



# Involvement in the HIV epidemic in the Primary Care Setting

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# Disclosures

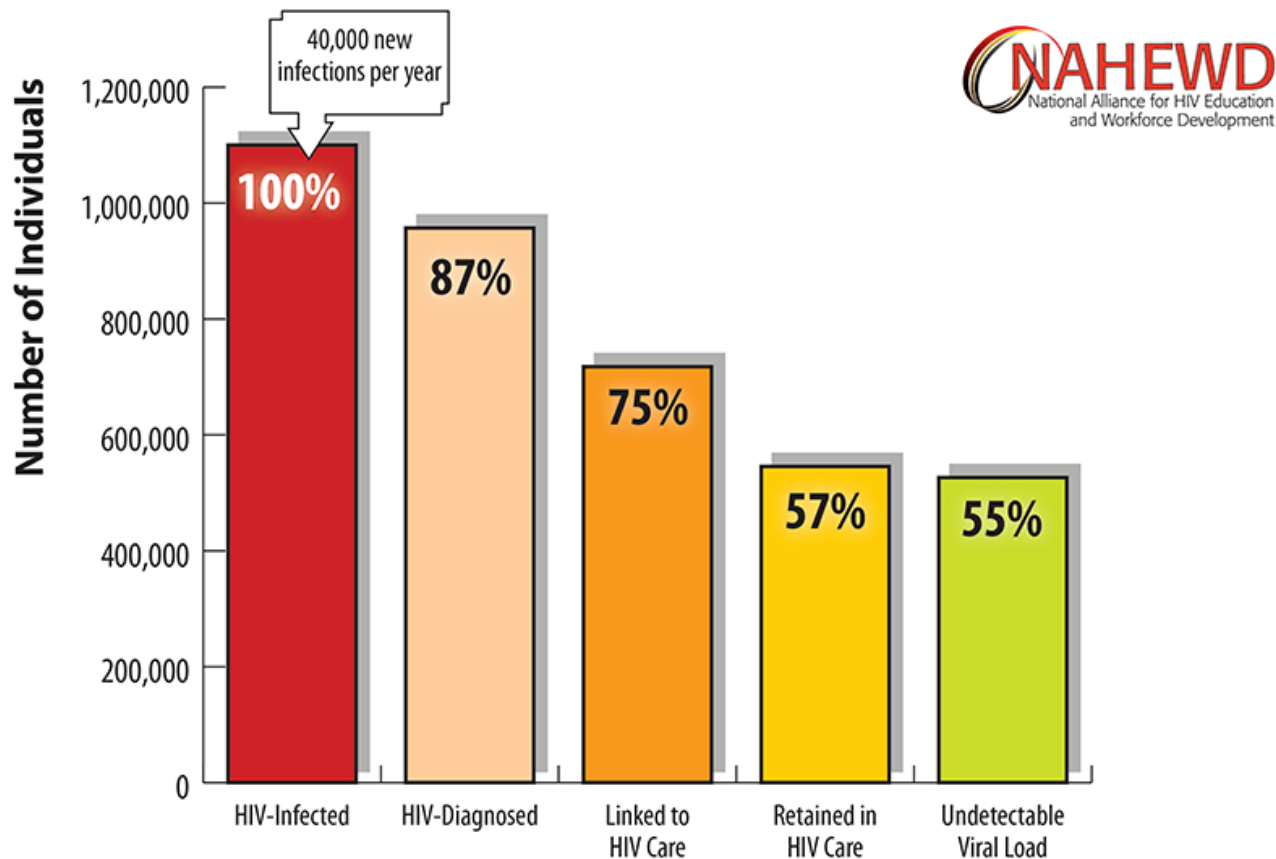
- Dr. Raffanti has no financial disclosures to make.

# Objectives

- After this presentation the attendee should be able to:
  - Describe current epidemiological trends in the HIV epidemic;
  - Describe key points in HIV pathogenesis;
  - Describe current treatment standards;
  - Describe various ways that clinics can manage HIV related healthcare.

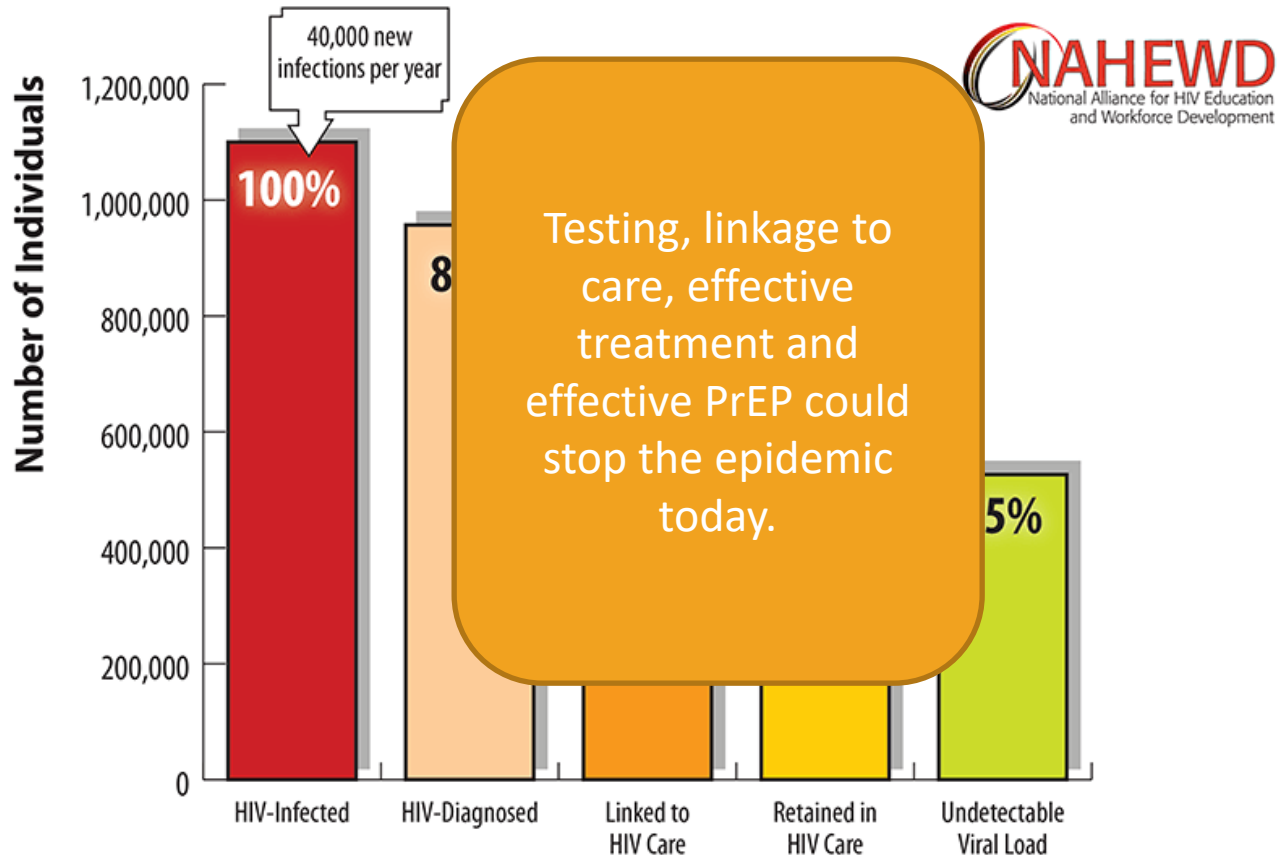
# HIV Care Continuum

## The U.S. HIV Care Continuum<sup>1</sup>

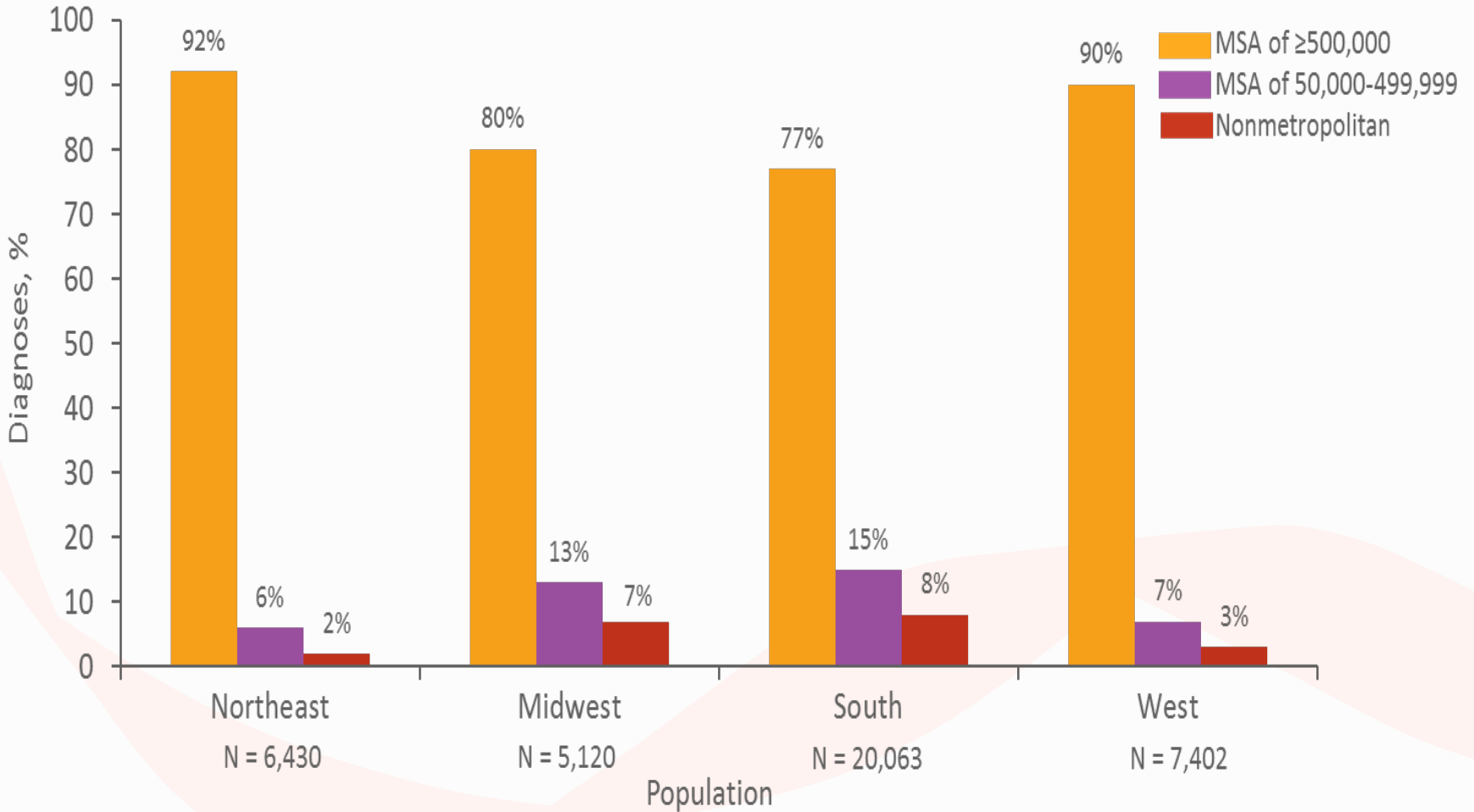


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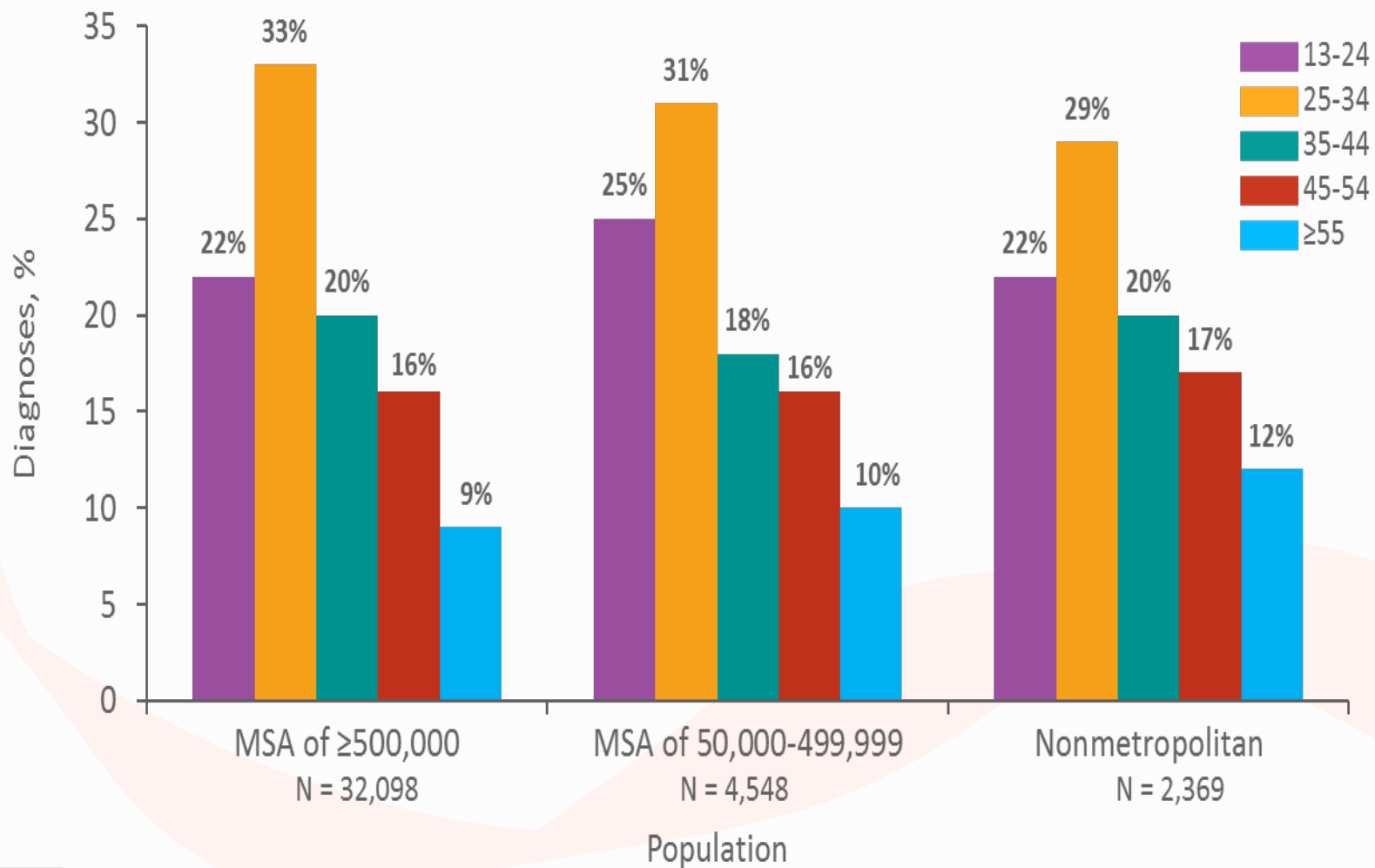
# Percentages of Diagnoses of HIV Infection among Adults and Adolescents, by Region and Population of Area of Residence, 2015—United States



Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. Data for the year 2015 are preliminary and based on 6 months reporting delay. Data exclude persons whose county of residence is unknown.



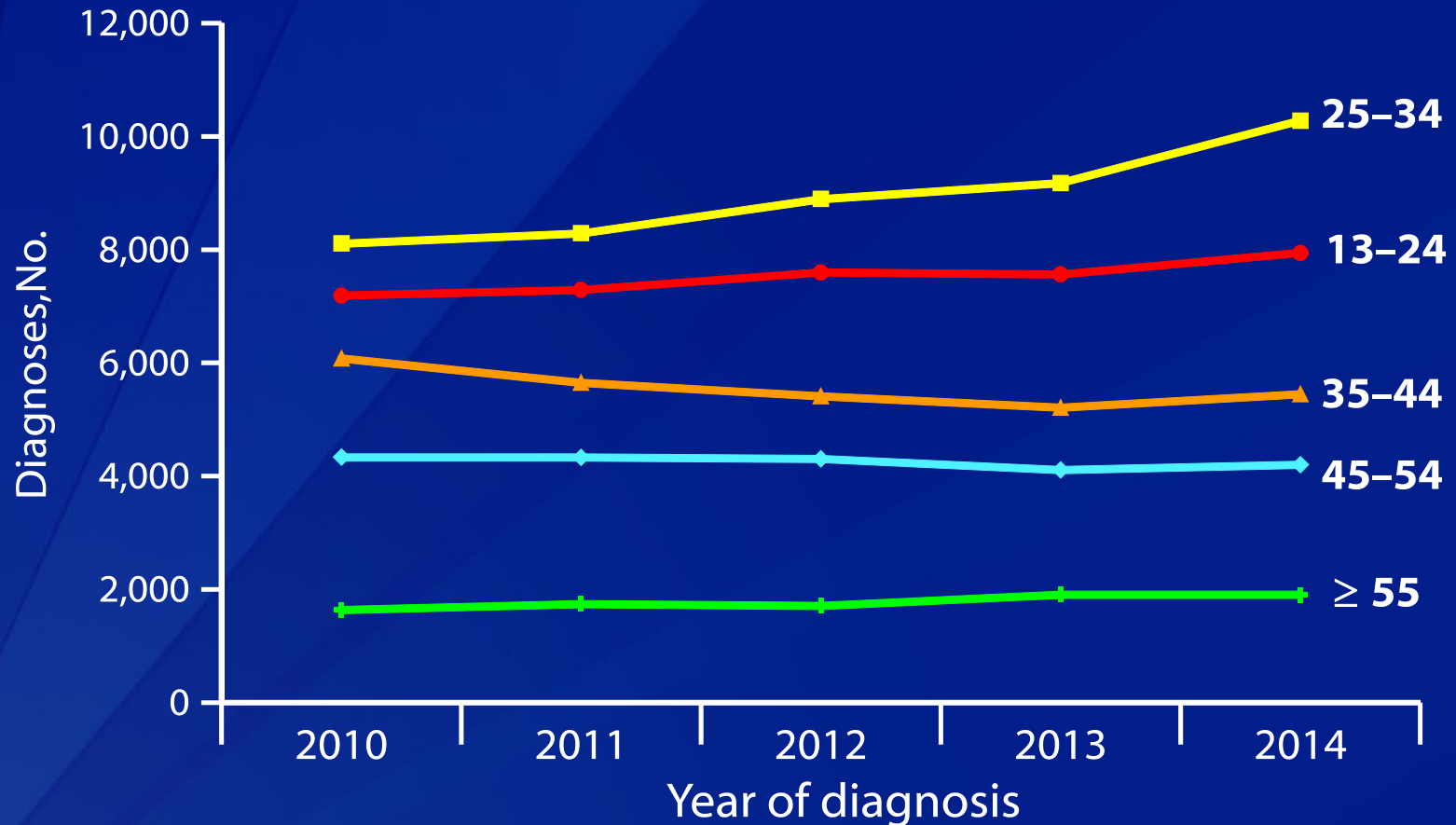
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# Diagnoses of HIV Infection among Men Who Have Sex with Men, by Age Group, 2010–2014—United States and 6 Dependent Areas

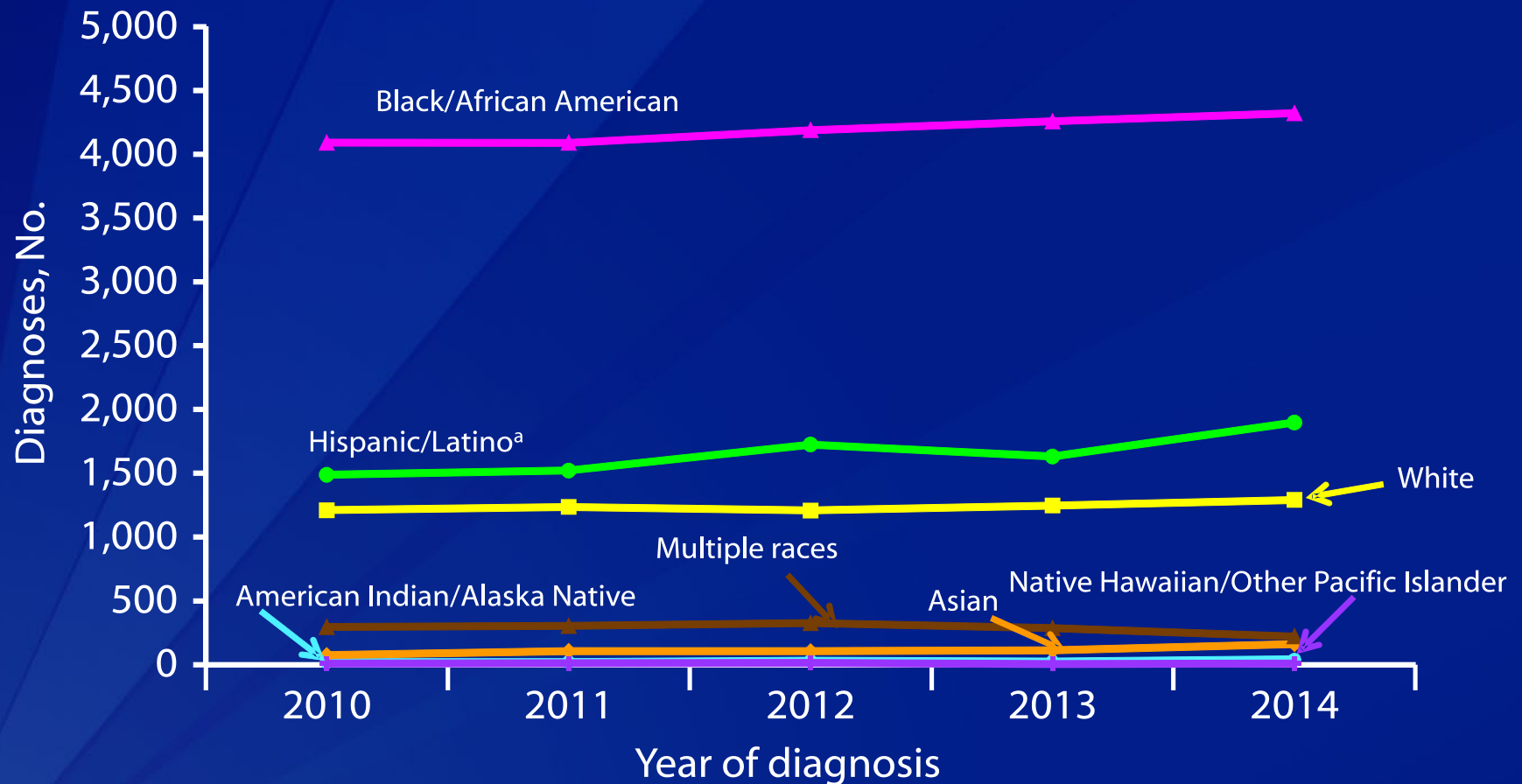


Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays and missing transmission category, but not for incomplete reporting. Data on men who have sex with men do not include men with HIV infection attributed to male-to-male sexual contact and injection drug use.





# Diagnoses of HIV Infection among Men Who Have Sex with Men Aged 13–24 Years, by Race/Ethnicity, 2010–2014 United States and 6 Dependent Areas

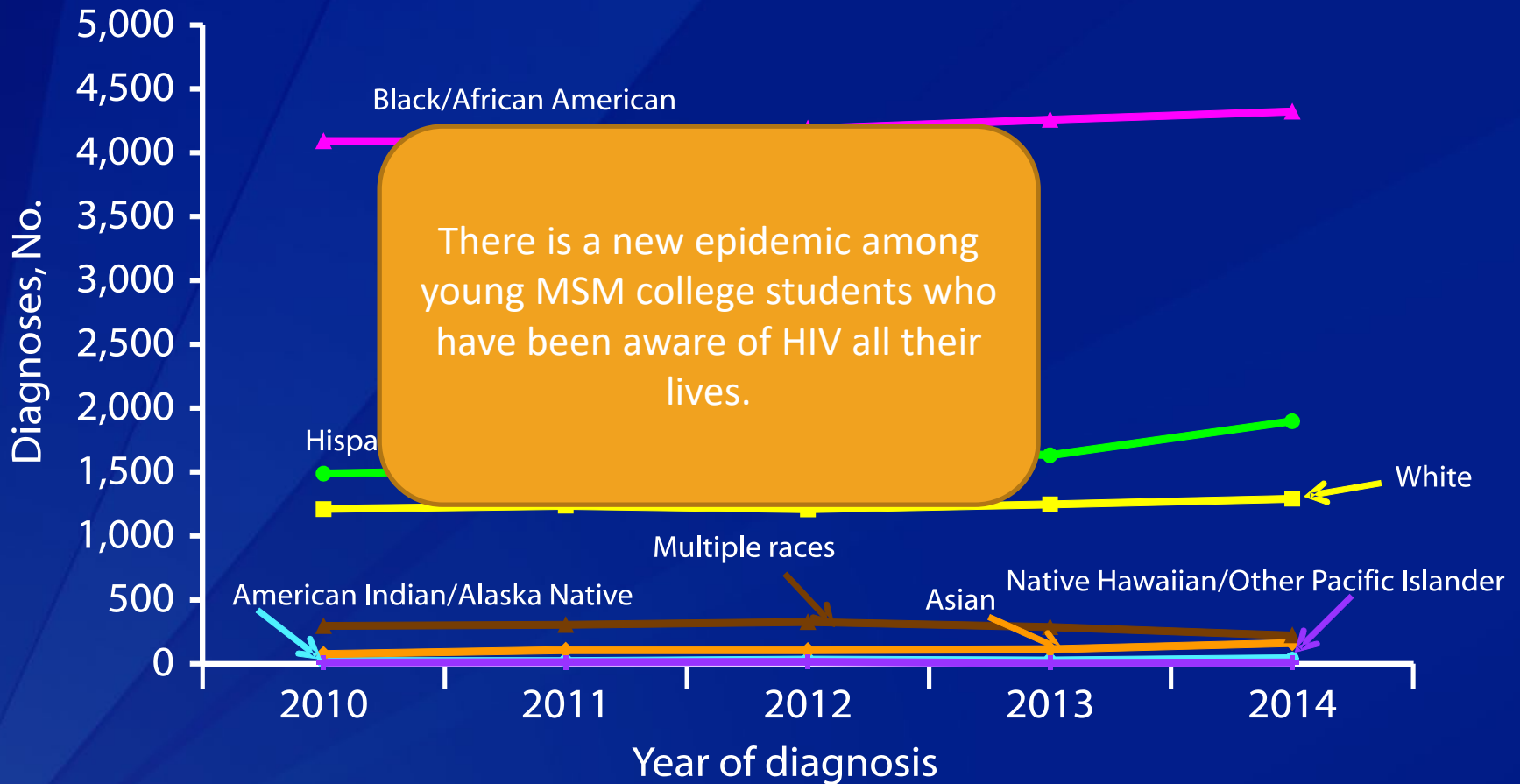


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<sup>a</sup> Hispanics/Latinos can be of any race.



# Diagnoses of HIV Infection among Men Who Have Sex with Men Aged 13–24 Years, by Race/Ethnicity, 2010–2014 United States and 6 Dependent Areas



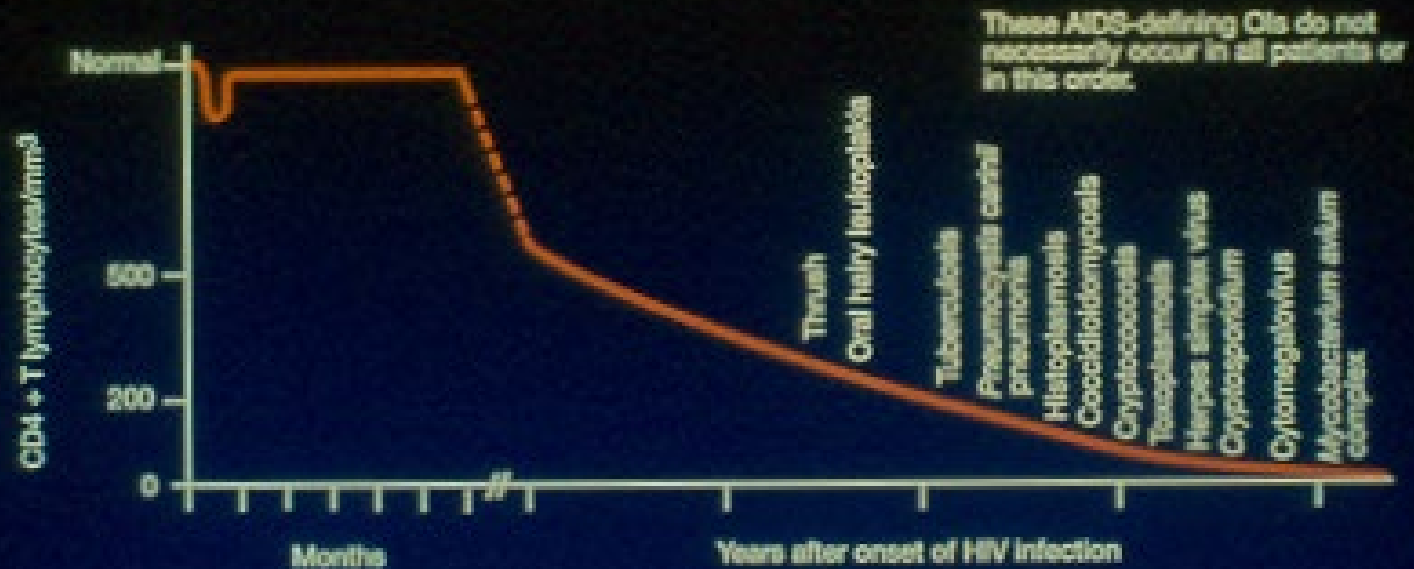
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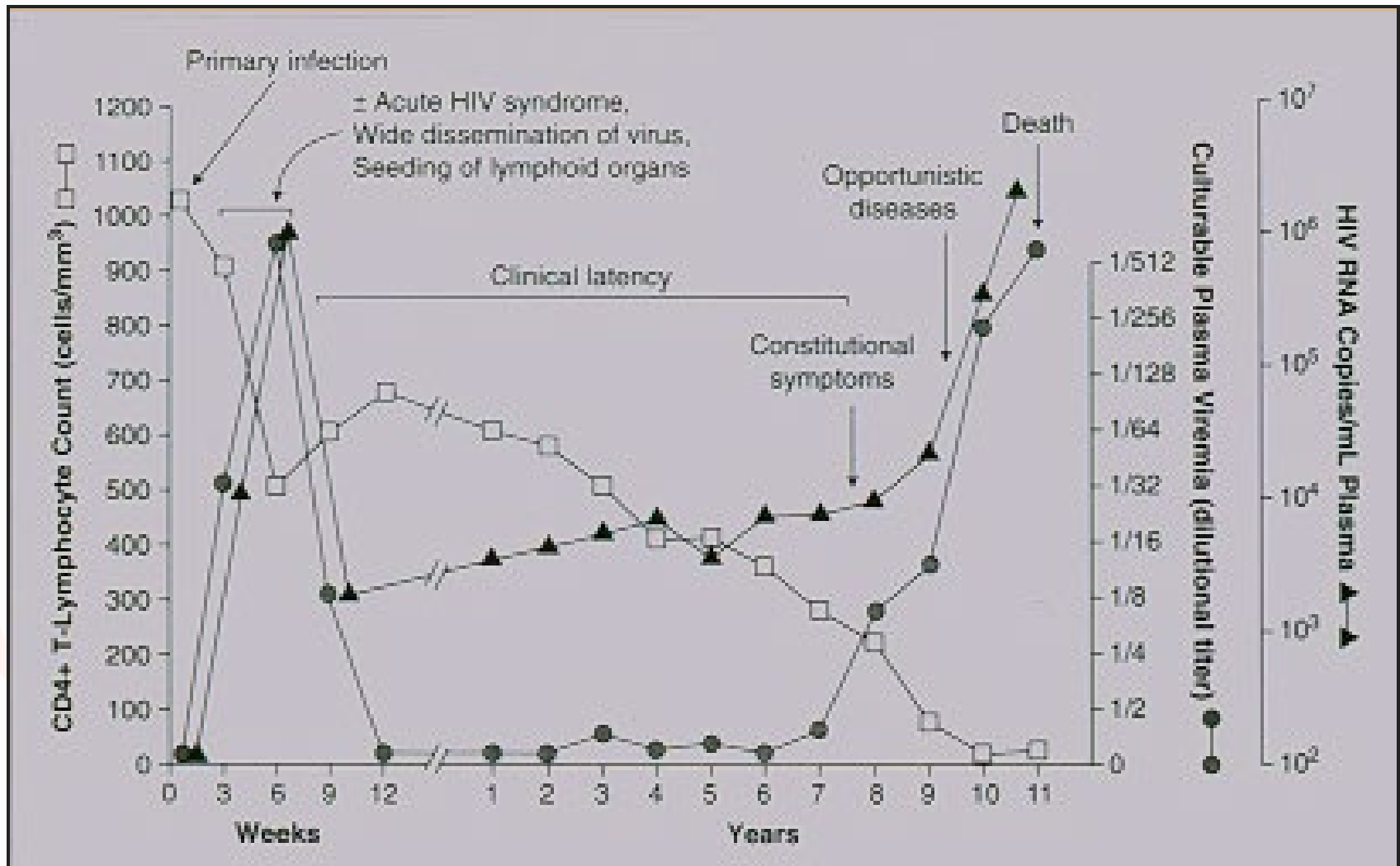


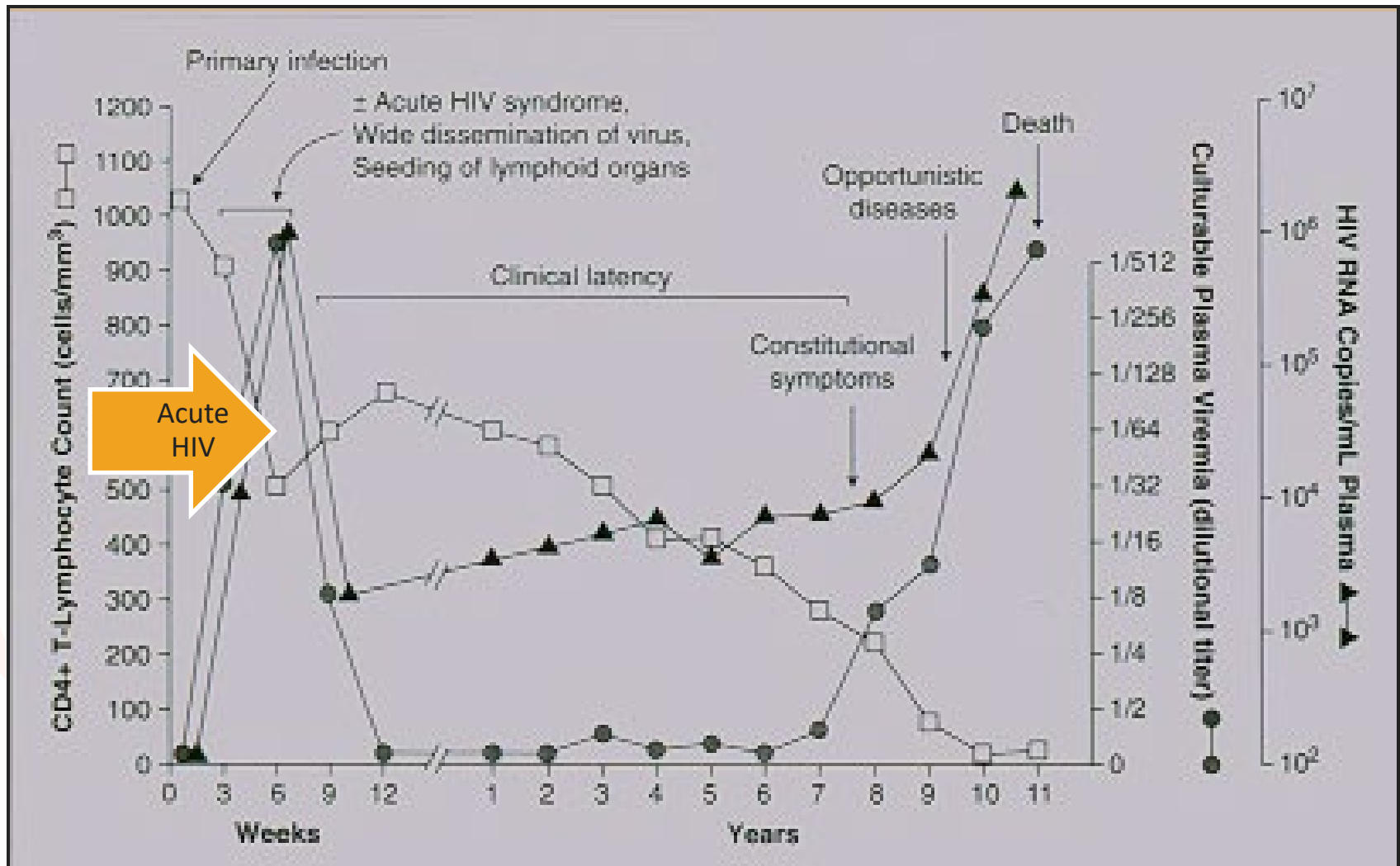
# HIV Pathogenesis

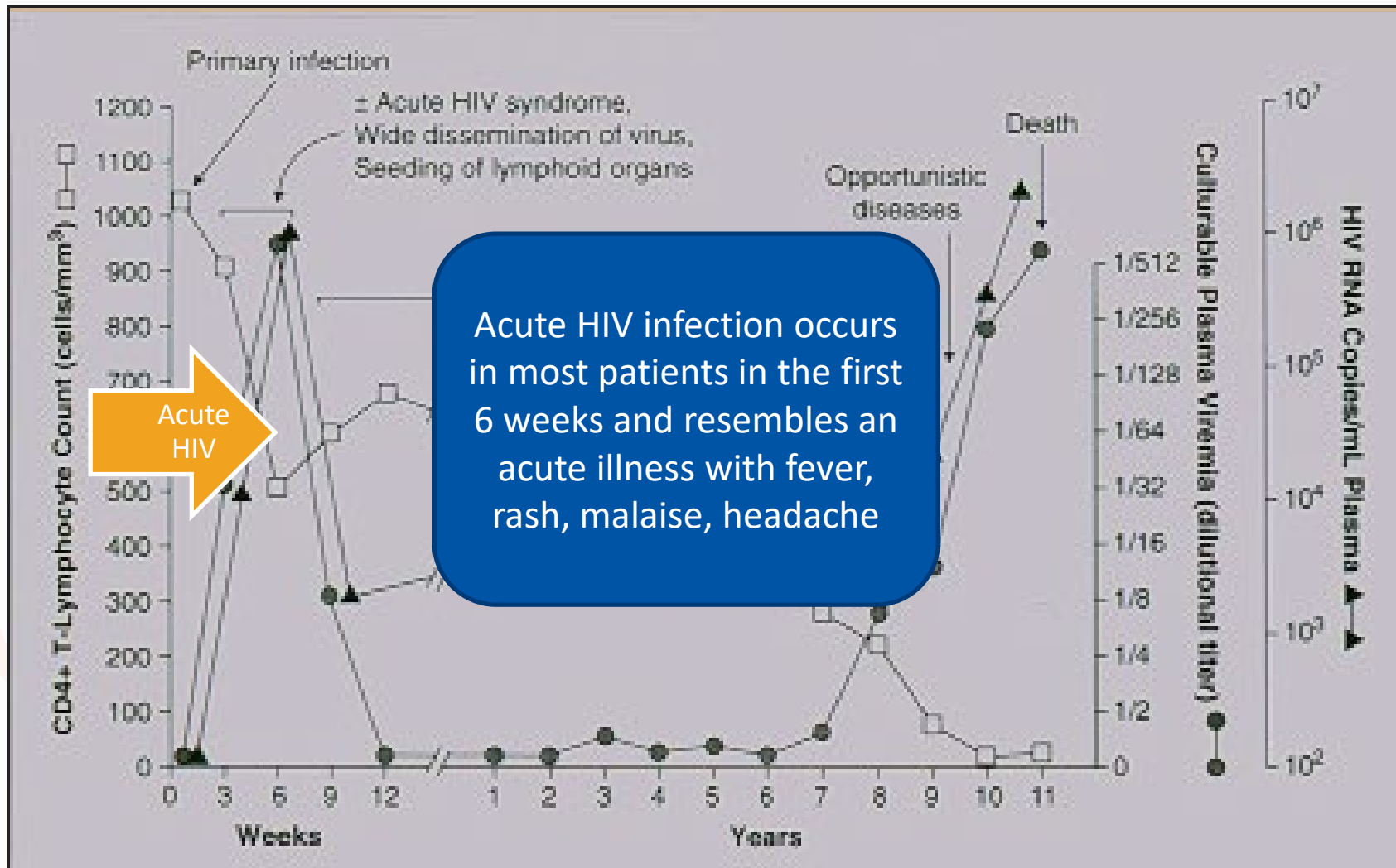
# Opportunistic Infections in HIV Disease

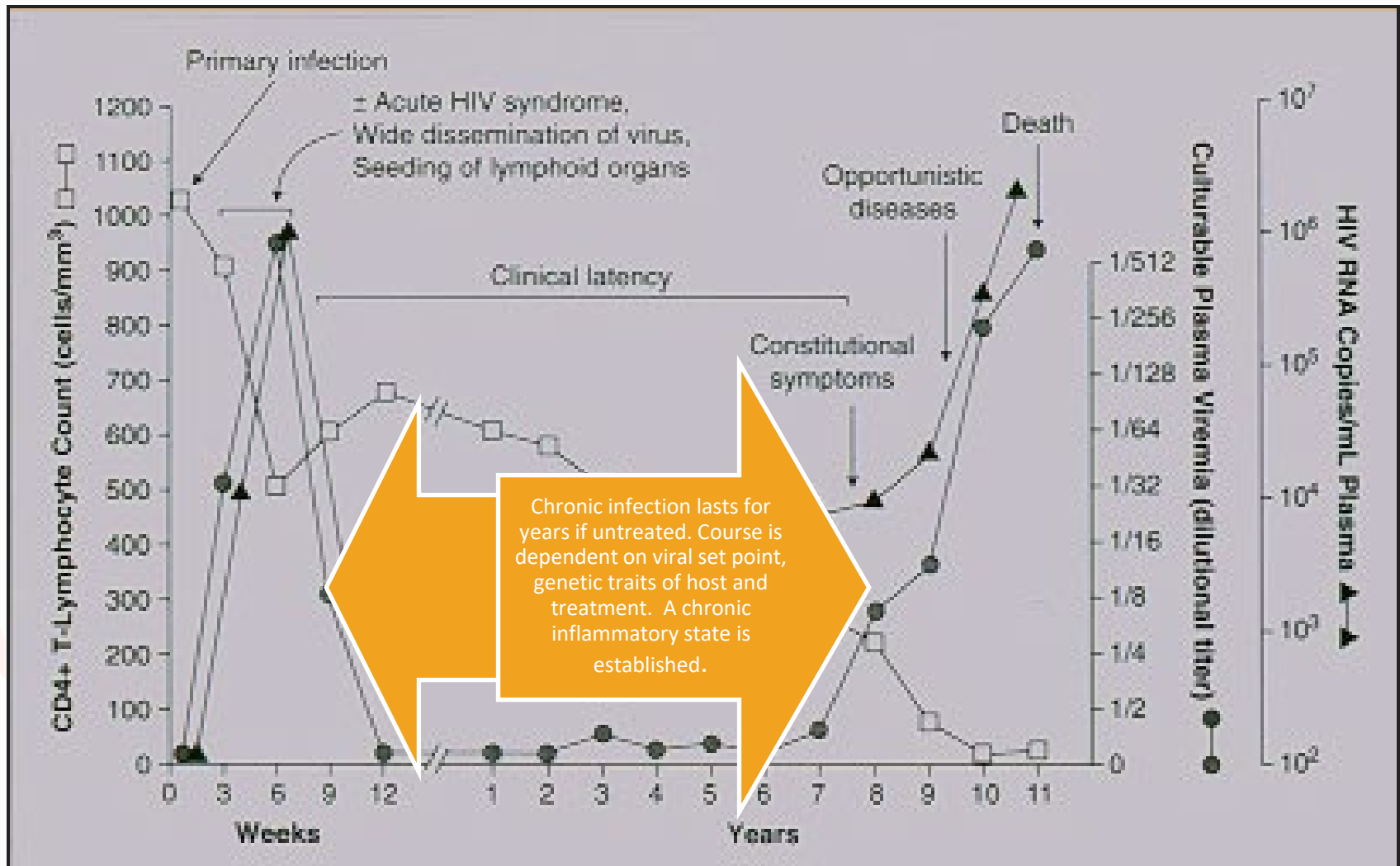


This graph is idealized. Specific OIs can occur earlier/later and at higher/lower CD4 cell counts.











# HIV Pathogenesis

- HIV infection disseminates quickly in the host and causes disease in almost all patients, if left untreated.
- Although thought of as an “Immune Deficiency “ disease, other critical factors are involved in generating poor outcomes for patients.
- Effective treatment of HIV ameliorates much of the damage done by the virus.

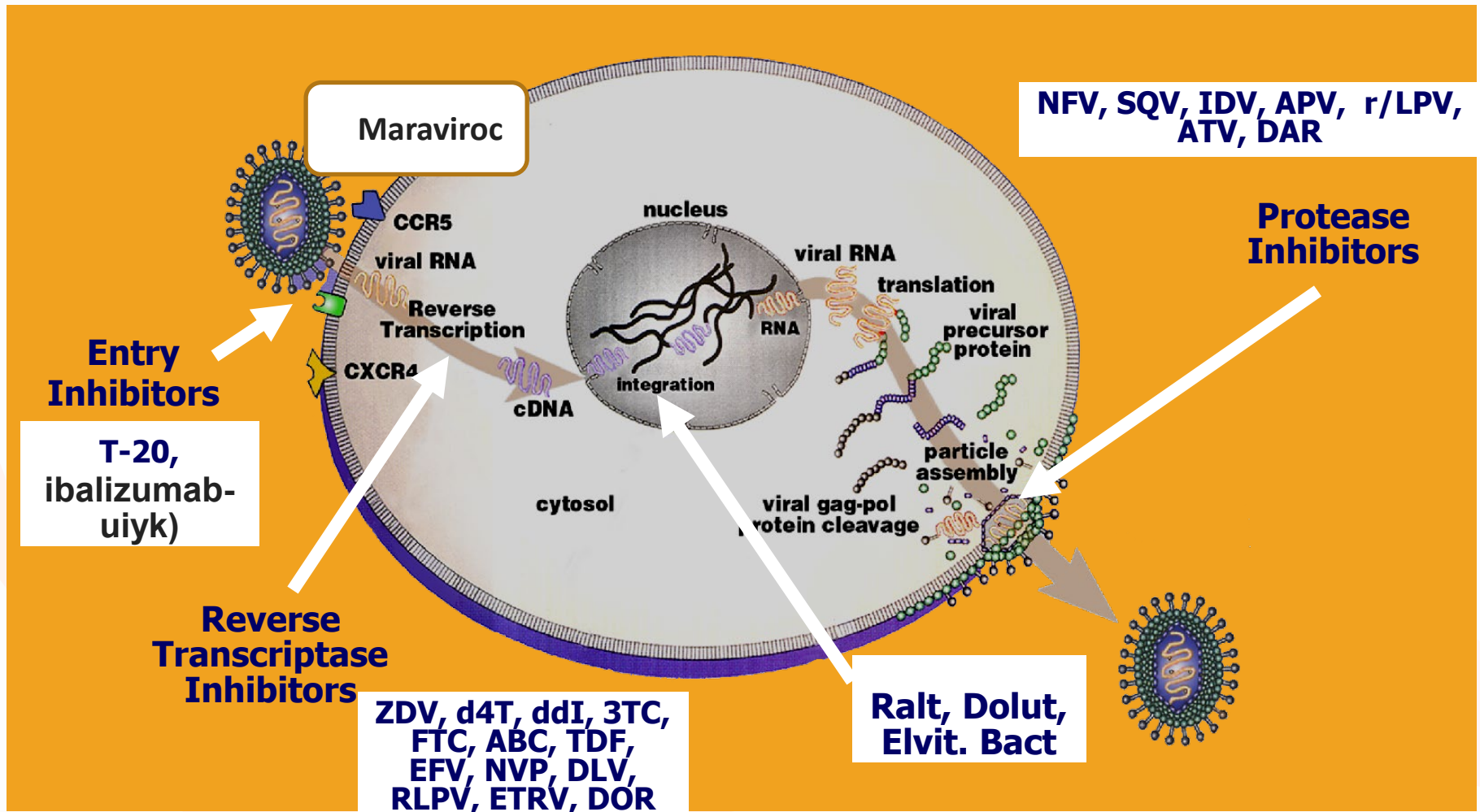
# Treatment



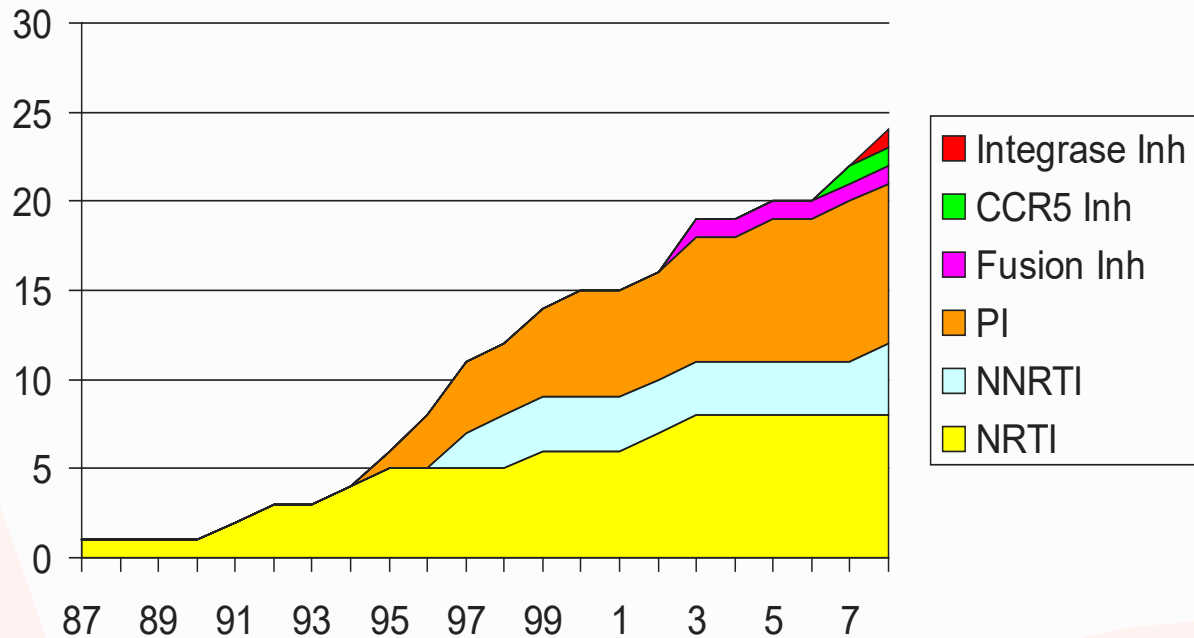
# Three Decades of Treatment Issues

- 1980's: AIDS described, PCP kills 90% of pts., clinicians develop skills in diagnosing, treating and preventing complications.
- 1990's: First effective treatments, patients respond, death rates drop.
- 2000's: New toxicities arise, resistance is critical, adherence issues emerge, limitations of therapy become apparent.
- 2007: Second round of effective antiretroviral agents- integrase and CCR5 inhibitors
- 2013: serious talk of cure.
- 2015: PrEP

# Targets for HIV Inhibition



# HIV Drug Approval



# Current Available Medications

- **NRTI's:** zidovudine, didanosine, stavudine, lamivudine, abacavir, emtricitabine, tenofovir, TAF
- **NNRTI's:** efavirenz, nevirapine, delavirdine; etravirine, rilpivirine, doravirine
- **PI's:** indinavir, ritonavir, saquinavir, nelfinavir, fosamprenavir, lopinavir, tipranavir, darunavir
- **Fusion I's:** enturvidine
- **CD4 binding:** ibalizumab-uiyk
- **CCR5 I's:** maraviroc
- **Integrase I's:** raltegravir, elvitegravir, dolutegravir, bictegravir

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Most patients starting treatment for HIV will be prescribed a co-formulation consisting of one pill a day.



# Benefits of Treatment

- Treating people with AIDS greatly improves survival and quality of life.
- Treating people with advanced HIV (200-350 CD4 count) **may** delay disease progression and improve quality of life.
- Treating people with early HIV (>350 CD4 count) **may** delay progression of disease and preserve immune function.
- *Treating HIV may have important benefits independent of immune function preservation.*

# Benefits of Treatment

- Treating people with AIDS greatly improves survival and quality of life.
- Treating people with AIDS (regardless of CD4 count) may delay disease progression.
- Treating people with AIDS (regardless of CD4 count) may delay progression of disease.
- *Treating HIV may help preserve immune function.*

**Why Treat all patients?**

- 1) Medications are much less toxic.
- 2) Treating HIV slows the inflammatory process.
- 3) Treating HIV decreases the risk of transmission.

# Comprehensive Care Center

- Established in 1994 as an independent non-profit;
- Close collaboration with Vanderbilt;
- Staff of 45; 1400 visits per month;
- Located at One Hundred Oaks since October, 2010;
- Now the **Vanderbilt Comprehensive Care Clinic (VCCC)**
- Over 10,000 patients enrolled at 4 sites (3700 active);
  - Age range 16-81 years;
  - 24% female;
  - 43% African American; 7% Hispanic
  - 50% substance abuse;
  - 40% mental health;

# VCCC Services

- Clinical and Laboratory Evaluation (Primary Care, Colposcopy, Obstetrics and HIV)
- Psychiatric Care and Mental Health Services
- Clinical Pharmacy Services and Patient Assistance Program
- Nutrition Services
- Case Management
- New Patient Navigation
- Transitions of Care Case Management
- Coordination of Home Care, Hospice, Infusion Transfusion Services
- Clinical Trials Access
- Inpatient Care Direction
- On-call Services

# VCCC Operations and Staff

- Over 10,000 patients enrolled
- Over 3,700 active patients
- Over 1,400 visits per month
- Approximately 300 new patients per year
- Approximately 30-40 pregnant women per year
- **Staff:** 4 ID attendings; 1 psychiatrist; 5 Nurse Practitioners; 6 RN's; 5 LPN's; 7 social services staff; 1 pharmacist, 1 mental health therapist; 3 PSR's; 1 dietitian and 6 administrative staff
- Three satellite rural clinics

# VCCC Programs

- ART conference
- OC3: Maternal-Fetal Program
- Clinical Pharmacy Services Team (PSCPS Collab.)
- HRA clinic
- Pathways Clinic
- Education Program
  - On-site training (1,958 hours); state-wide programs (4,811 trainees); annual symposium, monthly webinar, monthly nurses training, patient orientation meeting. VPIL, CCEX; now regional AETC for 8 State region, over 50,000 trainees.
- Research initiatives
  - Clinical trials (ACTG), epi-outcomes, repository, Vanderbilt BioVU

# VCCC Outcomes

- 88% of patients seen at the VCCC in 2020 achieved undetectable virus
- >500 Uninfected babies born to HIV infected mothers since 1999
- Percent of 2014 patients with medical office visits who were screened for:
  - Drug and alcohol: 100%
  - Mental illness: 100%
  - HIV risk reduction: 100%
- Percent of 2014 Ryan White patients who received:
  - Cervical Pap smears if indicated: 90%
  - PCP prophylaxis: 98%
  - HBV and HCV screening: 100%
  - TB screening: 93%
- 549 patients referred to the clinical trials group in 2019
- Joint Commission certified Primary Care Medical Home

# James

- 19 year old college freshman, presents to ED with fever, slight headache, some rash and cough.
  - Slightly elevated LFT's, CXR clear.
    - Sent home with OTC recs for fluids and antipyretics.
- Back to the ED 48 hours later, continued fever, severe malaise and myalgias.
  - HIV serology indeterminate, HIV-1 RNA 2,466,303 copies/ml



# James

- 19 year old college freshman, presents to ED with fever, slight headache, some rash and cough
  - Slightly elevated liver enzymes
    - Sent home with antibiotics.
- Back to the ED with severe malaise and myalgia
  - HIV serology, 1,303 copies/ml

James grew up in a small town in East TN. His family PCP knew him well but when James asked him to consider prescribing PrEP, he declined, saying he did not feel comfortable prescribing it.

# James

- Intake labs:
  - CBC, CMP, UA, wnl;
  - Treponemal, Toxoplasma serology negative;
  - HAV serology shows positive IgG, negative IgM;
  - HBV serology shows positive IgG, >20;
  - Urine screen for GC/Chlamydia negative;
  - CD4 count 443/22%;
  - HLA B2701: negative;
  - HIV 1 Genotype shows wild type.
- Physical exam:
  - No abnormal findings, some anxiety regarding diagnosis.
- Other:
  - No co-morbidities, on no meds. No known medication allergies. Family is supportive.

# James

- Intake labs:

- CBC, CMP, UA, ...

Provider provides detailed discussion of HIV pathogenesis, treatment and ongoing healthcare issues.

Living with HIV is discussed.

Transmission risks and strategies to decrease transmission risk as well as sexual health issues are reviewed.

STI screening for oral and anal exposure is obtained.

**Patient feels he is ready for treatment of his HIV infection.**

Options discussed include TAF/FTC/Bictegravir (Biktarvy);  
abacavir/lamivudine/dolutegravir (trumeq);

TAF/FTC/elvitegravir/cobicistat (Genvoya)

- Physical exam:

- No abnormal findings, some anxiety regarding diagnosis

# James

- Intake labs:

- CBC, CMP, UA, ...
  - Provider provides detailed discussion of HIV pathogenesis, treatment and ongoing healthcare issues.

- Living with HIV is discussed.

- Transmission risks and side effects of medication are discussed. Case transmission risk as well as side effects of medication are reviewed.

- STI screening is performed. Consent for blood pressure is obtained.

- **Patient feels hesitant about starting medication due to concerns of his HIV infection.**

- Options discussed include TAF/FTC/Bictegravir (Biktarvy);

- abacavir/lamivudine/dolutegravir (trumeq);

- TAF/FTC/elvitegravir/cobicistat (Genvoya)

- Physical exam:

- No abnormal findings, some anxiety regarding diagnosis

# James

- James agrees to starting TAF/FTC/bictegravir, one pill per day.
  - He meets with the RN CPS Case Manager who reviews treatment goals, potential side effects, adherence issues and how to contact us in case of issues with the medication.
  - The prescription is sent to the pharmacy of the patient's choice and the CPS RN calls to make sure there are no issues getting the medication filled.
- James is scheduled back in 4 weeks.
  - He has repeat CMP, and HIV 1 RNA done. Repeat STI screenings were negative.
    - HIV 1 RNA is now 942 copies/ml.
  - He will return in 8 weeks for follow up labs and then on follow up will be directed by his response to therapy and will ultimately be seen twice a year.

- What is the role of primary care in the management of the HIV epidemic?
- Different levels of HIV related services may be appropriate for different clinical settings.

# HIV care: Level 1

- Minimal (community standard of care):
  - Effectively screen, test and refer for HIV and STI's including referral for PrEP:
    - Knowledge of screening techniques and sexual history taking;
    - Knowledge of available resources in your community and effective linkage;
    - Non-judgmental and welcoming environment for patients who may be interested in these services.

# HIV care: Level 1

- Minimal (community standard of care):
  - Effectiveness, including PrEP:
    - Knowledge of PrEP and adherence;
    - Knowledge of and effective linkage to PrEP; and
    - Non-stigmatizing care for patients who may be interested in these services.

Champions are incredibly important. Issues like stigma and cultural humility are handled based on the leading example of champions.



# HIV care: Level 2

- Expand services to include PrEP, clear risk assessment for all patients, continue with effective linkage to care for patients testing positive for HIV.

# HIV care: Level 2

- Expand services to include PrEP, clear risk assessment for all patients, continue with effective linkage to care for patients testing positive for HIV

PrEP protocols will need to be developed and CQI review should be started.

# HIV care: Level 3

- Provide HIV care for uncomplicated patients, recognize need for referral to HIV specialists when care becomes more complicated.

# HIV care: Level 3

- Provide HIV care for patients who do not recognize need for referral for more complicated

Protocols for uncomplicated patients may be limited to newly diagnosed, wild type strain. Knowledge of recommended initial regimens and possible drug interactions will be required.

# HIV care: Level 4

- Provide HIV specialty care to more complicated patients, develop retention in care strategies, follow outcomes closely.

# HIV care: Level 4

- Provide HIV specialty care to more complicated patients, develop retention strategies, and monitor outcomes closely.

More complicated patients may be on 2<sup>nd</sup> or 3<sup>rd</sup> regimens, have new drug interactions or complicated co-morbidities.

Close monitoring and virological suppression rates become very important.

# HIV care: Level 5

- Complex care provision for complicated HIV infected patients with significant co-morbidities, especially psychiatric and substance use disorders.

# HIV care: Level 5

- Complex care for HIV infected patients with significant psychiatric and substance abuse issues

Multidisciplinary team which handles challenging patients either through on-site resources or close coordinated collaborations.



# HIV care: Level 6

- Establishment of a comprehensive HIV treatment center with wrap around services, specialty and primary care.

# HIV care: Level 6

- Establish a wrap-around care model for patients in a treatment center with wrap-around care.

One option is to pursue certification as a Patient Centered Medical Home (or Primary Care Medical Home).

# Summary

- The HIV epidemic is still a significant health problem and is involving an increasing number of young adults.
- Treatment is effective and relatively easy to manage in most patients.
- The epidemic can end with coordinated screening, testing, linkage to care, viral suppression and PrEP for those at risk.
- Each clinical setting can approach involvement in HIV management at different levels.
- Leaders (champions) at the clinic are essential for developing the “buy in” of the entire staff.

# Summary

- The HIV epidemic is still a significant health problem and is involving...
- Treatment... in most
- patient... testing,
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- linkage... testing,
- Each clinical setting can approach involvement in HIV management at different levels.
- Leaders (champions) at the clinic are essential for developing the “buy in” of the entire staff.

The care of uncomplicated HIV infected patients as well as the prevention of HIV infection in at-risk patients fit well in the primary care setting.

# AIDS 1985- One Patient's Experience

- 322 IV insertions
- 14 hospital admissions
- 11 months of hospital stay
- 60 phlebotomies
- 32 chest x-rays
- 5 CT scans of head
- 3 abdominal ct scans
- 6 bronchoscopies
- 8 intubations
- 4 lumbar punctures
- 3 bone marrows
- 5 cycles of chemo
- 2 lymph node bx

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If Pablo were to present with his HIV infection today, he would have labs drawn, be started on a pill to treat HIV and his wife would be started on PrEP. He would raise his kids and live out his life.

# Useful HIV Websites

<https://www.seaetc.com/>

[www.hiv.uw.edu](http://www.hiv.uw.edu) (National HIV Curriculum)

[www.aidsinfonet.org](http://www.aidsinfonet.org)

[www.aidsetc.org](http://www.aidsetc.org)

[www.hivatis.org](http://www.hivatis.org) (DHHS, USPHS/IDSA Guidelines)

[www.cdc.gov/nchstp/hiv\\_aids.htm](http://www.cdc.gov/nchstp/hiv_aids.htm)

[www.hiv-web.lanl.gov](http://www.hiv-web.lanl.gov) (Resistance mutations)

[www.niaid.nih.gov](http://www.niaid.nih.gov)

[www.AIDS.medscape.com](http://www.AIDS.medscape.com)

[www.hopkins-aids.edu](http://www.hopkins-aids.edu)

[www.iapac.org](http://www.iapac.org)

[www.igm.gov](http://www.igm.gov)

[www.ucsf.edu/medical](http://www.ucsf.edu/medical)

[www.virology.net](http://www.virology.net)

# Questions?

