Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) in the Long Term Care Setting

Part 1: The Basics

Omnicare Pharmacy Services

Carrie Allen PharmD, CGP, BCPS, BCPP, CCHP

Overview - Part 1: The Basics

- HIV vs. AIDS
- CD4 counts (brief overview)
- Concepts important in HIV and Aging
- Long term care (LTC) specific concerns
  - Social considerations and creating an environment conducive to care
    - Resident rights and privacy
    - Stigma
  - Regulations and ethical considerations
  - Comorbid conditions
  - Occupational post-exposure protocols
  - Vaccinations

HIV - Human Immunodeficiency Virus

- Infects human white blood cells (CD4 cells) and attacks the immune system
- Retrovirus: an encapsulated RNA virus
  - Enzyme allows it to insert itself into the DNA of human host cells
  - No cure and it cannot be removed from the body
  - Even when virus is undetectable in blood, it is replicating in sanctuary sites
    - lymphatic system, brain
- Now thought of as a chronic infection
- HIV infection eventually progresses to AIDS

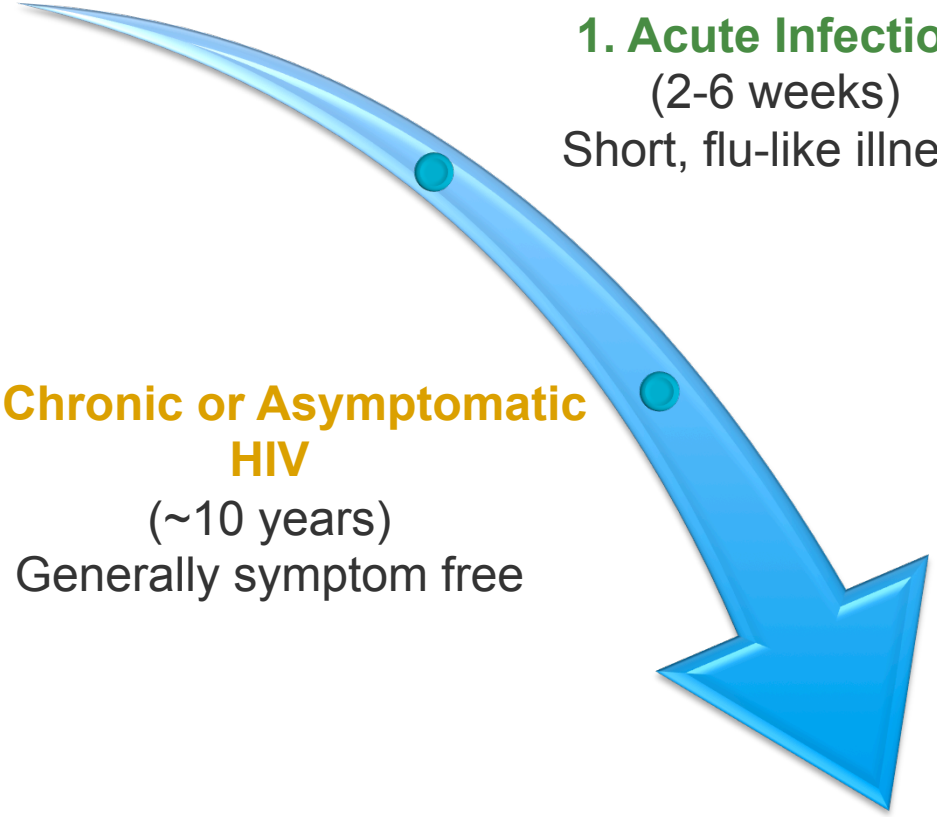
*CD4 count: lab measuring number of CD4 white blood cells (CD4 cells) in a blood sample; baseline CD4 count of a healthy adult: 500 cells/mm^3 to 1,200 cells/mm^3

AIDS - Acquired Immune Deficiency Syndrome

- Sometimes called advanced HIV infection
- Syndrome that occurs when the immune system fails and cannot fight off infections and disease
- Diagnoses may be based on the CD4 count (less than 200 cells/mm^3)*
- Can also be diagnosed based on the presence of one or more opportunistic infections
- People with AIDS require medical treatment to prevent death

*CD4 count: lab measuring number of CD4 white blood cells (CD4 cells) in a blood sample; baseline CD4 count of a healthy adult: 500 cells/mm^3 to 1,200 cells/mm^3

Stages of HIV

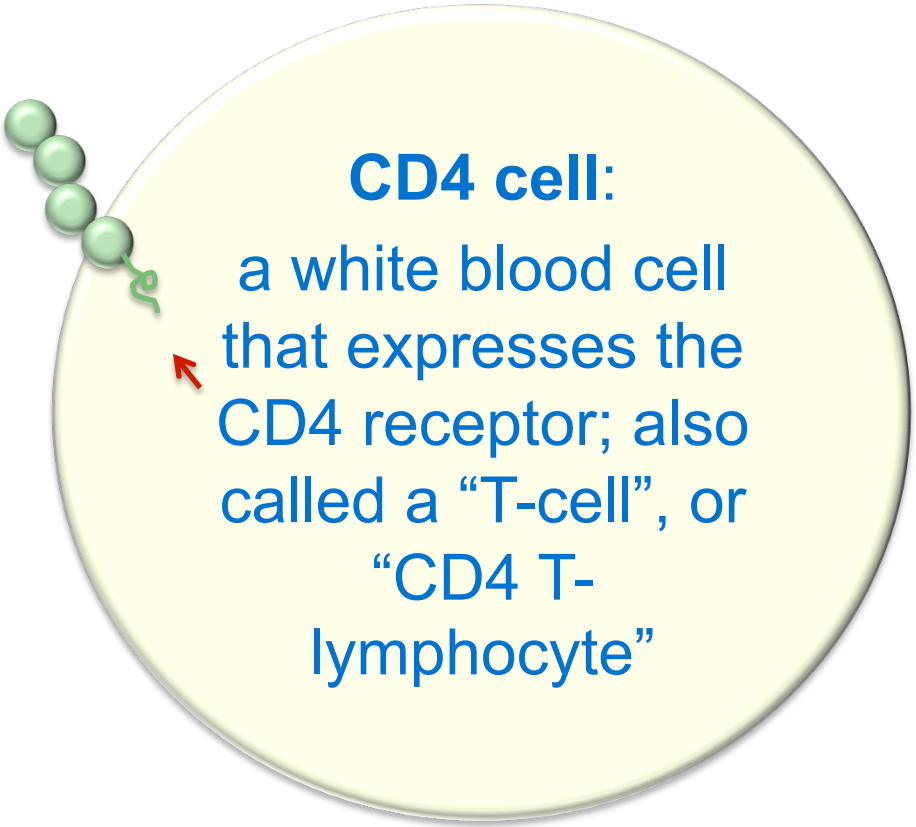


1. Acute Infection
(2-6 weeks)
Short, flu-like illness

2. Chronic or Asymptomatic HIV
(~10 years)
Generally symptom free

3. AIDS/Symptomatic HIV
CD4 count drops
HIV replicates, mutates, becomes more pathogenic
Immune system fails
Opportunistic infections and/or cancers occur

CD4 T-lymphocytes



- **CD4 count**: lab measuring the number of CD4 cells in a blood sample
  - Indicator of the health of the immune system
  - ↓ CD4 count = ↑ risk of infections
- **Healthy CD4 count** for adults = 500 cells/mm^3 to 1,200 cells/mm^3
- **CD4 count < 200 cells/mm^3** is one of the qualifications for a diagnosis of stage 3 infection (AIDS)

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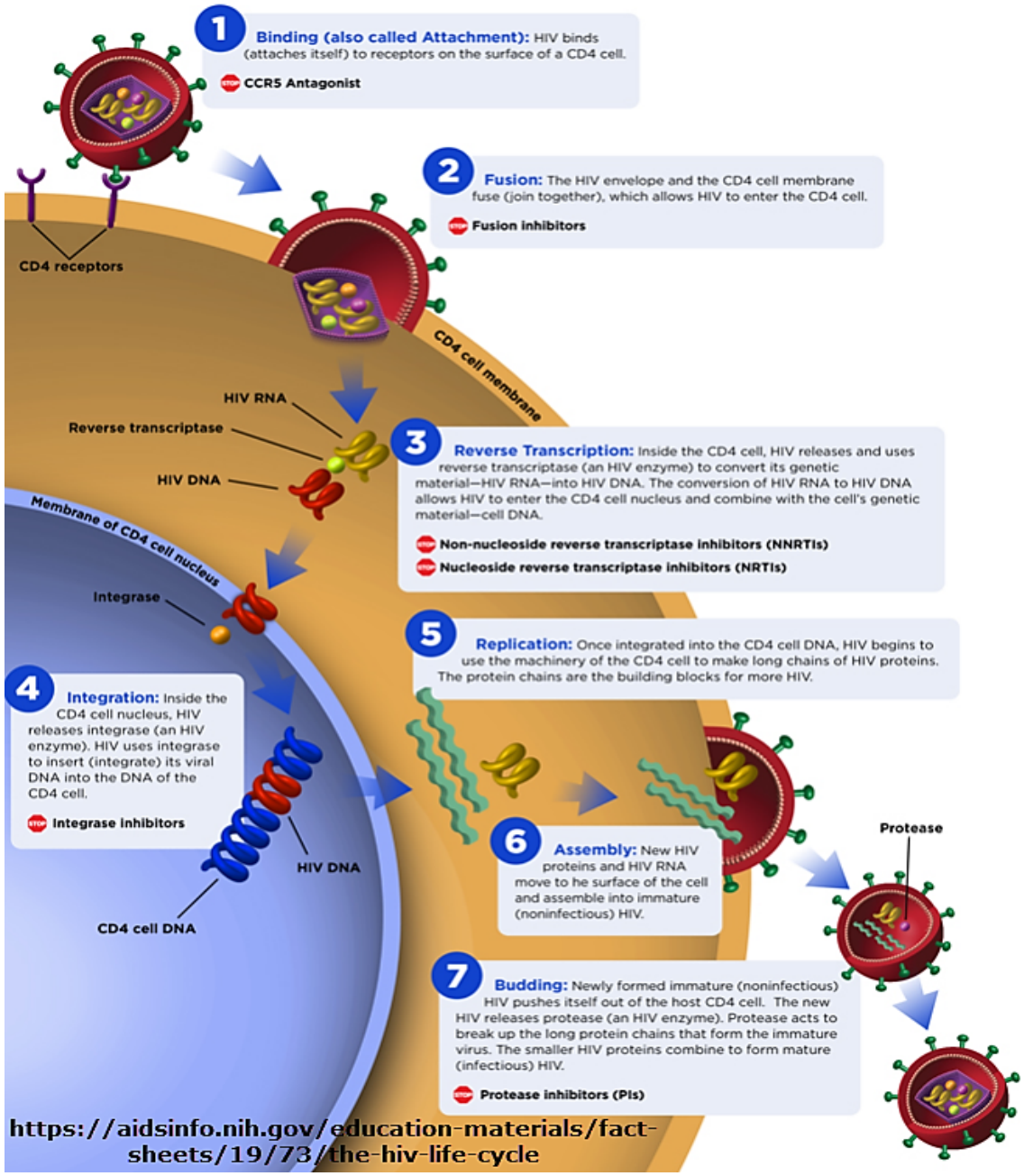
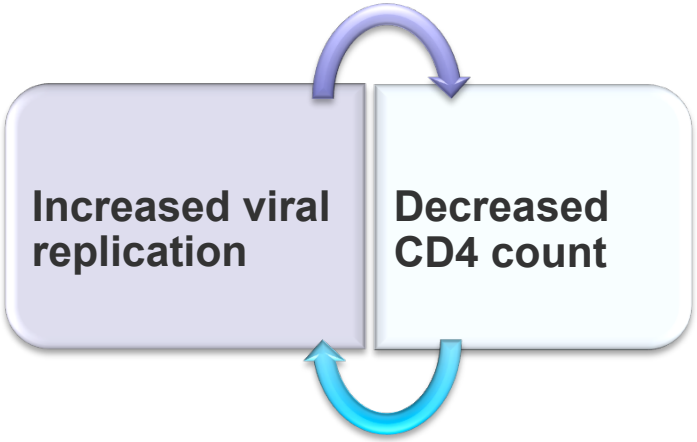
The HIV Life Cycle

HIV medicines in six drug classes stop HIV at different stages in the HIV life cycle.



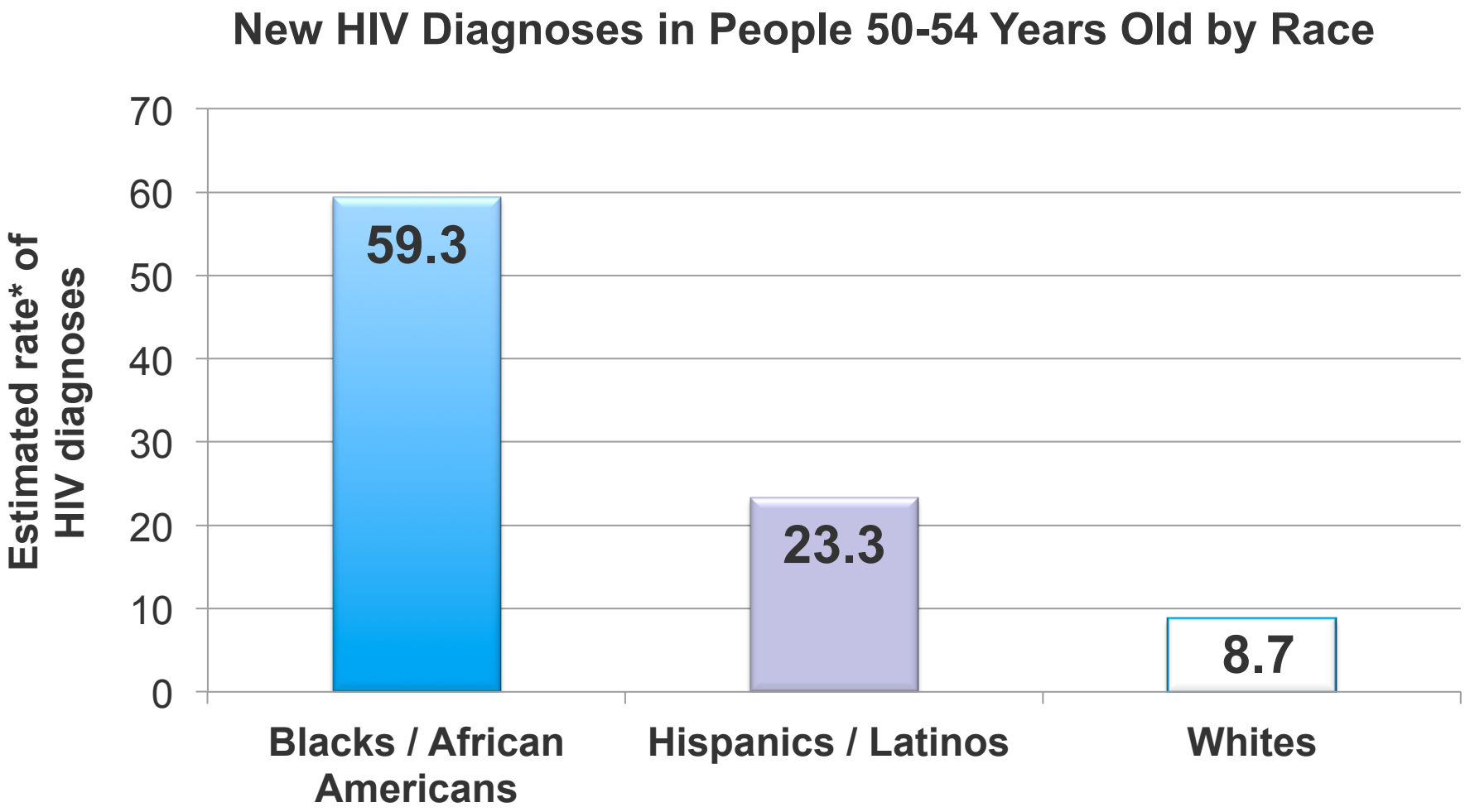


Aging HIV Population

- In the United States, approximately 30% of people currently living with HIV/AIDS are age 50 years or older
- Trends suggest that the proportion of older persons living with HIV will increase steadily
- We will see more adults 60 to 80 years of age with HIV, this is a population that is very understudied with regard to:
  - Clinical trials
  - Pharmacokinetics studies
    - absorption, distribution, metabolism, excretion of drugs

DHHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents https://aidsinfo.nih.gov/guidelines

Aging HIV Population



*Per 100,000
Centers for Disease Control HIV Website http://www.cdc.gov/hiv

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Aging HIV Population

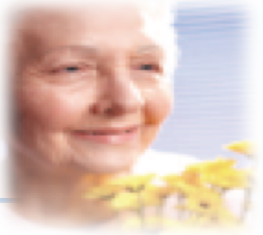
People are living longer with HIV infection:

- Chronic condition
- Increase in older people with HIV/AIDS and the need to care for them in LTC facilities

Goals for care in HIV positive elderly in LTC:

- Maintain highest level of functioning possible
- Provide individualized care in the least restrictive way possible, to increase quality of life
- Prevent opportunistic infections
- Limit toxicities and intolerabilities from HIV medications
- Avoid clinically significant drug-drug interactions
- Maintain a high CD4 count and low viral load to delay disease progression and improve overall outcomes

Aging HIV Population



Reduced mucosal and immunologic defenses

HIV disease may affect the biology of aging

May see signs of clinical syndromes associated with advanced age in younger persons

"Elderly" may mean a chronological age of 40, or 50-55, rather than 65

Older people and health care providers may mistake HIV symptoms for normal aging and don't consider HIV as a cause

HIV testing may not be performed

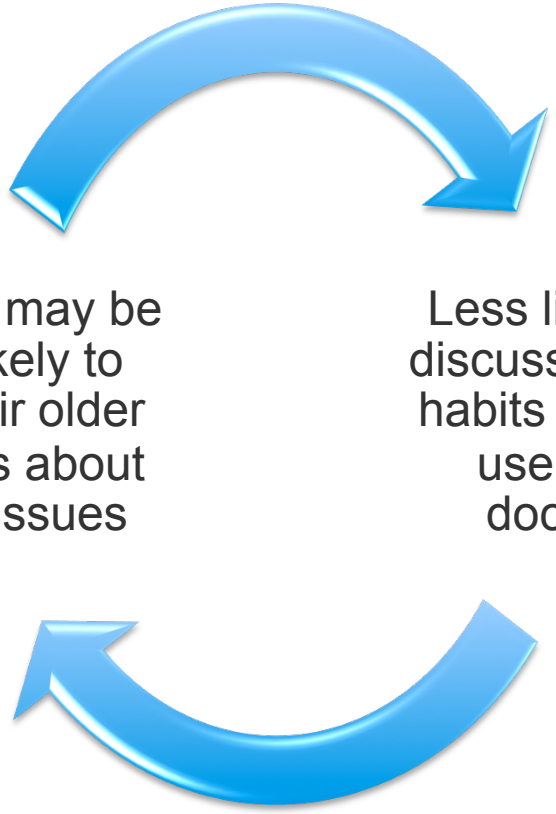
Diagnosed with HIV infection late in the course of the disease

Late start to treatment:

Potentially sustain more damage to the immune system prior to therapy initiation

Centers for Disease Control HIV Website http://www.cdc.gov/hiv

Aging HIV Population



Stigma of HIV Infection

- A concern for older Americans
- May already be isolated due to illness or loss of family and friends

- Stigma of HIV negatively affects:
  - Quality of life
  - Self-image
  - Behaviors
  - May prevent people from seeking HIV treatment and/or disclosing their HIV status

Centers for Disease Control HIV Website http://www.cdc.gov/hiv

Aging HIV Population – Sexual Risk Factors

Many older Americans are sexually active, even in the LTC setting, including those who have HIV, and may:

- Lack knowledge about preventing transmission
- Have multiple partners
- Be less educated about HIV than younger people - less likely to protect themselves
- No longer worry about pregnancy, and may be less likely to use a condom
- Have age-related thinning and dryness of vaginal tissue that increases risk for HIV infection

Centers for Disease Control HIV Website http://www.cdc.gov/hiv

Aging HIV Population – Sexual Risk Factors and Stigma

- In 2010, 44% of new HIV infections in people 55 and older were gay, bisexual, or other men who have sex with men (MSM).
- Among MSM 55 years or older:
  - 67% were White
  - 16% were Hispanic/Latino
  - 15% were Black/African American

Cultural competence and patient-centered care are essential to effective medical treatment

Centers for Disease Control HIV Website http://www.cdc.gov/hiv
*American Geriatrics Society Care of Lesbian, Gay, Bisexual, and Transgender Older Adults Position Statement. J Am Geriatr Soc. 2015; 1-4.

Aging HIV Population – Stigma of HIV

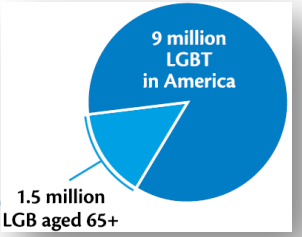
Fears about living in LTC

- Discrimination/lack of acceptance of sexual orientation by other residents or staff
- Having to be "in the closet"
  - only 22% feel they can be open about sexual orientation or gender identity in a nursing home or other LTC facility*
- Being thought of as unclean
- Being treated without privacy or dignity
- Shame about past behaviors or lifestyle
  - drug abuse, incarceration
- *Will the nursing staff know enough about HIV to care for them?*

Centers for Disease Control HIV Website http://www.cdc.gov/hiv

*American Geriatrics Society Care of Lesbian, Gay, Bisexual, and Transgender Older Adults Position Statement. J Am Geriatr Soc. 2015; 1-4.

American Geriatrics Society:
Care of Lesbian, Gay, Bisexual, and Transgender (LGBT) Older Adults Position Statement



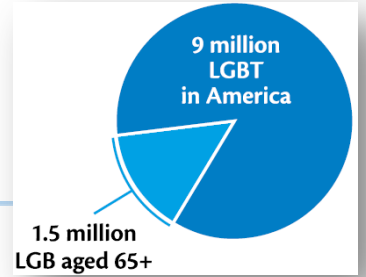
Healthcare organizations and professionals should ensure that care for older LGBT persons includes:

- Creation of a culture of respect and an environment free of discrimination for LGBT older persons in supportive living situations (e.g., assisted living facilities and nursing homes)
- **Training** for all types of healthcare workers, including physicians, nurses, and nursing assistants
  - http://glma.org/_data/n_0001/resources/live/GLMA%20guidelines%202006%20FINAL.pdf
  - http://www.trans-health.org/sites/www.trans-health.org/files/10_Tips_for_Providers.pdf
  - http://www.jointcommission.org/assets/1/18/LGBTFieldGuide.pdf

*American Geriatrics Society Care of Lesbian, Gay, Bisexual, and Transgender Older Adults Position Statement. J Am Geriatr Soc. 2015; 1-4.

Graphic: http://www.lgbtagingcenter.org/resources/pdfs/ResearchBrief_LGBT_Elders_508web.pdf

American Geriatrics Society:
Care of Lesbian, Gay, Bisexual, and Transgender (LGBT) Older Adults Position Statement



Healthcare organizations and professionals should ensure that care for older LGBT persons includes:

- Consideration of the role of partners or other chosen family in healthcare decision-making and caregiving
- Consideration of the resident's right to choose a healthcare proxy who may be a partner or friend
- Recognition of the preferred name and gender identity of transgender individuals, regardless of legal or biological gender status

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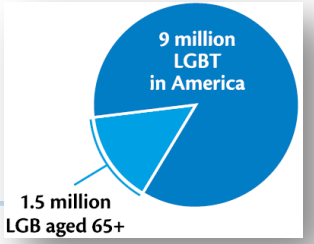


Healthcare organizations and professionals should ensure that care for older LGBT persons includes:

- Taking a medical and social history that is inclusive of the LGBT experience
  - Taking a sexual history and discussing sexuality in a nondiscriminatory manner
  - Should not assume heterosexuality when asking about sexual behavior or relationship status (clinician questions and written forms)

*American Geriatrics Society Care of Lesbian, Gay, Bisexual, and Transgender Older Adults Position Statement. J Am Geriatr Soc. 2015; 1-4.

Graphic: http://www.lgbtagingcenter.org/resources/pdfs/ResearchBrief_LGBT_Elders_508web.pdf

American Geriatrics Society:

Care of Lesbian, Gay, Bisexual, and Transgender (LGBT) Older Adults Position Statement

Essential that healthcare organizations explicitly include the following in their organizational policies:

Sexual orientation should be included in the **patient nondiscrimination policy**

Gender identity and gender expression should be included in the **patient nondiscrimination policy**

Visitation policy should grant equal access for same-sex and transgender couples

Should allow equal access to support persons the patient designates who may not be legal family members

Visitation policy for children should grant equal access for same-sex and transgender parents

http://geriatricscareonline.org/ProductStore/clinical-guidelines-recommendations/

*American Geriatrics Society Care of Lesbian, Gay, Bisexual, and Transgender Older Adults Position Statement. J Am Geriatr Soc. 2015; 1-4.

Long Term Care Specific Concerns: Privacy and Education

- HIV/AIDS patients have the right to privacy and dignity
- Staff has the right to be safe
- Facility should provide education and protocols for privacy and safety for resident *and* staff, including:
  - Counseling and behavioral interventions for residents to reduce secondary transmission
  - Competency assessments and ongoing education for staff (e.g., standard precautions)

https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/post-exposure-prophylaxis/

Long Term Care Specific Concerns: Education and Safety

OSHA® Occupational Safety and Health Administration
www.osha.gov 1-800-321-6742

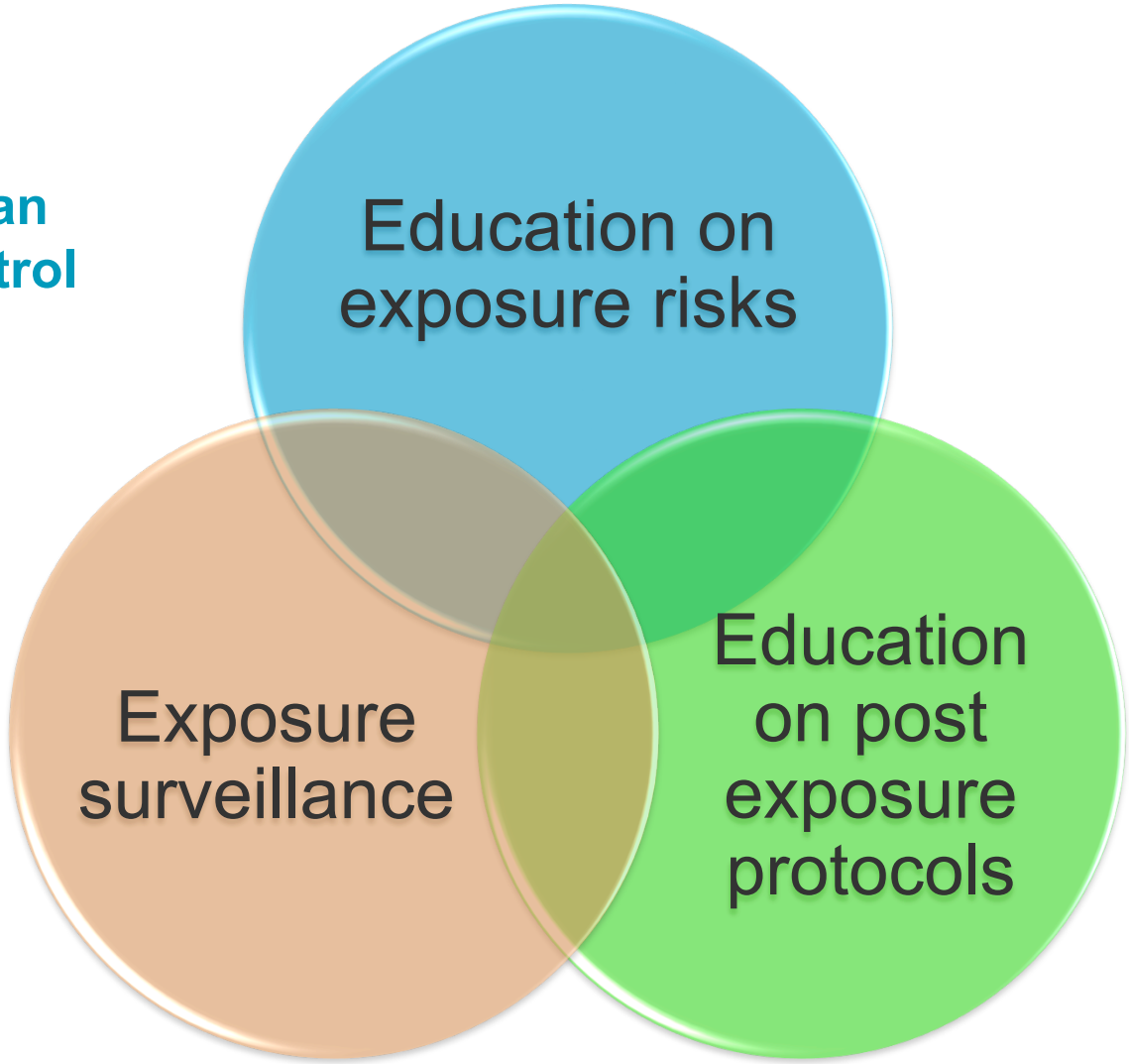
- OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) requires employers to make immediate confidential medical evaluation and follow-up available for workers who have an exposure incident, such as a needlestick.

- **Exposure incident** is a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials (OPIM), as defined in the standard that results from the performance of a worker's duties.

https://www.osha.gov/OshDoc/data_BloodborneFacts/bbfact04.pdf

Long Term Care Specific Concerns: Infection Control Programs

Every facility should have an infection control program that includes:



https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/post-exposure-prophylaxis/

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Long Term Care Specific Concerns: Post-exposure Prophylaxis (PEP)

Includes staff awareness of **post-exposure prophylaxis (PEP) protocols**:

- Who to alert (e.g., medical director)
- Medical evaluation of the exposure to determine if PEP is required
- Initiate HIV prophylaxis as soon as possible, but within 1st 72 hours with appropriate anti-retroviral therapy
  - typically: 2-3 medications for 28 days
- Baseline HIV testing, repeat at 4-6 weeks, 3 months, and 6 months post-exposure

https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/post-exposure-prophylaxis/

Post-Exposure Prophylaxis (PEP)

Evaluation for PEP is performed after:

- Getting cut or stuck with a needle that was used to draw blood from a person who may have HIV infection
- Getting blood or other body fluids likely to transmit HIV in eyes or mouth (e.g., semen, vaginal or rectal secretions, breast milk)
- Getting blood or other body fluids on skin when it is chapped, scraped, or affected by certain rashes

https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/post-exposure-prophylaxis/

Post-Exposure Prophylaxis (PEP)

The risk of getting HIV infection in these ways is low,

fewer than 1 in 100 for all exposures

PEP is **not** 100% effective

Use condoms with sex partners while taking PEP and do not use injection equipment that has been used by others

LTC Specific Concerns: Regulatory and Ethical

State regulations specific to care of HIV/AIDS patients or special licensure (know your state regulations)

- Nursing time increased per resident
- Dedicated (specifically assigned), educated, and experienced staff for residents with HIV/AIDS – **continuity of care**
- Substance abuse counseling
- Education (e.g., HIV risk/harm reduction)
- Comprehensive case management, including delivery of services
- Integrated care with access to specialized services
- Access to support from other HIV positive persons and pastoral care

Hospice or Palliative Care

- Educate on the disease and making informed choices
- Medications: to discontinue or to maintain?
  - HIV medications
  - Antibiotics/treatment for opportunistic infections

Common Comorbid Conditions in HIV positive LTC Residents

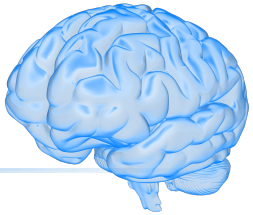
Older HIV-infected patients may suffer from aging-related comorbid illnesses that can complicate the management of HIV infection and vice versa

- Cardiovascular disease
- Elevated cholesterol
- Diabetes
- Osteoporosis and fractures
- Chronic pain syndromes (e.g., neuropathic pain)
- Weight loss, cachexia/muscle wasting
- Chronic non-infectious diarrhea (AIDS defining condition)

Common Comorbid Conditions in HIV positive LTC Residents

- Liver disease (e.g., hepatitis B, hepatitis C, cirrhosis, liver failure)
- Renal disease (e.g., chronic kidney disease, HIV associated nephropathy)
- Cancers: Non-AIDS-defining (e.g., lung, liver, and anal cancers)
- Cancers: AIDS-defining (e.g., Non Hodgkin's lymphoma)
- Depression, anxiety, insomnia
- Cognitive impairment (e.g., dementia, HIV associated dementia)

HIV Associated Neural Damage



HIV can persist in the CSF even with an undetectable HIV viral load

HIV-mediated neural damage can result in CNS disturbances:

- Anxiety
- Depression
- Insomnia
- Mania
- Psychosis

HIV-associated neurocognitive disorder (HAND) may develop

HAND has three subgroups of CNS disturbances

- Asymptomatic neurocognitive impairment
- Mild neurocognitive disorder
- HIV Associated Dementia (HAD; can resolve with HIV treatment)

Vaccinations

However, other vaccinations are important in HIV management

https://www.aids.gov/hiv-aids-basics/prevention/prevention-research/vaccines/

Vaccinations

Generally, continue with the age-specific immunization schedules that are recommended for all patients in those with HIV

ART, chemoprophylaxis, and vaccination directly prevent morbidity and mortality, they may also contribute to reduced rate of progression of HIV disease

Live attenuated vaccines are typically contraindicated

https://www.aids.gov/hiv-aids-basics/prevention/prevention-research/vaccines/

Vaccinations with Contraindications

Live Attenuated Influenza Vaccine (LAIV)

Contraindicated in all HIV-positive patients as well as those 65 years or older

Recommended alternatives:

- Standard-dose trivalent inactivated influenza vaccine (TIV)
- High-dose TIV (FLUZONE® High-Dose) intramuscularly (IM) or intradermally (ID) annually

Vaccinations

Recommended to be given to HIV positive individuals	Tetanus and Diphtheria Vaccine
Titers and boosters may be a consideration in some cases secondary to CD4 count at time of vaccination	Hepatitis A Vaccine
	Hepatitis B Vaccine
	Pneumococcal Vaccine

References

- Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents https://aidsinfo.nih.gov/guidelines
- Centers for Disease Control HIV Website http://www.cdc.gov/hiv/
- Omnicare Geriatric Pharmaceutical Care Guidelines: HIV/AIDS Management in Older Adults
- American Geriatrics Society Care of Lesbian, Gay, Bisexual, and Transgender Older Adults Position Statement. J Am Geriatr Soc. 2015; 1-4.
- Hardy WD, Goetz MB, Seeskin EP, et al. Treatment Update: Management Challenges in Patients Receiving Long-Term Antiretroviral Therapy. 2009. Clinical Care Options HIV http://www.clinicaloptions.com/HIV.aspx
- HIV Pharmacotherapy Practice-based Program. University of Buffalo School of Pharmacy and Pharmaceutical Sciences https://tdm.pharm.buffalo.edu/hiv_cert_main/
- American College of Clinical Pharmacy Pharmacotherapy Infectious Disease III HIV Infection Self-Assessment Program. 2015; 193-219
- Cahill S, Valadez R. Growing Older With HIV/AIDS: New Public Health Challenges. American Journal of Public Health. March 2013; 103 (3) e7-e15
- Morgan EE, Woods SP, Grant I, et al. Intraindividual variability in HIV Infection: Evidence for Greater Neurocognitive Dispersion in Older Seropositive Adults. Neuropsychology. 2011; 25 (5) 645-654
- Hughes A, Davies, B, Gudmundsdottir. “Can you give me respect?” Experiences of the Urban Poor on a Dedicated AIDS Nursing Home Unit. J. of Assoc. of Nurses in AIDS Care. 2008; 19 (5), 342-356
- Murray K, Cummins D, Bloom K. Developing a Protocol for People Living with HIV Entering Residential Aged Care Facilities. ANMJ. June 2014; 21 (11) 34-37
- American Medical Directors Association. Clinical Practice Guideline Common Infections. Columbia. MD: AMDA 2011
- Department of Health and Human Services Guidelines for the Treatment of Opportunistic Infections in HIV Infected Adults and Adolescents https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf

Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) in the Long Term Care Setting

Part 2: HIV Medications

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Overview - Part 2: HIV Medications

- Principles for treating the elderly for HIV
- Medications commonly used
  - Decrease in viral load and decreased risk of transmission
  - Risk of resistance inherent in treatment
- Storage
- Administration
- Common timing related concerns
- Compliance
  - Timing/scheduling medication pass
  - Process controls that can help compliance in LTC

Antiretroviral Therapy (ART)

ART is now recommended for all HIV-infected patients

HIV and the Older Patient (Last updated March 27, 2012; last reviewed March 27, 2012)

Key Considerations When Caring for Older HIV-Infected Patients

- Antiretroviral therapy (ART) is recommended in patients >50 years of age, regardless of CD4 cell count **(BIII)**, because the risk of non-AIDS related complications may increase and the immunologic response to ART may be reduced in older HIV-infected patients.
- ART-associated adverse events may occur more frequently in older HIV-infected adults than in younger HIV-infected individuals. Therefore, the bone, kidney, metabolic, cardiovascular, and liver health of older HIV-infected adults should be monitored closely.
- The increased risk of drug-drug interactions between antiretroviral (ARV) drugs and other medications commonly used in older HIV-infected patients should be assessed regularly, especially when starting or switching ART and concomitant medications.
- HIV experts and primary care providers should work together to optimize the medical care of older HIV-infected patients with complex comorbidities.
- Counseling to prevent secondary transmission of HIV remains an important aspect of the care of the older HIV-infected patient.

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*

- Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents https://aidsinfo.nih.gov/guidelines

Antiretroviral Therapy (ART), Highly Active Antiretroviral Therapy (HAART), Combination Antiretroviral Therapy (cART)

- MAINTAIN HEALTHY LIFESTYLE
  - EXERCISE
  - PROPER NUTRITION
  - REST
  - AVOID TOBACCO, ALCOHOL AND DRUG USE
- REGULAR EXAMINATIONS BY:
  - HIV SPECIALIST
  - PHYSICIAN WHO HAS COORDINATED CARE WITH AN HIV OR INFECTIOUS DISEASE SPECIALIST

Antiretroviral Therapy (ART)

ART can:

- ✓ Increase lifespan
- ✓ Decrease risk of developing illnesses
- ✓ Decrease (but not eliminate) the risk of spreading the disease

Antiretroviral Therapy (ART)

HIV mutates	The virus can become resistant to medications
Especially with non-compliance	Can also occur with prolonged exposure

Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents https://aidsinfo.nih.gov/guidelines

Antiretroviral Therapy (ART): Compliance

Facility should have protocols to maintain compliance

Keep doctors appointments, coordinate transport

- Be aware of insurance coverage issues so medications are not missed
- Prior authorizations in HIV care specifically have been reported to cost over $40 each in provider personnel time (a hidden cost) and have substantially reduced timely access to medications*

*Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents https://aidsinfo.nih.gov/guidelines

Antiretroviral Therapy (ART): Compliance

Facility should have protocols to maintain compliance

If “self-administration” is occurring have a policy in place to ensure compliance

- Implement daily medication counts
- Document refusal of ART and communicate to prescriber
- If ART must be stopped for a procedure or a treatment, coordinate that in the plan of care and with primary and specialist physicians, document follow up and restarting the medication
- Avoid prolonged “hold” orders or misinterpreting discontinuation orders as permanent

Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents https://aidsinfo.nih.gov/guidelines

Classes of HIV Medications

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Currently 6 different classes of HIV medications

Nucleoside/ Nucleotide Reverse Transcriptase Inhibitors (NRTIs)	Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)	Protease Inhibitors (PIs)	Entry Inhibitors	Fusion Inhibitors	Integrase Inhibitors

Each class attacks the virus at different points in its life cycle

People generally are prescribed 3 different antiretroviral drugs from 2 different classes

Often these medications are combined into 1 pill

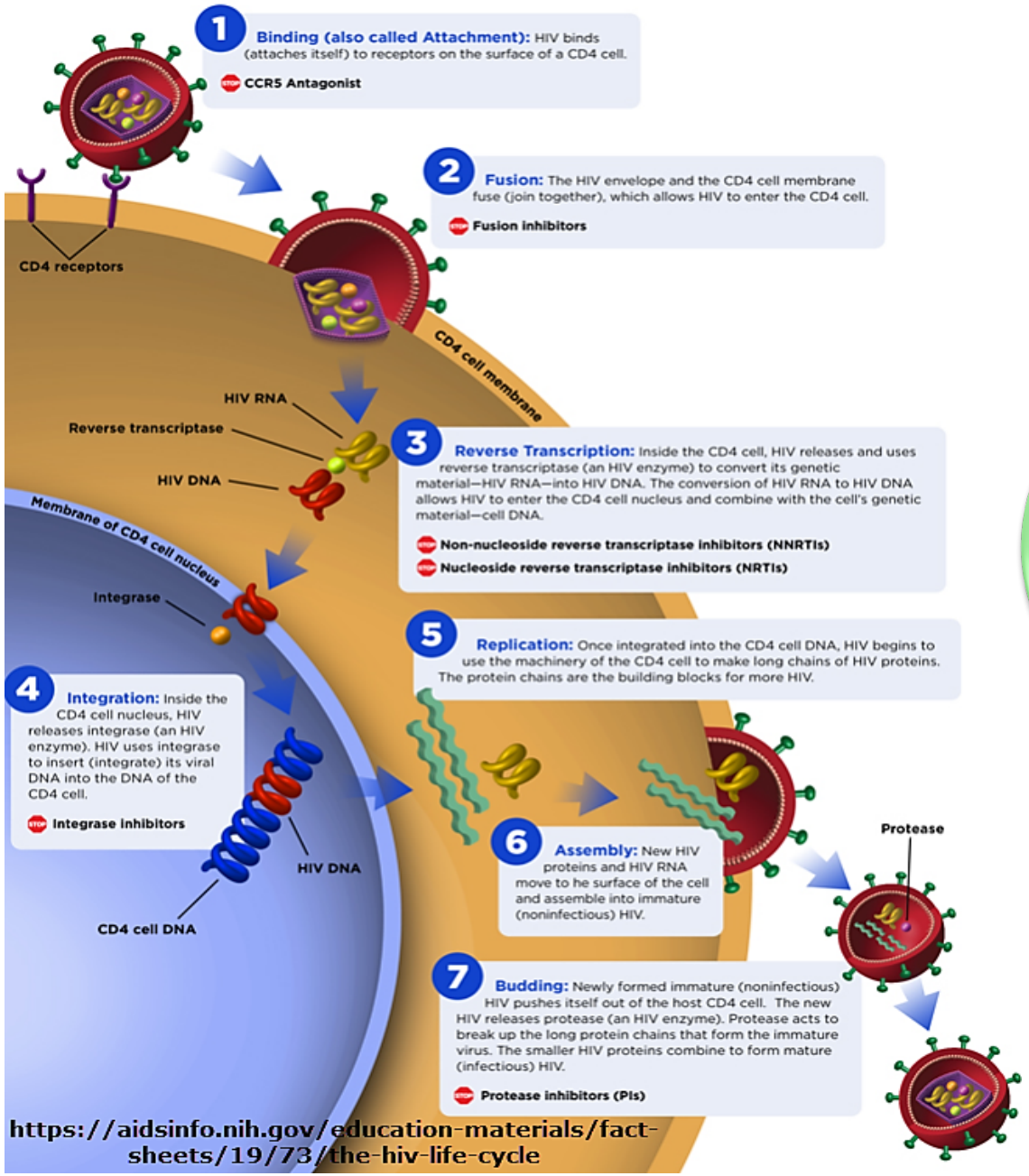
Increases compliance	Can cause confusion	Spell out the name of all medications on the MAR and physicians orders

Classes of HIV Medications: Combination therapy vs. Monotherapy

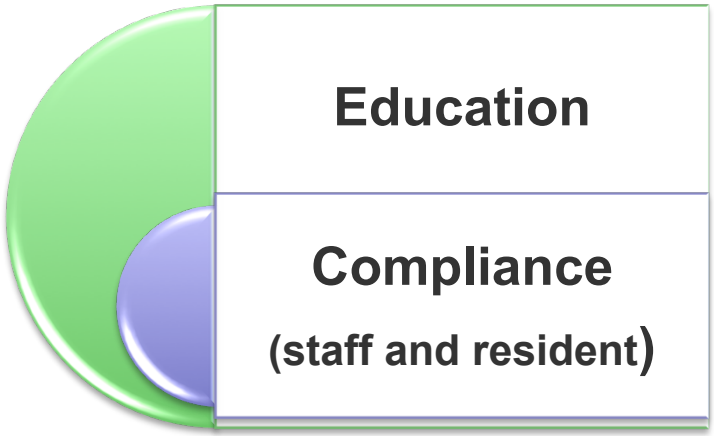
- Treating HIV with one pill containing multiple medications (e.g., fixed dose combination therapy) is acceptable
- Treating HIV with only one medication (monotherapy) is rarely acceptable
- Recommend checking this upon transitions in care (e.g., new admission, readmission from hospital, change of condition that resulted in a new provider consult)

The HIV Life Cycle

HIV medicines in six drug classes stop HIV at different stages in the HIV life cycle.



https://aidsinfo.nih.gov/education-materials/fact-sheets/19/73/the-hiv-life-cycle



Classes of HIV Medications (there's an app for that https://aidsinfo.nih.gov/apps)

FDA-Approved HIV Medicines			
Drug Class	**Generic Name (Other names and acronyms)**	**Brand Name**	**FDA Approval Date**
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)			
NRTIs block reverse transcriptase, an enzyme HIV needs to make copies of itself	**abacavir** (abacavir sulfate, ABC)	**Ziagen**	Dec.17, 1998
	didanosine (delayed-release didanosine, dideoxyinosine, enteric-coated didanosine, ddI, ddI EC)	**Videx**	October 9, 1991
		Videx EC (enteric-coated)	October 31, 2000
	emtricitabine (FTC)	**Emtriva**	July 2, 2003
	lamivudine (3TC)	**Epivir**	Nov. 17, 1995
	stavudine (d4T)	**Zerit**	June 24, 1994
	tenofovir disoproxil fumarate (tenofovir DF, TDF)	**Viread**	October 26, 2001
	zidovudine (azidothymidine, AZT, ZDV)	**Retrovir**	March 19, 1987

https://aidsinfo.nih.gov/education-materials/fact-sheets/21/58/fda-approved-hiv-medicines

Classes of HIV Medications (there's an app for that https://aidsinfo.nih.gov/apps)

FDA-Approved HIV Medicines			
Drug Class	**Generic Name (Other names and acronyms)**	**Brand Name**	**FDA Approval Date**
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)			
NNRTIs bind to and later alter reverse transcriptase, an enzyme HIV needs to make copies of itself	**delavirdine** (delavirdine mesylate, DLV)	**Rescriptor**	April 4, 1997
	efavirenz (EFV)	**Sustiva**	Sept. 17, 1998
	etravirine (ETR)	**Intelence**	January 18, 2008
	nevirapine (extended-release nevirapine, NVP)	**Viramune**	June 21, 1996
		Viramune XR (extended release)	March 25, 2011
	rilpivirine (rilpivirine hydrochloride, RPV)	**Edurant**	May 20, 2011

https://aidsinfo.nih.gov/education-materials/fact-sheets/21/58/fda-approved-hiv-medicines

Classes of HIV Medications (there's an app for that https://aidsinfo.nih.gov/apps)

FDA-Approved HIV Medicines			
Drug Class	**Generic Name (Other names and acronyms)**	**Brand Name**	**FDA Approval Date**
Protease Inhibitors (PIs)			
PIs block HIV protease, an enzyme HIV needs to make copies of itself	**atazanavir** (atazanavir sulfate, ATV)	**Reyataz**	June 20, 2003
	darunavir (darunavir ethanolate, DRV)	**Prezista**	June 23, 2006
	fosamprenavir (fosamprenavir calcium, FOS-APV, FPV)	**Lexiva**	October 20, 2003
	indinavir (indinavir sulfate, IDV)	**Crixivan**	March 13, 1996
	nelfinavir (nelfinavir mesylate, NFV)	**Viracept**	March 14, 1997
	ritonavir (RTV)	**Norvir**	March 1, 1996
	saquinavir (saquinavir mesylate, SQV)	**Invirase**	December 6, 1995
	tipranavir (TPV)	**Aptivus**	June 22, 2005

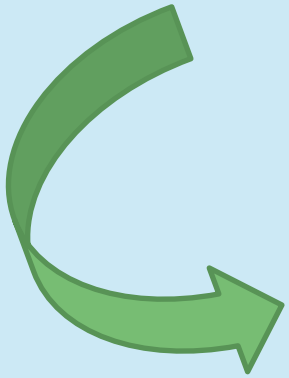
https://aidsinfo.nih.gov/education-materials/fact-sheets/21/58/fda-approved-hiv-medicines

Classes of HIV Medications (there's an app for that https://aidsinfo.nih.gov/apps)

FDA-Approved HIV Medicines			
Drug Class	**Generic Name (Other names and acronyms)**	**Brand Name**	**FDA Approval Date**
Fusion Inhibitors			
Fusion inhibitors block HIV from entering the CD4 cells of the immune system	**enfuvirtide** (T-20)	**Fuzeon**	March 13, 2003
Entry Inhibitors			
Entry inhibitors block proteins on the CD4 cells that HIV needs to enter the cells	**maraviroc** (MVC)	**Selzentry**	August 6, 2007
Integrase Inhibitors			
Integrase inhibitors block HIV integrase, an enzyme HIV needs to make copies of itself	**dolutegravir** (DTG)	**Tivicay**	August 13, 2013
	elvitegravir (EVG)	**Vitekta**	Sept. 24, 2014
	raltegravir (raltegravir potassium, RAL)	**Isentress**	October 12, 2007

https://aidsinfo.nih.gov/education-materials/fact-sheets/21/58/fda-approved-hiv-medicines

Classes of HIV Medications (there's an app for that https://aidsinfo.nih.gov/apps)

FDA-Approved HIV Medicines			
Drug Class	**Generic Name (Other names and acronyms)**	**Brand Name**	**FDA Approval Date**
Pharmacokinetic Enhancer: cobicistat			
Cobicistat is used in HIV treatment to increase the effectiveness of another HIV medicine. It is included in an HIV regimen, not a treatment given by itself. 	**cobicistat** (COBI)	**Tybost**	Sept. 24, 2014
	atazanavir and cobicistat (atazanavir sulfate / cobicistat; ATV / COBI)	**Evotaz**	January 29, 2015
	darunavir and cobicistat (darunavir ethanolate / cobicistat; DRV / COBI)	**Prezcobix**	January 29, 2015
	elvitegravir, cobicistat, emtricitabine, and tenofovir disoproxil fumarate (QUAD, EVG / COBI / FTC / TDF)	**Stribild**	August 27, 2012

https://aidsinfo.nih.gov/education-materials/fact-sheets/21/58/fda-approved-hiv-medicines

Classes of HIV Medications (there's an app for that https://aidsinfo.nih.gov/apps)

FDA-Approved HIV Medicines			
Drug Class	**Generic Name (Other names and acronyms)**	**Brand Name**	**FDA Approval Date**
Combination HIV Medicines			
Combination HIV medicines contain two or more HIV medicines from one or more drug classes	**abacavir and lamivudine** (abacavir sulfate / lamivudine, ABC / 3TC)	**Epzicom**	August 2, 2004
	abacavir, dolutegravir, and lamivudine (abacavir sulfate / dolutegravir sodium / lamivudine, ABC / DTG / 3TC)	**Triumeq**	August 22, 2014
	abacavir, lamivudine, and zidovudine (abacavir sulfate / lamivudine / zidovudine, ABC / 3TC / ZDV)	**Trizivir**	Nov. 14, 2000
	efavirenz, emtricitabine, and tenofovir disoproxil fumarate (efavirenz / emtricitabine / tenofovir, efavirenz / emtricitabine / tenofovir DF, EFV / FTC / TDF)	**Atripla**	July 12, 2006

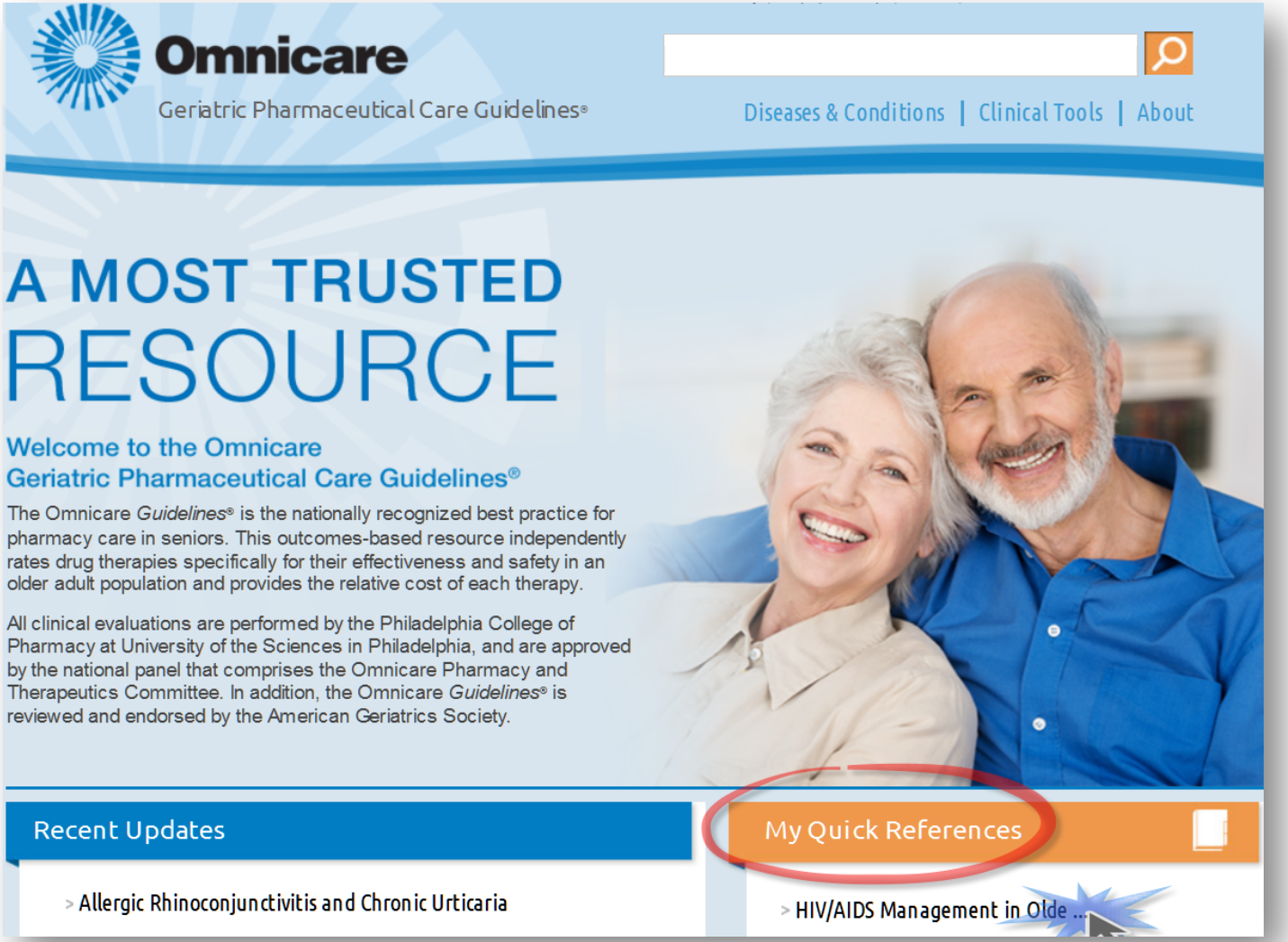
https://aidsinfo.nih.gov/education-materials/fact-sheets/21/58/fda-approved-hiv-medicines

Classes of HIV Medications (there's an app for that https://aidsinfo.nih.gov/apps)

FDA-Approved HIV Medicines			
Drug Class	**Generic Name (Other names and acronyms)**	**Brand Name**	**FDA Approval Date**
Combination HIV Medicines (continued)			
Combination HIV medicines contain two or more HIV medicines from one or more drug classes	**emtricitabine, rilpivirine, and tenofovir disoproxil fumarate** (emtricitabine / rilpivirine hydrochloride / tenofovir disoproxil fumarate, emtricitabine / rilpivirine / tenofovir, FTC / RPV / TDF)	**Complera**	August 10, 2011
	emtricitabine and tenofovir disoproxil fumarate (emtricitabine / tenofovir, FTC / TDF)	**Truvada**	August 2, 2004
	lamivudine and zidovudine (3TC / ZDV)	**Combivir**	Sept. 27, 1997
	lopinavir and ritonavir (ritonavir-boosted lopinavir, LPV/r, LPV / RTV)	**Kaletra**	Sept. 15, 2000

https://aidsinfo.nih.gov/education-materials/fact-sheets/21/58/fda-approved-hiv-medicines

Classes of HIV Medications and HIV/AIDS Treatment in Older Adults: Omnicare Geriatric Pharmaceutical Care Guidelines

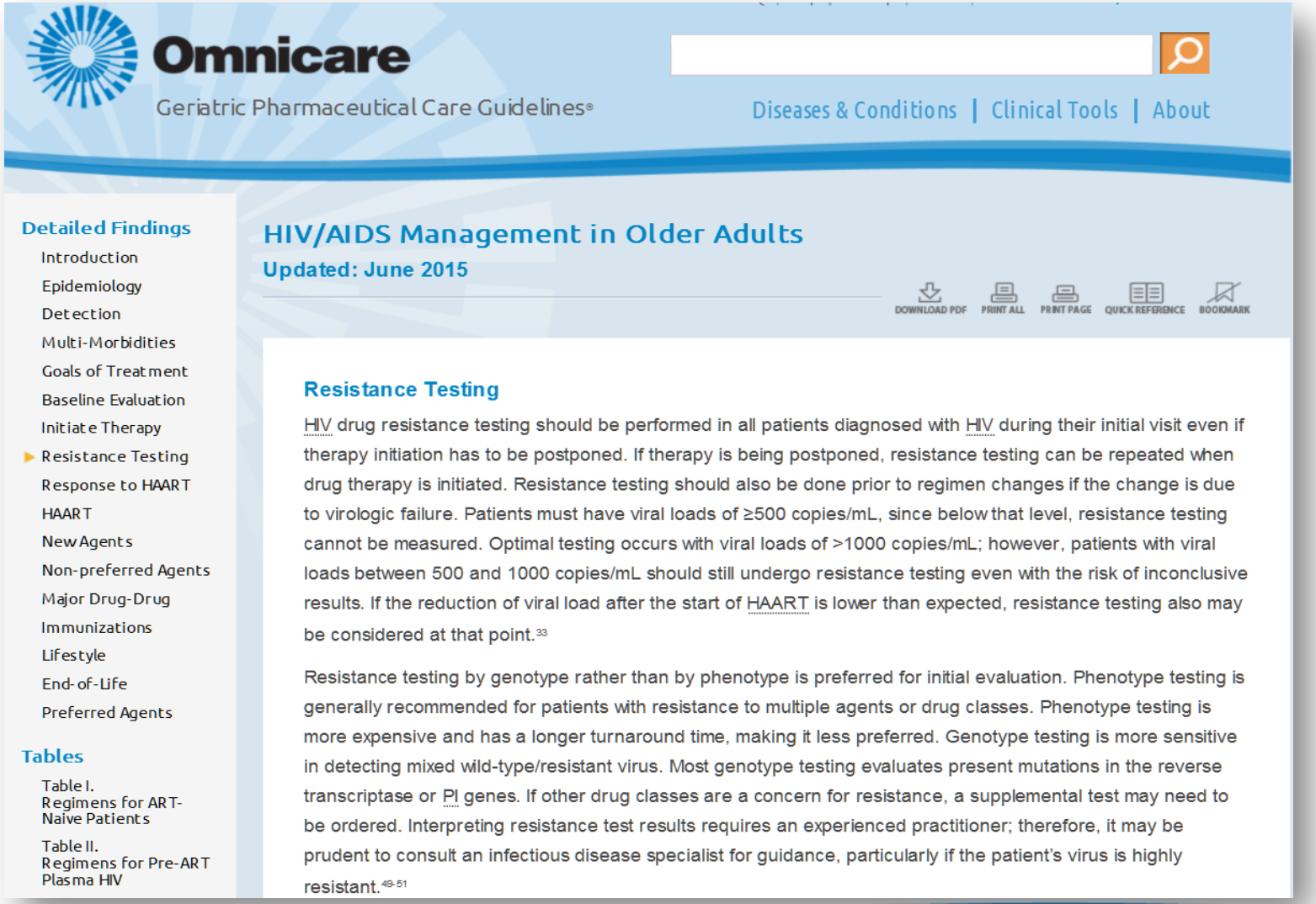


Classes of HIV Medications and HIV/AIDS Treatment in Older Adults: Omnicare Geriatric Pharmaceutical Care Guidelines

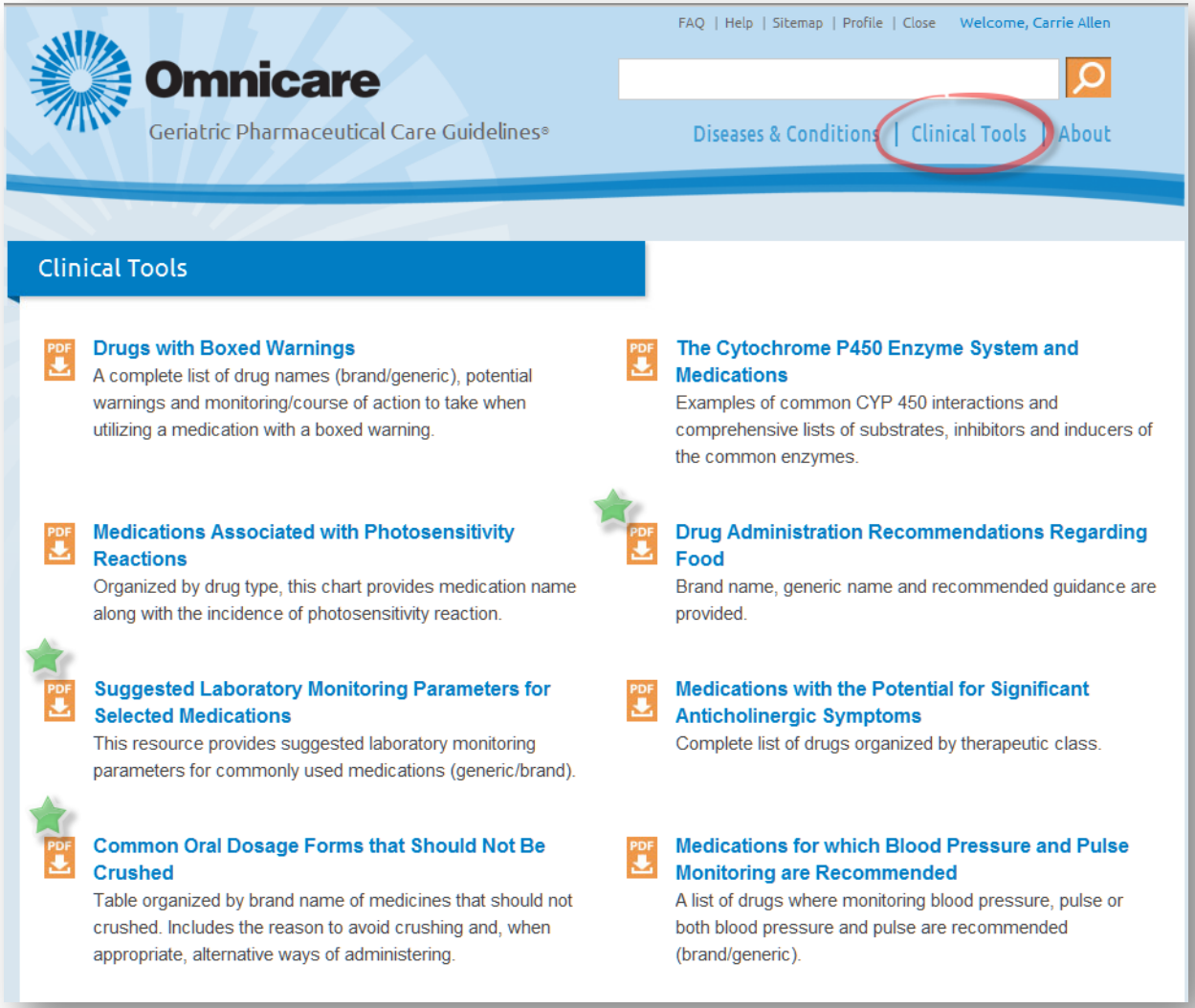
Table I. Preferred Regimens for ART-Naïve Patients Regardless of Baseline Viral Load or CD4 Count

Regimen	Components	Usual Dosage Range (mg) and Adjustments for Organ Dysfunction	Rationale	Considerations for Older Adult Patients
NNRTI-Based Regimen	EFV/TDF/FTC* (ATRIPLA®)[70-75]	600/300/200 → Once-daily regimen (1 tablet total) **Renal:** Split components in patients with creatinine clearance (CrCl) <50 mL/min; consider another NRTI instead of TDF **Hepatic:** Split components in moderate/severe hepatic impairment;	Once daily Very low pill burden Well tolerated Active against HBV EFV is the preferred NNRTI because of virologic efficacy and tolerability Resistance mutations and cross-resistance	TDF can cause renal failure (RF) → not recommended w/CrCl <50 mL/min TDF/FTC can decrease BMD Neuropsychiatric effects with EFV EFV not recommended in patients with Child-Pugh Class B, C hepatic impairment Lower genetic barrier to resistance than

Medication Information and HIV/AIDS Treatment in Older Adults: Omnicare Geriatric Pharmaceutical Care Guidelines



Medication Information and HIV/AIDS Treatment in Older Adults: Omnicare Geriatric Pharmaceutical Care Guidelines



Concerns with Commonly Used HIV Medications

Drug Class	Generic Name (Other names and acronyms)	Administration Tips and Common Concerns
Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTIs)		
Class disadvantages: • **Lactic acidosis with hepatic steatosis** • **Dyslipidemia** • **Liver damage**	**abacavir** (abacavir sulfate, ABC)	**Abacavir hypersensitivity reaction (HSR):** 5 to 8% of patients ; usually observed during the first 6 weeks HLA-B*5701 allele is present in patients who are at risk of developing a HSR to abacavir, **contraindicated** if positive Risk of MI - use with caution in those with high risk for cardiovascular disease
	emtricitabine (FTC)	Hyperpigmentation (not harmful)
	lamivudine (3TC)	Diarrhea, nausea, insomnia, headaches

Concerns with Commonly Used HIV Medications

Drug Class	Generic Name (Other names and acronyms)	Administration Tips and Common Concerns
Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTIs) - continued		
Class disadvantages: • **Lactic acidosis with hepatic steatosis** • **Dyslipidemia** • **Liver damage**	**tenofovir disoproxil fumarate** (tenofovir DF, TDF)	Can be administered with or without food Can decrease bone mineral density Can cause renal impairment Renal dosing adjustments are required Use with caution in pre-existing renal insufficiency
	zidovudine (azidothymidine, AZT, ZDV)	Bone marrow suppression, lipoatrophy, lactic acidosis, myopathy

https://aidsinfo.nih.gov/education-materials Table 14 ART Adverse Effects

Concerns with Commonly Used HIV Medications

Drug Class	Generic Name (Other names and acronyms)	Administration Tips and Common Concerns
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)		
Class disadvantages: • **Greater risk for resistance than some other classes** • **Risk of cross-resistance** • **Skin rash**	**efavirenz** (EFV)	Neuropsychiatric and central nervous system (CNS) related side effects Administer at bedtime on an empty stomach Avoid administering with high fat meals; as this increases absorption of EFV, and increases the risk of CNS side effects St. John's Wort may decrease EFV: combination not recommended

https://aidsinfo.nih.gov/education-materials Table 14 ART Adverse Effects

Concerns with Commonly Used HIV Medications

Drug Class	Generic Name (Other names and acronyms)	Administration Tips and Common Concerns
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) - continued		
Class disadvantages: • **Greater risk for resistance than Protease Inhibitors (PIs)** • **Risk of cross-resistance** • **Skin rash**	**rilpivirine** (rilpivirine HCl, RPV)	Should be taken with a normal-to-high-calorie meal for adequate absorption (protein supplement drinks do not qualify) Use of proton pump inhibitors (e.g., omeprazole) is **contraindicated** Antacids and H2-Receptor Antagonists (e.g., ranitidine) may decrease its effects Give 4 hr. before or 12 hr. after H2-receptor antagonists St. John's Wort decreases RPV avoid combination

https://aidsinfo.nih.gov/education-materials Table 14 ART Adverse Effects

Omeprazole, ranitidine, and antacids examples of medications that are often obtained from central supply

This means there is **no** interaction check done by pharmacy

Always ask the pharmacist before giving OTC meds to people taking ART

Omnicare

Concerns with Commonly Used HIV Medications

Drug Class
Protease Inhibitors (PIs)

Class disadvantages:

- **Metabolic complications: dyslipidemia, insulin resistance, hepatotoxicity**
- **Significant GI effects: nausea, flatulence, diarrhea, dyspepsia**
  - **Can recommend pre-treatment with simethicone for flatulence**
  - **Can recommend other remedies for dyspepsia, nausea and diarrhea**
    - **Caution with antacids, PPI, and H2-Receptor Antagonists (H2RA; e.g., ranitidine)**

https://aidsinfo.nih.gov/education-materials Table 14 ART Adverse Effects

Concerns with Commonly Used HIV Medications

Drug Class: Protease Inhibitors (PIs) Generic Name (Other names and acronyms)	Administration Tips and Common Concerns
atazanavir (atazanavir sulfate, ATV)	Always take with meals, to increase absorption Gastric upset Strict rules on separating timing from PPI (12 h), and H2RA (10 h) and reducing dose of the acid suppressing agent Administer ATV 2 hours before or 1 hour after taking antacids
ritonavir (RTV)	Gastric upset, metabolic concerns (including central obesity), musculoskeletal pain, parasthesias, peripheral neuropathy Note: many other PIs are given in combination with ritonavir, *example*: ritonavir-boosted atazanavir (ATZ/r)

https://aidsinfo.nih.gov/education-materials Table 14 ART Adverse Effects

Concerns with Commonly Used HIV Medications

Drug Class	Generic Name (Other names and acronyms)	Administration Tips and Common Concerns
Integrase Inhibitors		
Class disadvantages: • **Insomnia** • **GI effects**	**dolutegravir** (DTG)	Administer with or without food Without food: take DTG 2 hours before or 6 hours after cation-containing antacids (e.g., Tums) or supplements (e.g., calcium)
	elvitegravir (EVG)	Administer with food St. John's Wort may decrease EVG
	raltegravir (raltegravir potassium, RAL)	Administer with or without food St. John's Wort may decrease RAL Depression Hypersensitivity reaction (HSR) has occurred when RAL + other drugs known to cause HSR. Stop all ARVs if HSR occurs and get a medical evaluation

Concerns with Commonly Used HIV Medications

Be aware of issues noted on the previous slides

Be prepared to counsel patients, anticipate their needs, and to be supportive

Concerns with Commonly Used HIV Medications

Collaborate with the resident, prescribers, coworkers, and pharmacists

Everyone should share information to avoid:

- Treatment failure and resistance
- Harmful adverse effects or intolerable side effects
- Permanent harm and debility
- Opportunistic infections
- Missed doses

References

- Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents https://aidsinfo.nih.gov/guidelines
- Centers for Disease Control HIV Website http://www.cdc.gov/hiv/
- Omnicare Geriatric Pharmaceutical Care Guidelines: HIV/AIDS Management in Older Adults
- American Geriatrics Society Care of Lesbian, Gay, Bisexual, and Transgender Older Adults Position Statement. J Am Geriatr Soc. 2015; 1-4.
- Hardy WD, Goetz MB, Seeskin EP, et al. Treatment Update: Management Challenges in Patients Receiving Long-Term Antiretroviral Therapy. 2009. Clinical Care Options HIV http://www.clinicaloptions.com/HIV.aspx
- HIV Pharmacotherapy Practice-based Program. University of Buffalo School of Pharmacy and Pharmaceutical Sciences https://tdm.pharm.buffalo.edu/hiv_cert_main/
- American College of Clinical Pharmacy Pharmacotherapy Infectious Disease III HIV Infection Self-Assessment Program. 2015; 193-219
- Cahill S, Valadez R. Growing Older With HIV/AIDS: New Public Health Challenges. American Journal of Public Health. March 2013; 103 (3) e7-e15
- Morgan EE, Woods SP, Grant I, et al. Intraindividual variability in HIV Infection: Evidence for Greater Neurocognitive Dispersion in Older Seropositive Adults. Neuropsychology. 2011; 25 (5) 645-654
- Hughes A, Davies, B, Gudmundsdottir. “Can you give me respect?” Experiences of the Urban Poor on a Dedicated AIDS Nursing Home Unit. J. of Assoc. of Nurses in AIDS Care. 2008; 19 (5), 342-356
- Murray K, Cummins D, Bloom K. Developing a Protocol for People Living with HIV Entering Residential Aged Care Facilities. ANMJ. June 2014; 21 (11) 34-37
- American Medical Directors Association. Clinical Practice Guideline Common Infections. Columbia. MD: AMDA 2011
- Department of Health and Human Services Guidelines for the Treatment of Opportunistic Infections in HIV Infected Adults and Adolescents https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf

Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) in the Long Term Care Setting

Part 3: Monitoring, Care Planning, and Counseling

Omnicare Pharmacy Services

Carrie Allen PharmD, CGP, BCPS, BCPP, CCHP

Overview - Part 3: Monitoring, Care Planning and Counseling

- Monitoring therapy and coordination of care
- Common opportunistic infections (OI) and treatments
- Counseling and pharmacy services

Monitoring Therapy: An Ongoing Process

- Continually monitor for side effects or adverse events related to HIV medications, or combinations of medications
- Work with your pharmacist

Table 18. Drugs That Should Not Be Used With Antiretroviral Agents (Last updated April 8, 2015; last reviewed April 8, 2015) (page 1 of 2)

This table only lists drugs that should not be coadministered at any dose, regardless of RTV or COBI enhancing. See Tables 19 and 20 for more detailed PK interaction data.

ARV Agents[a,b]	Cardiac Agents	Lipid-Lowering Agents	Antimycobacterial Agents	Antiepileptic Agents	Neurologic Agents	Herbs	HCV Agents[o]	Other Agents
ATV +/– RTV or COBI	Dronedarone Ranolazine	Lovastatin Simvastatin	Rifampin Rifapentine[d]	None	Lurasidone Midazolam[e] Pimozide Triazolam	St. John's wort	Boceprevir Simeprevir	Alfuzosin Cisapride[f] Ergot derivatives Irinotecan Salmeterol Sildenafil for PAH
DRV/c or DRV/r	Dronedarone Ranolazine	Lovastatin Simvastatin	Rifampin Rifapentine[d]	None	Lurasidone Midazolam[e] Pimozide Triazolam	St. John's wort	Boceprevir Dasabuvir Ombitasvir Paritaprevir Simeprevir	Alfuzosin Cisapride[f] Ergot derivatives Salmeterol Sildenafil for PAH
FPV +/– RTV	Dronedarone Flecainide Propafenone Ranolazine	Lovastatin Simvastatin	Rifampin Rifapentine[d]	None	Lurasidone Midazolam[e] Pimozide Triazolam	St. John's wort	Boceprevir Dasabuvir Ombitasvir Paritaprevir Simeprevir	Alfuzosin Cisapride[f] Ergot derivatives Salmeterol Sildenafil for PAH
LPV/r	Dronedarone Ranolazine	Lovastatin Simvastatin	Rifampin[p] Rifapentine[d]	None	Lurasidone Midazolam[e] Pimozide Triazolam	St. John's wort	Boceprevir Dasabuvir Ombitasvir Paritaprevir Simeprevir	Alfuzosin Cisapride[f] Ergot derivatives Salmeterol Sildenafil for PAH
SQV/r	Amiodarone Dofetilide Dronedarone Flecainide Lidocaine Propafenone Quinidine Ranolazine	Lovastatin Simvastatin	Rifampin[p] Rifapentine[d]	None	Lurasidone Midazolam[e] Pimozide Trazodone Triazolam	Garlic supplements St. John's wort	Boceprevir Dasabuvir Ombitasvir Paritaprevir Simeprevir	Alfuzosin Cisapride[f] Ergot derivatives Salmeterol Sildenafil for PAH
TPV/r	Amiodarone Dronedarone Flecainide Propafenone Quinidine Ranolazine	Lovastatin Simvastatin	Rifampin Rifapentine[d]	None	Lurasidone Midazolam[e] Pimozide Triazolam	St. John's wort	Boceprevir Dasabuvir Ledipasvir Ombitasvir Paritaprevir Simeprevir Sofosbuvir	Alfuzosin Cisapride[f] Ergot derivatives Salmeterol Sildenafil for PAH

Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents
https://aidsinfo.nih.gov/guidelines
Table 18. Drugs That Should Not Be Used With Antiretroviral Agents

Monitoring

- Ongoing process of assessment
  - Labs
  - Physical
  - Psychological/psychosocial
- Residents are not only aging in place, they have multiple comorbid conditions that impact HIV and vice versa

Monitoring

- HIV brings unusual issues that require vigilance and understanding, these residents may be different from day to day
  - Example: neurocognitive dispersion - secondary to HIV and aging, resident displays an inconsistent, changing pattern of deficits in neurocognitive functioning, may indicate an incipient decline
  - Rule out: dementia progression, or HIV associated dementia (HAD; can typically be treated with the proper HIV medication)
- Due to this variability, an interdisciplinary approach and consistency in care is crucial to avoid missing critical symptoms of a change in condition

Wasting Syndrome: AIDS Defining Condition

Wasting Syndrome - HIV-associated wasting syndrome is considered an AIDS-defining condition

- Involuntary loss of more than **10%** of total body weight from baseline (or **≥ 5%** of usual body weight in 2-3-months), AND more than ***30 days*** of either diarrhea *or* weakness and fever
- Wasting refers to a loss of muscle mass, though part of the weight loss may also be due to loss of fat

https://www.aids.gov/hiv-aids-basics/
http://www.hivguidelines.org/clinical-guidelines/adults/general-nutrition-weight-loss-and-wasting-syndrome/

Wasting Syndrome: AIDS Defining Condition

Wasting Syndrome - HIV-associated wasting syndrome is considered an AIDS-defining condition

- While this is often a sign of late stage disease, wasting syndrome can be treated by:
  - Proper diet
  - Medications to stimulate appetite
  - Medications to control diarrhea
  - Hormonal therapy to build muscle

https://www.aids.gov/hiv-aids-basics/
http://www.hivguidelines.org/clinical-guidelines/adults/general-nutrition-weight-loss-and-wasting-syndrome/

Monitoring: Labs

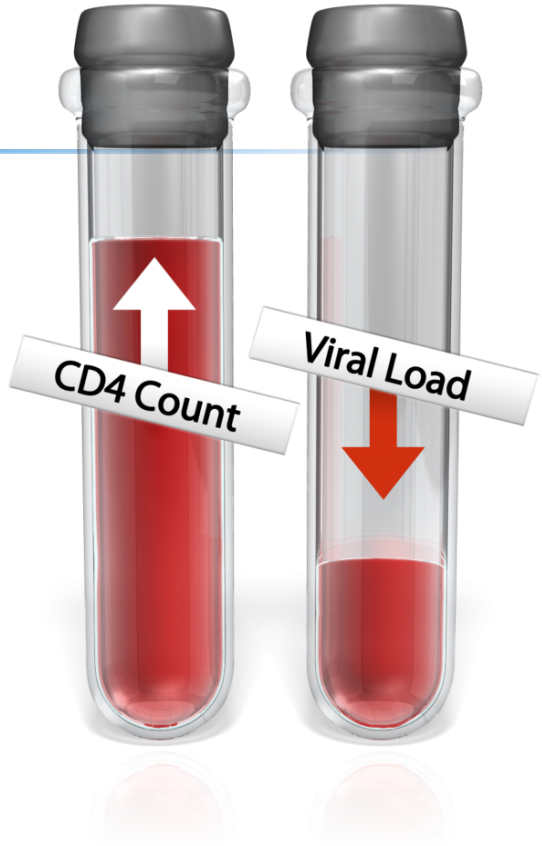
A number of laboratory tests are important in HIV treatment, timing is important:

- Initial evaluation of HIV-infected patients upon entry into care
- During follow-up if antiretroviral therapy (ART) is not initiated
- Before and after initiation or modification of therapy
- Assess the virologic and immunologic efficacy of ART regularly
- Monitor for laboratory abnormalities that may be associated with antiretroviral (ARV) drugs

All monitoring should be individualized in the care plan and updated as needed

Monitoring: Labs

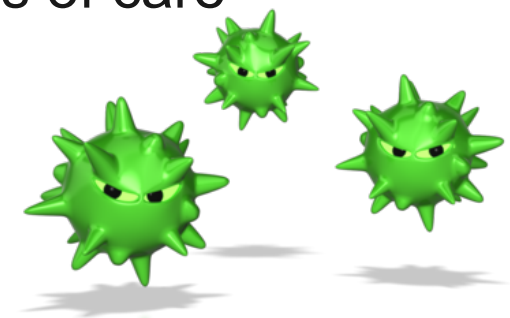
- Two surrogate markers are used routinely to assess immune function and level of HIV viremia:
  - CD4 T-cell count (CD4 count) – measures immune function and HIV disease progression
  - Plasma HIV RNA (viral load) – measures response to therapy, goal is viral suppression



Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents https://aidsinfo.nih.gov/guidelines

Monitoring: Labs

- Resistance testing should be used to guide selection of the initial ARV regimen and/or when switching an ARV regimen
  - Resistance testing is often done with a specialist at a clinic
  - Facilities should try to get these results and place them in the chart for reference, to note in the care plan, and to assist if there are transitions of care



Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents https://aidsinfo.nih.gov/guidelines

Monitoring: Viral Load

Measure after initiation of ART or modification of therapy due to treatment failure

- **Plasma viral load should be measured:**
- Before initiation of ART ***and***
- Within 2 to 4 weeks but no later than 8 weeks after treatment initiation or modification
- Repeat viral load measurement at 4 to 8 week intervals until the level falls below the assay's limit of detection

In virologically suppressed patients in whom ART was modified due to drug toxicity or for regimen simplification

- Viral load measurement should be performed within 4 to 8 weeks after changing therapy
- The purpose of viral load monitoring at this point is to confirm the effectiveness of the new regimen

Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents https://aidsinfo.nih.gov/guidelines

Monitoring: Viral Load

In patients on a stable, suppressive ARV regimen

- Viral load should be repeated every 3 to 4 months, or as clinically indicated to confirm continuous viral suppression
- Doctors may extend the interval to 6 months for adherent patients whose viral load has been suppressed for ≥2 years and whose clinical and immunologic status is stable

In patients with suboptimal response

- The frequency of viral load monitoring will depend on clinical circumstances
- Patient adherence to prescribed medications, suboptimal drug exposure, or drug interactions, should be assessed
- Patients who do not achieve viral suppression require resistance testing to help select an alternative regimen

Goal viral load is HIV RNA less than 20 to 75 copies/mL

Note: the exact number depends on the lab that analyzes the sample

Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents https://aidsinfo.nih.gov/guidelines

Monitoring: CD4 Count

- **CD4 count is how we measure response to ART**
  - An adequate response is defined as an increase in CD4 count by 50 to150 cells/mm^3 in the 1st first year of ART
  - Subsequent increases average approximately 50 to 100 cells/ mm^3 per year until a steady state level is reached
  - Patients who initiate therapy with a low CD4 count or at an older age may have a blunted response, even when they have achieved virologic suppression

Goal CD4 count is ≥ 500 cells/mm^3

Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents https://aidsinfo.nih.gov/guidelines

Monitoring: CD4 Count

- **CD4 count frequency**
  - The frequency of CD4 count monitoring depends on clinical circumstances, but generally:
  - If untreated with ART, every 3 to 6 months to assess the urgency of ART initiation and the need for OI prophylaxis
  - 3 months after ART initiation, and for the first 2 years following ART initiation, at 3 to 6-month intervals, or as directed by a specialist
  - Residents taking ART whose CD4 count has consistently been between 300 and 500 cells/mm^3 $\geq$ 2 years, CD4 monitoring can occur on an annual basis, unless otherwise indicated

Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents https://aidsinfo.nih.gov/guidelines

Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents

Table 3. Laboratory Monitoring Schedule for HIV-Infected Patients Before and After Initiation of Antiretroviral Therapy

(page 1 of 2)

https://aidsinfo.nih.gov/guidelines

Laboratory Test	Timepoint/Frequency of Testing								
	Entry into Care	Follow Up Before Initiation of ART	ART Initiation or Modification[b]	Follow-Up 2 to 8 Weeks After ART Initiation or Modification	Every 3 to 6 Months	Every 6 Months	Every 12 Months	Treatment Failure	Clinically Indicated
HIV Serology	√ If HIV diagnosis has not been confirmed								
CD4 Count	√	√ Every 3–6 months	√		√ During first 2 years of ART or if viremia develops while patient on ART or CD4 count <300 cells/mm^3		√ After 2 years on ART with consistently suppressed viral load: *CD4 Count 300–500 cells/mm^3:* • Every 12 months *CD4 Count >500 cells/mm^3:* • CD4 monitoring is optional	√	√
HIV Viral Load	√	Repeat testing is optional	√	√[c]	√[d]	√[d]		√	√
Resistance Testing	√		√[e]					√	√
HLA-B*5701 Testing			√ If considering ABC						
Tropism Testing			√ If considering a CCR5 antagonist					√ If considering a CCR5 antagonist or for failure of CCR5 antagonist-based regimen	√

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	Entry into Care	Follow Up Before Initiation of ART	ART Initiation or Modification[b]	Follow-Up 2 to 8 Weeks After ART Initiation or Modification	Every 3 to 6 Months	Every 6 Months	Every 12 Months	Treatment Failure	Clinically Indicated
Hepatitis B Serology[f]	√		√ May repeat if HBsAg (-) and HBsAb (-) at baseline						√
Hepatitis C Serology, with Confirmation of Positive Results	√								√
Basic Chemistry[g,h]	√	√ Every 6–12 months	√	√	√				√
ALT, AST, T. bilirubin	√	√ Every 6–12 months	√	√	√				√
CBC with Differential	√	√ Every 3–6 months	√	√ If on ZDV	√				√
Fasting Lipid Profile	√	√ If normal, annually	√	√ Consider 4–8 weeks after starting new ART regimen that affects lipids		√ If abnormal at last measure-ment	√ If normal at last measurement		√
Fasting Glucose or Hemoglobin A1C	√	√ If normal, annually	√		√ If abnormal at last measure-ment		√ If normal at last measurement		√
Urinalysis[g]	√		√			√ If on TDF[i]	√		√
Pregnancy Test			√ In women with child-bearing potential						√

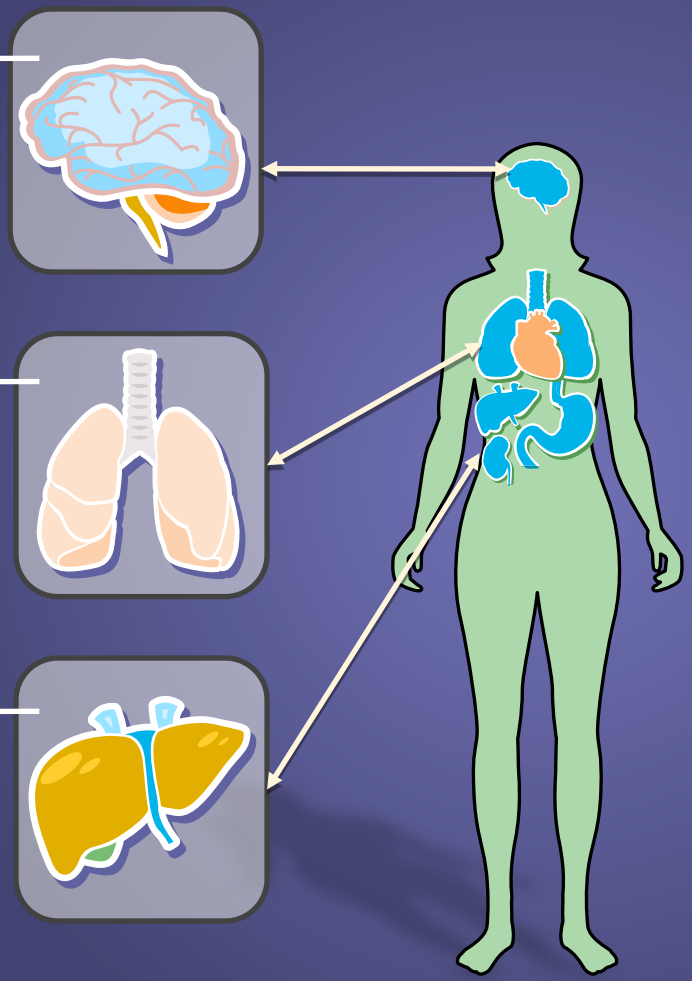
Opportunistic Infections (list not all inclusive)

BRAIN: Toxoplasmic Encephalitis

LUNGS: *Pneumocystis* pneumonia (PCP)

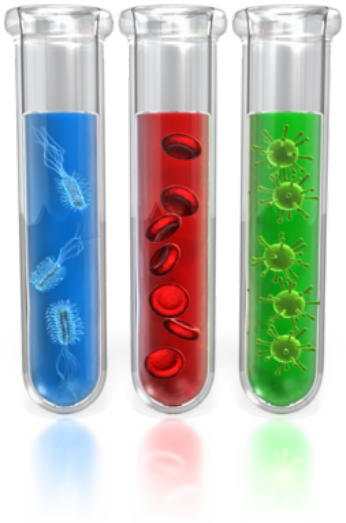
Tuberculosis

LIVER: Liver cancers often secondary to co-infection with hepatitis B and/or C



Multi-Organ Disease: *Mycobacterium avium* Complex (MAC)

Opportunistic Infections and Treatments



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

Recommendations for Prevention and Treatment of *Pneumocystis* Pneumonia (PCP)

Preventing 1st Episode of PCP (Primary Prophylaxis)

Indications for Initiating Primary Prophylaxis:

- CD4 count <200 cells/mm³ **(AI)** *or*
- Oropharyngeal candidiasis **(AII)** *or*
- CD4% <14% **(BII)** *or*
- History of AIDS-defining illness **(BII)** *or*
- CD4 count >200 but <250 cells/mm³ and if CD4 cell count monitoring (e.g., every 3 months) is not possible **(BII)**.

Note—Patients who are receiving pyrimethamine/sulfadiazine for treatment or suppression of toxoplasmosis do not require additional prophylaxis for PCP **(AII)**.

Preferred Therapy:

- TMP-SMX, 1 DS PO daily[a] **(AI)** *or*
- TMP-SMX, 1 SS PO daily[a] **(AI)**.

Alternative Therapy:

- TMP-SMX 1 DS PO three times weeklya **(BI)** *or*
- Dapsone[b,c] 100 mg PO daily or 50 mg PO BID **(BI)** *or*
- Dapsone[b] 50 mg PO daily + (pyrimethamine 50 mg + leucovorin 25 mg) PO weekly **(BI)** *or*
- (Dapsone[b] 200 mg + pyrimethamine 75 mg + leucovorin 25 mg) PO weekly **(BI)** *or*
- Aerosolized pentamidine[c] 300 mg via Respigard II™ nebulizer every month **(BI)** *or*
- Atovaquone 1500 mg PO daily with food **(BI)** *or*
- (Atovaquone 1500 mg + pyrimethamine 25 mg + leucovorin 10 mg) PO daily with food **(CIII)**.

Indication for Discontinuing Primary Prophylaxis:

- CD4 count increased from <200 cells/mm³ to ≥200 cells/mm³ for at least 3 months in response to ART **(AI)**

Indication for Restarting Primary Prophylaxis:

- CD4 count <200 cells/mm³ **(AIII)**

Treating PCP

Note—Patients who develop PCP despite TMP-SMX prophylaxis usually can be treated effectively with standard doses of TMP-SMX **(BIII)**.

For Moderate to Severe PCP—Total Duration = 21 Days (AII):

Preferred Therapy:

- TMP-SMX: (TMP 15–20 mg and SMX 75–100 mg)/kg/day IV given q6h or q8h **(AI)**, may switch to PO after clinical improvement **(AI)**.

Alternative Therapy:

- Pentamidine 4 mg/kg IV once daily infused over at least 60 minutes **(AI)**; may reduce the dose to 3 mg/kg IV once daily because of toxicities **(BI)** *or*
- Primaquine[b] 30 mg (base) PO once daily + (Clindamycin [IV 600 q6h or 900 mg q8h] or [PO 450 mg q6h or 600 mg q8h]) **(AI)**.

**Adjunctive corticosteroid may be indicated in some moderate to severe cases (see indications and dosage recommendations below)

Department of Health and Human Services Guidelines for the Treatment of Opportunistic Infections in HIV Infected Adults and Adolescents https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf

NO OPPORTUNISTIC INFECTION TREATMENT IS EFFECTIVE WITHOUT ART

Opportunistic Infections and Treatments*

CD4 count: 500 cells/mm^3 to 200 cells/mm^3

- **Candidiasis (Thrush)**
  - Fungal infection that is commonly seen in patients with CD4 counts in this range
  - Treated with antifungal medications (e.g., fluconazole)

- List not all-inclusive for OI, or for treatments

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Opportunistic Infections and Treatments*

CD4 count: 200 cells/mm^3 to 100 cells/mm^3

- ***Pneumocystis* Pneumonia (PCP)**
  - Caused by *Pneumocystis jirovecii* (formerly *carinii*); frequently causes death in patients with HIV
  - Medications: trimethoprim-sulfamethoxazole (TMP-SMX) is the recommended prophylactic agent and treatment
  - Alternative medications: dapsone plus pyrimethamine plus leucovorin; aerosolized pentamidine administered with the Respirgard II nebulizer, or atovaquone
- **Progressive Multifocal Leukoencephalopathy (PML)**
  - PML is a severe neurological condition caused by the JC virus with no definitive treatment; however, it has been shown to be responsive to antiretroviral therapy.

- List not all-inclusive for OI, or for treatments

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Opportunistic Infections and Treatments*

CD4 count: 100 cells/mm^3 to 50 cells/mm^3

- **Toxoplasmosis**
  Caused by the parasite *Toxoplasma gondii,* causes encephalitis and neurological disease
  - Preventative Medications: trimethoprim-sulfamethoxazole (TMP-SMX)
  - Medications for treatment: pyrimethamine plus sulfadiazine plus leucovorin
- **Cryptosporidiosis**
  - Cryptosporidiosis is a severe chronic diarrheal disease caused by the protozoa *Cryptosporidium*.
  - Medications: Nitazoxanide, appropriate ART

- List not all-inclusive for OI, or for treatments

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Opportunistic Infections*

CD4 count: 50-100 cells/mm^3

- **Cytomegalovirus (CMV)**
  - Common virus, a majority of the population have had CMV by age 40
  - Retinitis is the most common clinical manifestation of CMV end-organ disease, regular eye exams are important
  - Medications: ART plus oral valganciclovir, intravenous (IV) ganciclovir, IV ganciclovir followed by oral valganciclovir, IV foscarnet, and IV cidofovir

- List not all-inclusive for OI, or for treatments

Department of Health and Human Services Guidelines for the Treatment of Opportunistic Infections in HIV Infected Adults and Adolescents https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf

Opportunistic Infections*

CD4 count: less than 50 cells/mm^3

- ***Mycobacterium avium* Complex (MAC)**
  - MAC is a type of bacteria that can be found in soil, water, and many places in the environment
  - Medications: azithromycin, clarithromycin, or rifabutin

- List not all-inclusive for OI, or for treatments

Department of Health and Human Services Guidelines for the Treatment of Opportunistic Infections in HIV Infected Adults and Adolescents https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf

CD4 Counts and Treatment* of Selected Opportunistic Infections

***Pneumocystis* pneumonia (PCP)**: Often treated with sulfamethoxazole/trimethoprim

Used to treat other conditions such as skin infections and urinary tract infections

Can be discontinued prematurely if the indication for use and intended duration of therapy are not noted on the order

Toxoplasmic encephalitis (TE):

Treated with numerous medications such as: clindamycin, sulfamethoxazole/trimethoprim, or pyrimethamine

Pyrimethamine causes bone marrow suppression, which is prevented by co-administration of leucovorin (folinic acid)

Detrimental side effects can occur if folic acid is given instead of folinic acid

- List not all-inclusive for OI, or for treatments

Department of Health and Human Services Guidelines for the Treatment of Opportunistic Infections in HIV Infected Adults and Adolescents https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf

CD4 Counts and Treatment* of Selected Opportunistic Infections

***Mycobacterium avium* complex (MAC)**: Often treated with azithromycin, longer/different dose than a Z-Pak

Clarithromycin and rifabutin are also used

Again, these meds can be prematurely discontinued if staff are unaware of the indication and intended duration of therapy

- List not all-inclusive for OI, or for treatments

Department of Health and Human Services Guidelines for the Treatment of Opportunistic Infections in HIV Infected Adults and Adolescents https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf

CD4 Counts and Treatment of Selected Opportunistic Infections (OI)

Often a CD4 count < 200 cells/mm^3 is a reason to start antibiotics to **prevent** an OI from occurring, particularly if a resident has had the infection in the past

Sometimes antibiotics or other treatments are initiated based irrespective of the CD4 count, but the intent is to treat or prevent an OI

These treatments are often medications frequently used for another condition in the LTC facility, and sometimes the resident has both an OI and another, more commonly seen infection

The duration of the antibiotic depends on many factors, but is typically prolonged in treatment or prophylaxis against an OI

Treatment for an OI can be accidentally discontinued too early, if the correct indication for use and expected duration of therapy is not noted in the chart

Note: if the electronic data entry system only allows for one diagnosis to be listed, we need a workaround to protect the resident

Counseling

- Never forget how valuable you are as a resource to your residents
- Residents with HIV need your clinical expertise, compassion, and communication skills on an ongoing basis
- Medication facts and information on disease progression are an integral part of the counseling process
- However, lifestyle modification reminders, such as avoiding alcohol, drugs, tobacco, and unsafe practices is just as important
- Pharmacists are here to help at the pharmacy, through medication therapy management (MTM) services, and through consulting services

References

- Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents https://aidsinfo.nih.gov/guidelines
- Centers for Disease Control HIV Website http://www.cdc.gov/hiv/
- Omnicare Geriatric Pharmaceutical Care Guidelines: HIV/AIDS Management in Older Adults
- American Geriatrics Society Care of Lesbian, Gay, Bisexual, and Transgender Older Adults Position Statement. J Am Geriatr Soc. 2015; 1-4.
- Hardy WD, Goetz MB, Seeskin EP, et al. Treatment Update: Management Challenges in Patients Receiving Long-Term Antiretroviral Therapy. 2009. Clinical Care Options HIV http://www.clinicaloptions.com/HIV.aspx
- HIV Pharmacotherapy Practice-based Program. University of Buffalo School of Pharmacy and Pharmaceutical Sciences https://tdm.pharm.buffalo.edu/hiv_cert_main/
- American College of Clinical Pharmacy Pharmacotherapy Infectious Disease III HIV Infection Self-Assessment Program. 2015; 193-219
- Cahill S, Valadez R. Growing Older With HIV/AIDS: New Public Health Challenges. American Journal of Public Health. March 2013; 103 (3) e7-e15
- Morgan EE, Woods SP, Grant I, et al. Intraindividual variability in HIV Infection: Evidence for Greater Neurocognitive Dispersion in Older Seropositive Adults. Neuropsychology. 2011; 25 (5) 645-654
- Hughes A, Davies, B, Gudmundsdottir. “Can you give me respect?” Experiences of the Urban Poor on a Dedicated AIDS Nursing Home Unit. J. of Assoc. of Nurses in AIDS Care. 2008; 19 (5), 342-356
- Murray K, Cummins D, Bloom K. Developing a Protocol for People Living with HIV Entering Residential Aged Care Facilities. ANMJ. June 2014; 21 (11) 34-37
- American Medical Directors Association. Clinical Practice Guideline Common Infections. Columbia. MD: AMDA 2011
- Department of Health and Human Services Guidelines for the Treatment of Opportunistic Infections in HIV Infected Adults and Adolescents https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf