/Planner	Reported Relevant Financial Relationships
Tom Casey *Faculty*	Disclosed no relevant financial relationships.

Learning Objectives

At the completion of this activity, participants should be able to:

1. Identify important health care legislation and regulations and their major provisions.
2. Describe the timeline and important milestones regarding implementation of the Inflation Reduction Act.
3. Discuss how recent court rulings may influence states' ability to regulate employer-sponsored pharmacy benefits.

Pre-Test

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LQ1: How long after FDA approval will single-source small-molecule drugs and biologics be eligible for Medicare price negotiation?

a) 13 years for both small-molecules and biologics
b) 7 years for small-molecules and 11 years for biologics
c) 9 years for small-molecules and 13 years for biologics
d) 15 years for both small-molecules and biologics

LQ2: Which of the following PBM reform bills has passed at least 1 chamber of Congress

a) PBM Reform Act (S. 1339)
b) Health Care Price Transparency Act (H.R. 4822)
c) Lower Costs, More Transparency Act (H.R. 5378)
d) Safe Step Act (S. 652/H.R. 2630)

LQ3: Which federal court case impacts ERISA pre-emption of state PBM regulations?

a) *PCMA v. Mulready*
b) *Alliance for Hippocratic Medicine v. FDA*
c) *Dayton Area Chamber of Commerce et al. v. Becerra et al.*
d) *Dobson v. Secretary of Health and Human Services*

LQ4: Which of the following PBM contract provisions does SB 1550 require?

a) Rebate pass-through pricing model
b) Participation of unaffiliated pharmacies in pharmacy networks
c) Prohibition on charges, withholds, or recoupments outside of the pharmacy audit or MAC pricing appeal processes
d) All of the above

Federal Update

Inflation Reduction Act (IRA) Health Provisions in Effect

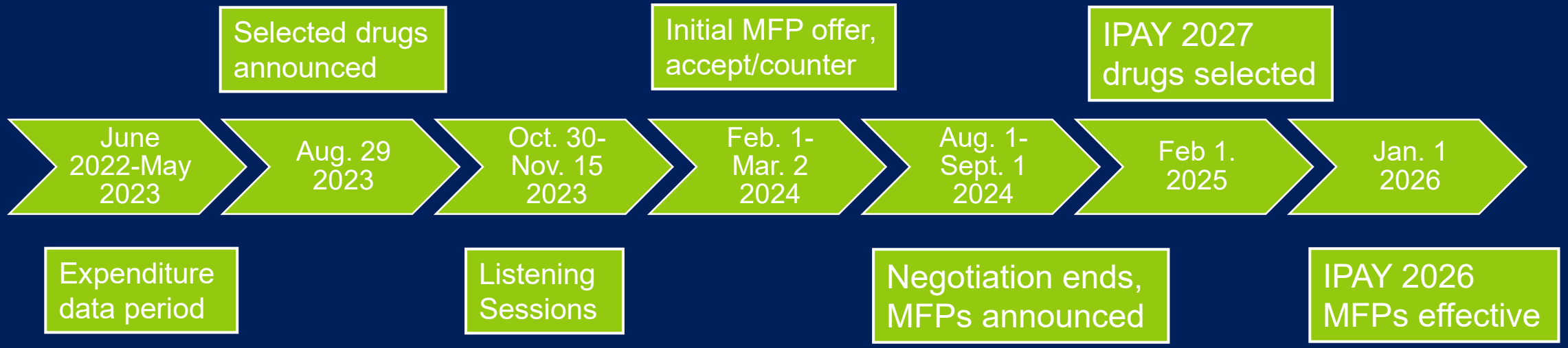
- Parts B & D Drug Inflation Rebate
- Part D insulin copay cap
- Part D vaccine coverage w/o cost-sharing
- Extends enhanced Marketplace premium tax credit thru 2025
- Enhanced Part B biosimilar payments (ASP+8) for 5 years
- Rebate Rule delay until 2032

IRA: Drug Price Negotiation Program

- Products eligible for selection include small molecule drugs approved >7 years ago and biologics licensed >11 years ago
- Exemptions:
  - Products with generic or biosimilar competition
  - Orphan drugs (limited to 1 indication)
  - Products made by small biotech firms (2026-2028)
- CMS released guidance this summer on negotiation factors that will inform its initial Maximum Fair Price (MFP) offer
- Statute establishes MFP ceiling for short-monopoly and long-monopoly drugs, which for IPAY 2026 are 75% and 40% of the product's non-FAMP in CY 2021

IRA: Drug Price Negotiation Program

- CMS will select 10 Part D drugs for 2026, 15 additional Part D drugs for 2027, 15 more Part B or Part D drugs for 2028, and 20 more Part B or Part D drugs for each subsequent year.
- Timeline for Initial Price Applicability Year (IPAY) 2026:



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IRA: Drug Price Negotiation Program

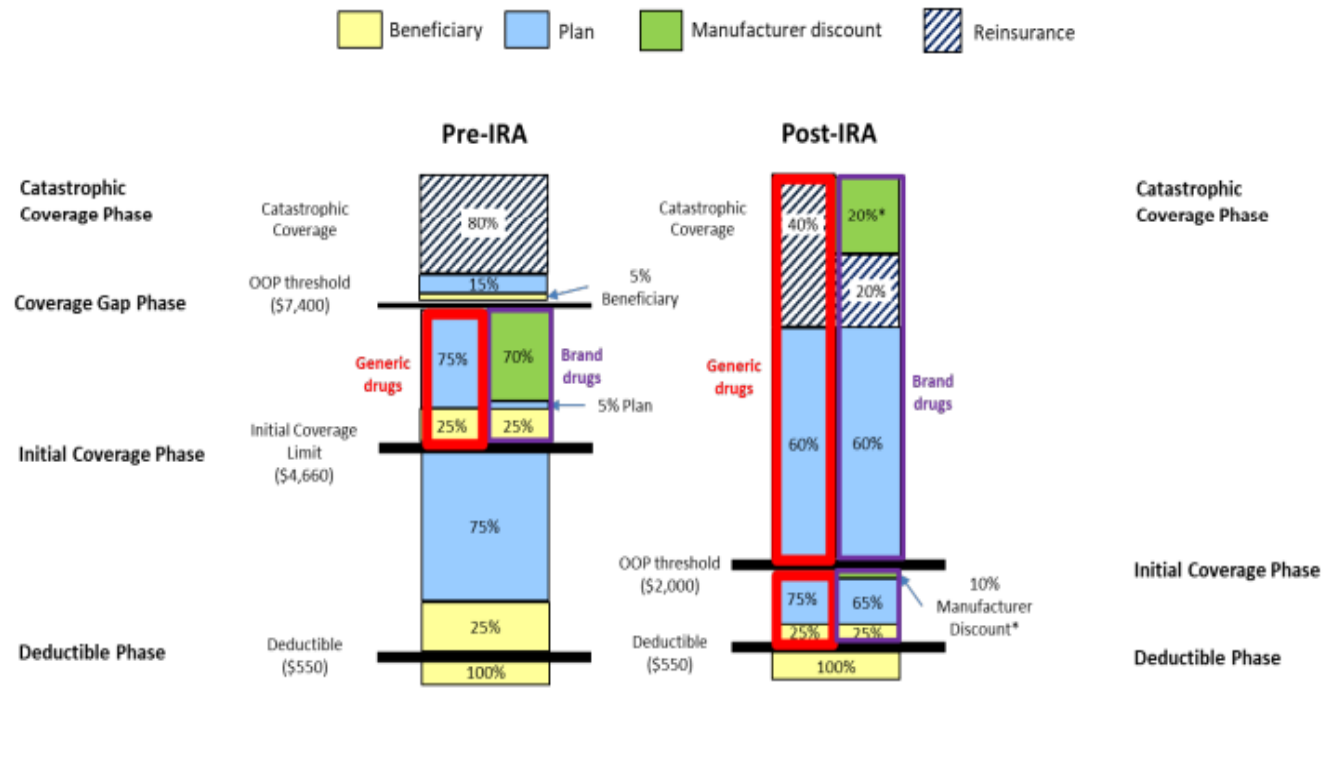
Selected Drug (Manufacturer)	Usage	Total Part D Gross Spend
Eliquis (BMS)	Blood thinner	$16.5B
Jardiance (Eli Lilly)	Diabetes	$7.1B
Xarelto (J&J)	Blood thinner	$6.0B
Januvia (Merck)	Diabetes	$4.1B
Farxiga (AstraZeneca)	Diabetes, Heart failure	$3.3B
Entresto (Novartis)	Heart failure	$2.9B
Enbrel (Amgen)	Inflammatory/Autoimmune Conditions	$2.8B
Imbruvica (Abbvie /J&J)	Leukemia	$2.7B
Stelara (J&J)	Inflammatory/Autoimmune Conditions	$2.6B
Fiasp / Novolog (Novo Nordisk)	Diabetes	$2.6B
	TOTAL	**$50.5B**

IRA: Part D Redesign

Changes in 2025:

- Out-of-pocket threshold lowered to $2k, catastrophic liability adjusted
- Manufacturer Discount Program
- Medicare Prescription Payment Plan

Figure 1. IRA Changes to the Part D Benefit for Non-LIS Enrollees in 2025



Notes: Figure 1 represents Part D payment benefit structure before and after the IRA redesign in 2025 for non-LIS enrollees. Pre-IRA and Post-IRA benefit are scaled to $10,000 of total liability in 2023.

*IRA Manufacturer Discount phased in during the initial coverage phase from 2025 through 2029 and in the catastrophic phase from 2025 through 2031. Full details of the IRA changes are available at: Inflation Reduction Act and Medicare | CMS

Source: Centers for Medicare and Medicaid Services

IRA = Inflation Reduction Act

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Medicaid Drug Rebate Program Changes

- American Rescue Plan Act of 2021 included provision removing the cap on rebates manufacturers may be liable to pay under the Drug Rebate Program, starting Jan. 1, 2024
- CMS released a proposed rule in May 2023 (“Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program”) that would require manufacturers to stack cumulative discounts, rebates, or other arrangements provided to different price eligible entities to generate a final best price
- Combined impact of these changes, pending finalization?

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Pressing Issues

Government funding:

- Short-term continuing resolution (CR) passed on Sept. 30, leads to Speaker McCarthy vacated
- "Laddered" CR passed on Nov. 14 which funds government programs thru Jan. 19 and Feb. 2
  - FDA and VA funding expires Jan. 19, HHS expires Feb. 2
- Congress negotiating supplemental funding bill

Must-pass healthcare legislation:

- SUPPORT Act reauthorization – SUD programs and medication-assisted treatment coverage
- PAHPA Act reauthorization – HHS preparedness and response programs
- Medicaid DSH cuts, authorizations for community health centers and Teaching Health Center GME

Lower Costs, More Transparency Act (HR 5378)

- **Transparency and reporting in group health plan contracts:** drug claims and plan/enrollee spending, formulary management, and affiliated pharmacies/patient steering
- **Patient Benefit Transparency:** specifies the cost-sharing and other benefit information group health plans must publish under the Transparency in Coverage Rule, in-network vs. out-network costs
- **Spread pricing and pharmacy reimbursement:** bans spread pricing and requires rebate pass-throughs in Medicaid, adds specialty drugs to NADAC survey
- **Medicare Integration:** beginning in 2029, MedPAC will report on the impact of vertical integration on utilization, access to clinician administered drugs, and pharmacy networks

Lower Costs, More Transparency Act (HR 5378)

- Passed the House on Dec. 11, 2023 with bipartisan vote
- Drafted by the leaders of the Energy & Commerce, Ways & Means, and Education & the Workforce Committees
- Expands provider transparency reporting requirements and lowers hospital reimbursement for certain services (parity)
- Includes some must-pass healthcare provisions: delays Medicaid DSH cuts to 2026, reauthorizes community health center and Teaching Health Center GME
- Cuts the Safe Step Act, MA-PD ePA, and Part D cost-sharing limits which was included in some committee drafts

Pharmacy Benefit Manager (PBM) Reform - Senate

Bill Name (#)	Committee	Key Provisions
PBM Reform Act (S. 1339)	HELP	• PBM group health plan client reporting & transparency requirements • Restrictions on PBM contracting (bans commercial spread pricing & requires full rebate pass-through) • Restrictions on step therapy (Safe Step Act)
Pharmacy Benefit Transparency Act (S. 127)	Commerce	• PBM group health plan client reporting & transparency requirements • Restrictions on PBM contracting (bans commercial spread pricing & requires full rebate pass-through) • Expands FTC authority over PBMs
Modernizing and Ensuring PBM Accountability Act (S. 2973)	Finance	• PBM transparency requirements to PDP sponsors • Limiting PBM reimbursement to a “bona fide” service fee in Part D • Requiring transparency of contracts and agreements between PBMs and manufacturers

Biosimilars Legislation

- AMCP is tracking 15 bills related to biosimilars (not including PBM reform bills):
  - Interchangeability designation/barriers to substitution – *Biosimilar Red Tape Elimination Act (S. 2305)*
  - Anti-competitive practices – *Stop STALLING Act (S. 148)*
  - Coverage mandates and cost-sharing – *Ensuring Access to Lower-Cost Medicines for Seniors Act (H.R. 5461/S. 2129)*
  - Enabling mid-year plan changes – *Expanding Seniors' Access to Lower Cost Medicines Act (H.R. 5372)*
  - Increasing payment rates for biosimilars under Part B – (H.R. 6400)

PCMA v. Mulready

PCMA v. Mulready Background

- 10th Circuit case concerning a 2019 Oklahoma state law (Patient's Right to Pharmacy Choice Act) that included the following provisions related to all PBMs operating in the state:
  - Retail-only network adequacy standards, i.e., prohibiting the use of mail-order pharmacy in determining adequacy.
  - Prohibits the use of cost-share and copay discounts to incentivize use of network pharmacies.
  - Requires PBMs to admit any pharmacy willing to accept the terms and conditions to the preferred pharmacy network (any willing provider)
  - Prohibits PBMs from terminating, limiting, or denying a contract with a pharmacy based on an employed pharmacist's probationary status

PCMA v. Mulready Decision

- 10th Circuit found all four provisions were pre-empted by ERISA, and the any-willing provider provision was also pre-empted by Medicare Part D
- Many state Attorneys General signed on to an amicus brief supporting the Oklahoma law
- The Biden administration agreed with PCMA that all four provisions were pre-empted by federal law
- Oklahoma filing for rehearing before 10th Circuit, unlikely to be granted
- Oklahoma will likely ask the Supreme Court to review
    - Many stakeholders feel SCOTUS will not take up the case, Adam isn't so sure

PCMA v. Mulready Implications

- For time being, greater stability for ERISA and Part D prescription drug plans
  - Both in terms of consistency across states and less risk of new regulation on these specific issues
- 10th Circuit was very careful to describe how their decision was consistent with *Rutledge v. PCMA* SCOTUS decision, so part of the *Rutledge* landscape for now
- **IF** SCOTUS takes up case, finding that those provisions are **not** pre-empted would be huge change of interpretation and severely narrow the scope of pre-emption

State Update

Prescription Drug Reform Act (FL SB 1550)

- Signed into law by Gov. DeSantis in May 2023; OIR released guidance to industry on July 19, 2023, rule was released September 18, 2023
- Requires manufacturers to report any price increase that would result in a 15% increase over a calendar year or a 30% increase over a 3-year period
- Requires PBMs to be licensed with the Office of Insurance Regulation (OIR) and hold a valid certificate of authority as an administrator starting Jan. 1, 2024
- Establishes reporting requirements, contract and data protection standards, and prohibits certain practices

Prescription Drug Reform Act (FL SB 1550)

- PBM contracts with pharmacy benefit plans beginning Jan. 1, 2024:
  - Must use a pass-through pricing model with all manufacturer rebates going to offset defined cost-sharing and reduce premiums for covered persons
  - Meet or exceed Part D network adequacy requirements, which may not limit a network solely to affiliated pharmacies, require utilization of mail order or 3rd party delivery services, require use of an affiliated pharmacy or provider for in-person administration, or require or provide certain promotional items related to affiliated pharmacies

Prescription Drug Reform Act (FL SB 1550)

- PBM contracts with pharmacy benefit plans:
  - PBMs may not condition participation in one pharmacy network on participation in any other network or penalize a pharmacy for refusing to participate in a network
  - PBMs may not require pharmacies to meet accreditation standards more stringent than federal and state standards for licensure, except in the case of specialty networks
  - Require PBMs to provide at least a 60-day continuity-of-care period after revising its formulary during a plan year

Prescription Drug Reform Act (FL SB 1550)

- PBM contracts with pharmacies beginning Jan. 1, 2024:
  - At the time of adjudication or reimbursement, PBMs must provide the pharmacy with information necessary to identify the reimbursement schedule for the specific network for the claim
  - PBMs must ensure that basis of reimbursement information is shared with the pharmacy using NCPDP Telecommunication Standard Implementation Guide
  - Prohibits charges, withholds, or recoupments; does not apply to quality incentive payments, recoupment due to error or fraud, a MAC appeal price adjustment, or in accordance with a pharmacy audit that meets the state's standards

Prescription Drug Reform Act (FL SB 1550)

- PBM contracts with pharmacies beginning Jan. 1, 2024:
  - PBMs must provide a reasonable appeal process for its MAC pricing and reimbursement
  - PBM may not unilaterally change the terms of a participation contract
  - PBM may not prohibit a pharmacy from offering mail or delivery services
  - Upon request, PBM must provide a pharmacy a list of pharmacy benefit plans in which the pharmacy is part of the network. Must notify a pharmacy within 7 days of a change

Prescription Drug Reform Act (FL SB 1550)

- OIR reporting requirements:
  - Audited financial statements
  - Notice of violations
  - Network adequacy attestations
  - Ownership changes
  - MAC list appeals and denials
  - Attestations from plan or program contracting with the PBM

Canadian Drug Importation

- On Jan. 5, 2024, after much cajoling, FDA approved Florida's plan for a period of 2 years.
- State proposal would make imported drugs available to public programs like Medicaid and correctional facilities. Proposal suggests drugs to treat conditions like HIV/AIDs, Hep C, diabetes and mental health would be prioritized.
  - Florida estimates it will save $183 million the first year, primarily Medicaid
- Agency for Health Care Administration will contract with a vendor to identify drugs with the highest potential for cost savings and serve as intermediary between Canadian suppliers and pharmacies/wholesalers.
- Obstacles? Canada, drug manufacturers, other states getting in on the action

Collaborative Practice – Chronic Conditions

- Bill passed in 2020 authorized pharmacists to provide patient care services for patients with chronic conditions pursuant to a collaborative practice agreement.
- The statute authorizes pharmacists to initiate, modify, or discontinue drug therapy for the following conditions:
  - Arthritis
  - Asthma
  - COPD
  - Type 2 diabetes
  - HIV or AIDS
  - Obesity, and
  - Any other chronic condition adopted by the Florida Board of Pharmacy

Collaborative Practice – Chronic Conditions

- In October 2020, the Florida Board of Pharmacy adopted a rule adding 5 conditions to the list of chronic conditions eligible for pharmacist care services under a collaborative practice agreement
- On Sept. 27, 2023, the Board adopted a finalized a rule amendment which added Hepatitis C to the list
- According to the Florida Department of Health, 12,518 Floridians were reported to have chronic Hep C

Post-Test

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AMCP Florida

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LQ2: Which of the following PBM reform bills has passed at least 1 chamber of Congress

a) PBM Reform Act (S. 1339)
b) Health Care Price Transparency Act (H.R. 4822)
c) Lower Costs, More Transparency Act (H.R. 5378)
d) Safe Step Act (S. 652/H.R. 2630)

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LQ3: Which federal court case impacts ERISA pre-emption of state PBM regulations?

a) *PCMA v. Mulready*
b) *Alliance for Hippocratic Medicine v. FDA*
c) *Dayton Area Chamber of Commerce et al. v. Becerra et al.*
d) *Dobson v. Secretary of Health and Human Services*

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LQ4: Which of the following PBM contract provisions does SB 1550 require?

a) Rebate pass-through pricing model
b) Participation of unaffiliated pharmacies in pharmacy networks
c) Prohibition on charges, withholds, or recoupments outside of the pharmacy audit or MAC pricing appeal processes
d) All of the above

LQ4: Which of the following PBM contract provisions does SB 1550 require?

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c) Prohibition on charges, withholds, or recoupments outside of the pharmacy audit or MAC pricing appeal processes
d) All of the above

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Saturday, January 20th, 2024

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