AETC AIDS Education & Training Center Program Southeast

HIV Medicine 2017

Stephen Raffanti, M.D., M.P.H.
Medical Director, VCCC
Professor of Medicine VU

HIV Medicine 2017

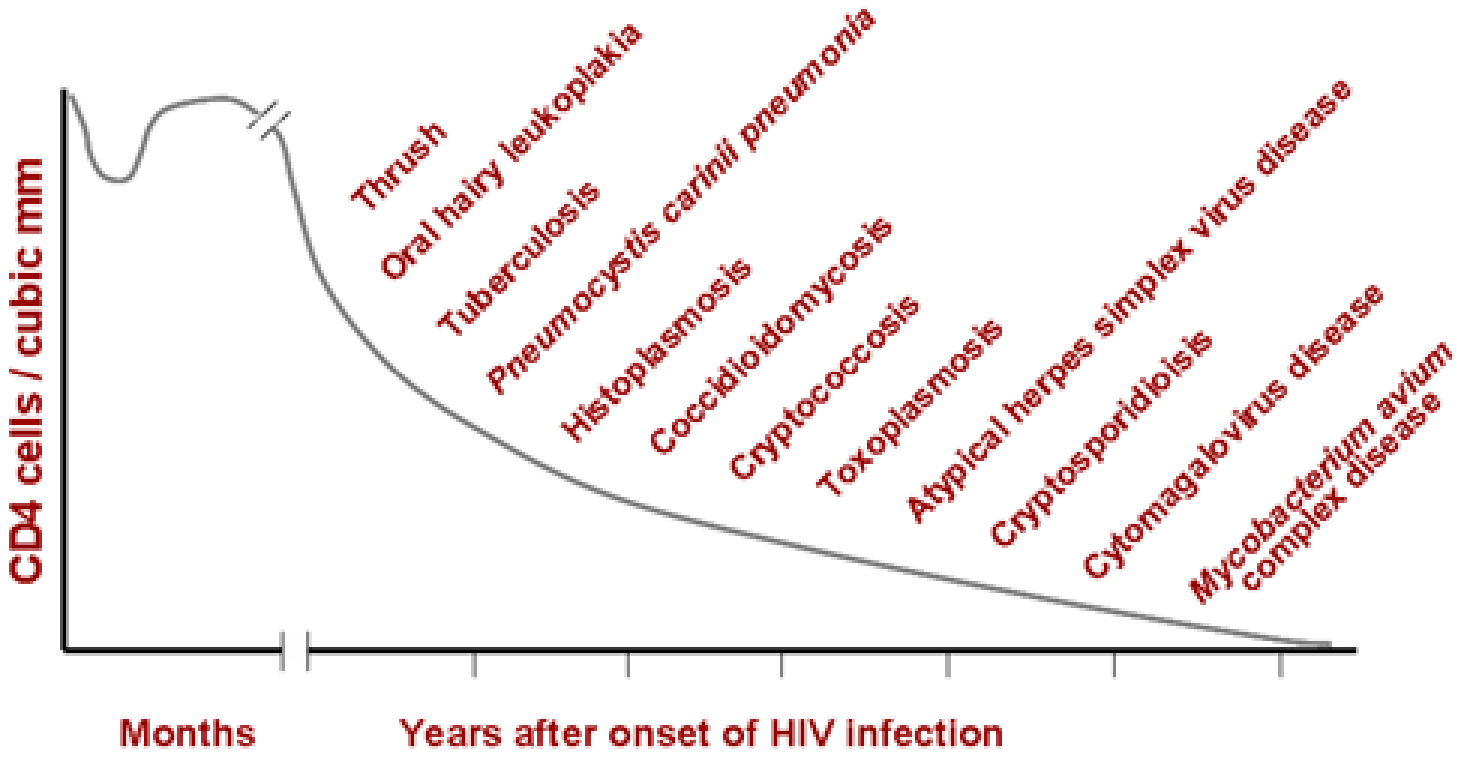
- HIV pathogenesis and why we treat HIV infection;
- The challenges of treating a life-long chronic infection with toxic agents;
- How we put all the information together to make the best choice.
- ART Conference Case presentations
- Special Programs
- Future Challenges

AIDS: Not Just Another Disease

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

Opportunistic Infections in HIV Disease



The Face Of HIV care: 1981 through 1996

- Endless procession of dying young people with no hope of treatment:
  - Minimal lab technology;
  - AIDS defining illnesses dominated;
  - Wasting, dementia, KS, lymphoma, CMV;
  - Limited number of toxic inefficient medications:
    - Antiretrovirals: AZT, ddC and ddI
    - OI treatments: antifungals, antivirals, anti-mycobacterials
  - Heavy imprint of stigma;
  - Hospice expertise.

The Social Political Fabric of AIDS: 1982-1987

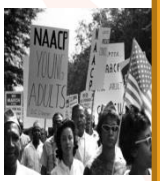
On July 25,1983, San Francisco General Hospital opens the first dedicated AIDS ward in the U.S. It is fully occupied within days

Civil R
Movement

In January 1982 , first American AIDS clinic is established in S.F.

Ryan White, an Indiana teenager who contracted AIDS through contaminated blood products used to treat his *hemophilia*, is refused entry to his middle school. He goes on to speak publicly against AIDS stigma and discrimination

On December 10, 1982, CDC reports a case of AIDS in an infant who received blood transfusions. The following week, the *MMWR* reports 22 cases of unexplained immunodeficiency and opportunistic infections in infants.



In October, 1984 San Francisco officials order bathhouses closed due to high-risk sexual activity occurring in these venues.

On January 7,1983 CDC reports cases of AIDS in female sexual partners of males with AIDS.

The Ray Brothers' home is burned down by angry neighbors

In March, playwright and AIDS activist Larry Kramer founds the AIDS Coalition to Unleash Power (ACT UP) in New York City

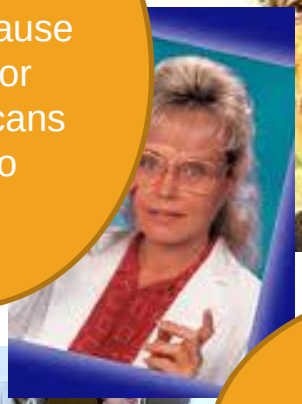
The Social Political Fabric of AIDS: 1987-1988

1987
Larry Kramer founds the AIDS Coalition To Unleash Power (ACT UP)

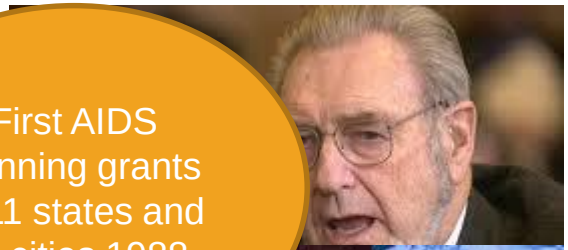
On October 11, 1988, ACT UP protests at FDA headquarters about the drug-approval process. Eight days later, FDA announces new regulations to speed up drug approvals.

The Social Political Fabric of AIDS: 1988-1994

1994 AIDS becomes the leading cause of death for all Americans ages 25 to 44.



First AIDS planning grants to 11 states and 10 cities 1988



Magic 1991

Visual AIDS artists caucus launches red ribbon 1991

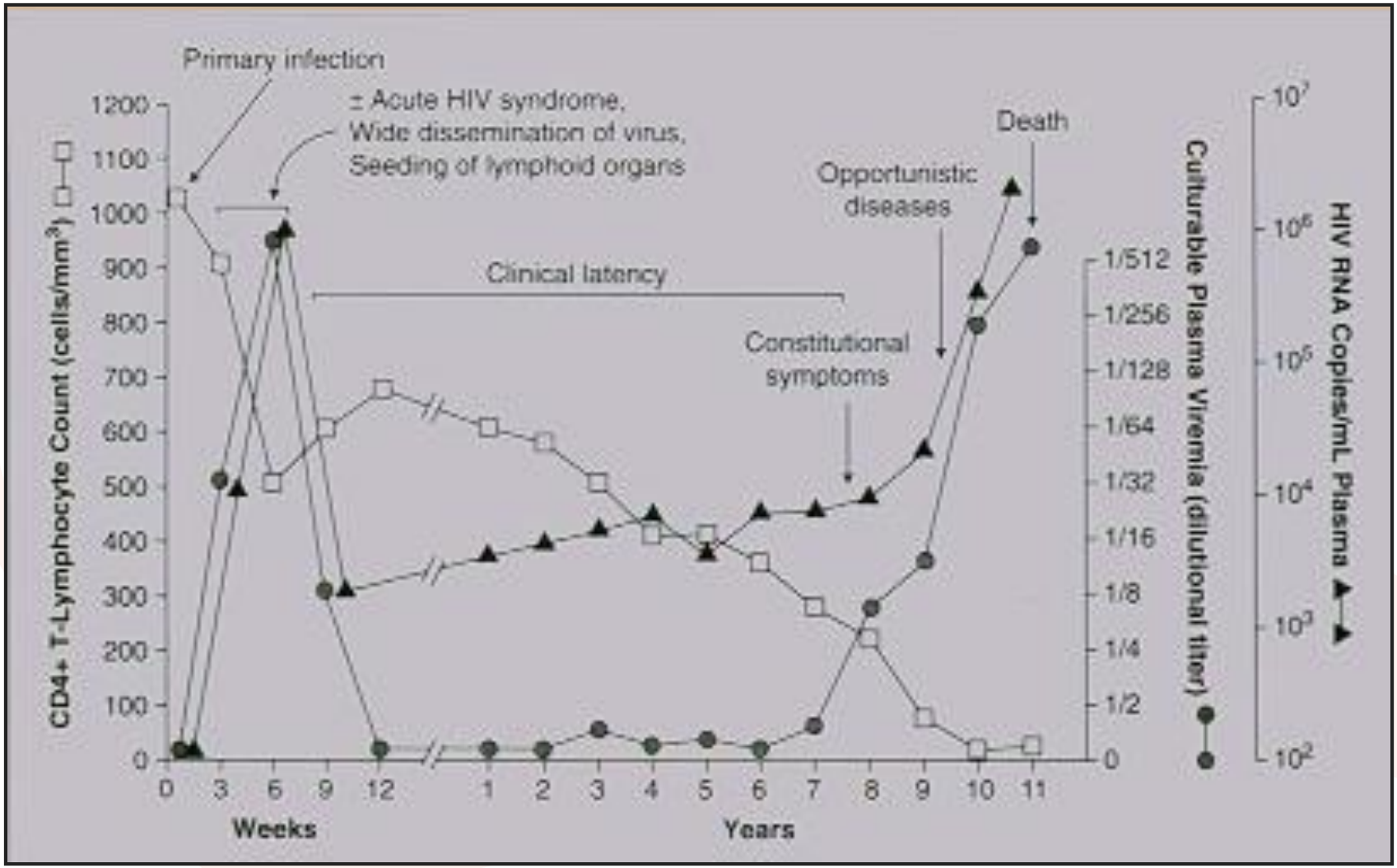
Ryan White Care Act funded 1990

Nureyev 1993

Pediatric AIDS Foundation 1988

The Face Of HIV care: 1996 through 2006

- New technology available;
- Multiple new antiretrovirals developed;
- First sign of response to therapy;
- Dramatic drop in mortality;
- First experience with polypharmacy:
  - Drug-drug interactions
  - Adherence
  - Development of resistance
- Importance of co-morbidities


Primary infection
± Acute HIV syndrome,
Wide dissemination of virus,
Seeding of lymphoid organs
Death
Opportunistic diseases
Clinical latency
Constitutional symptoms
CD4+ T-Lymphocyte Count (cells/mm³)
Culturable Plasma Viremia (dilutional titer)
HIV RNA Copies/mL Plasma
1200
1100
1000
900
800
700
600
500
400
300
200
100
0
1/512
1/256
1/128
1/64
1/32
1/16
1/8
1/4
1/2
0
10⁷
10⁶
10⁵
10⁴
10³
10²
0 3 6 9 12 1 2 3 4 5 6 7 8 9 10 11
Weeks
Years

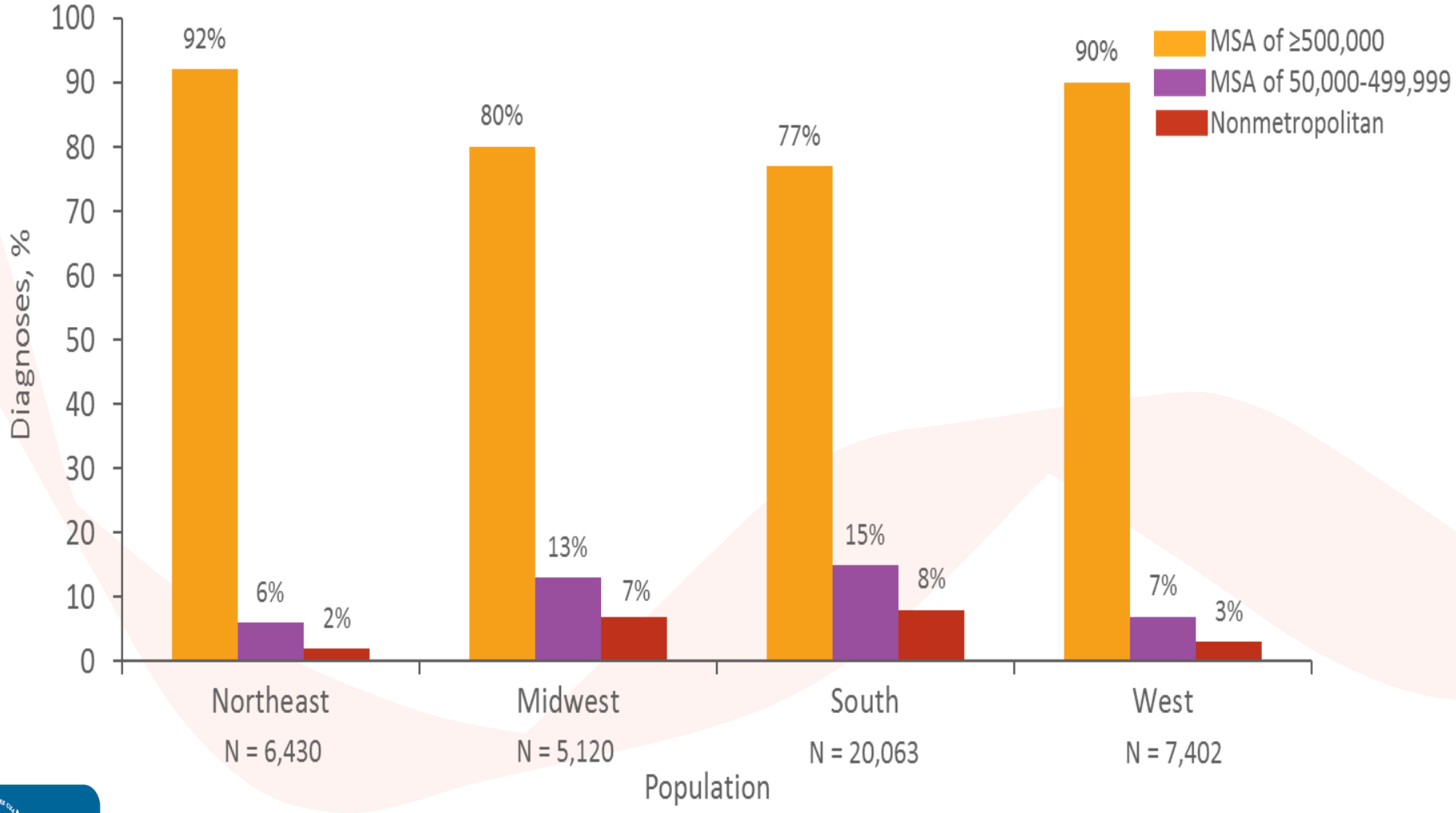
Inflammatory Disease in HIV

- HIV infected individuals have higher levels of inflammatory markers c/w matched HIV- individuals.
- Successful treatment of HIV may lower these markers.
- Some antiretrovirals are associated with a higher risk of cardiovascular events.
- Classic cardiovascular risk factors are more common in HIV infected patients and may have an even greater impact on outcomes.

The Face Of HIV care: 2007 to present

- New, extremely well tolerated potent agents;
- New understanding of inflammatory state;
- Less concern about resistance;
- Less stigma; but still present!
- Aging population;
- Aging workforce;
- Health maintenance is essential;
- New epidemic.

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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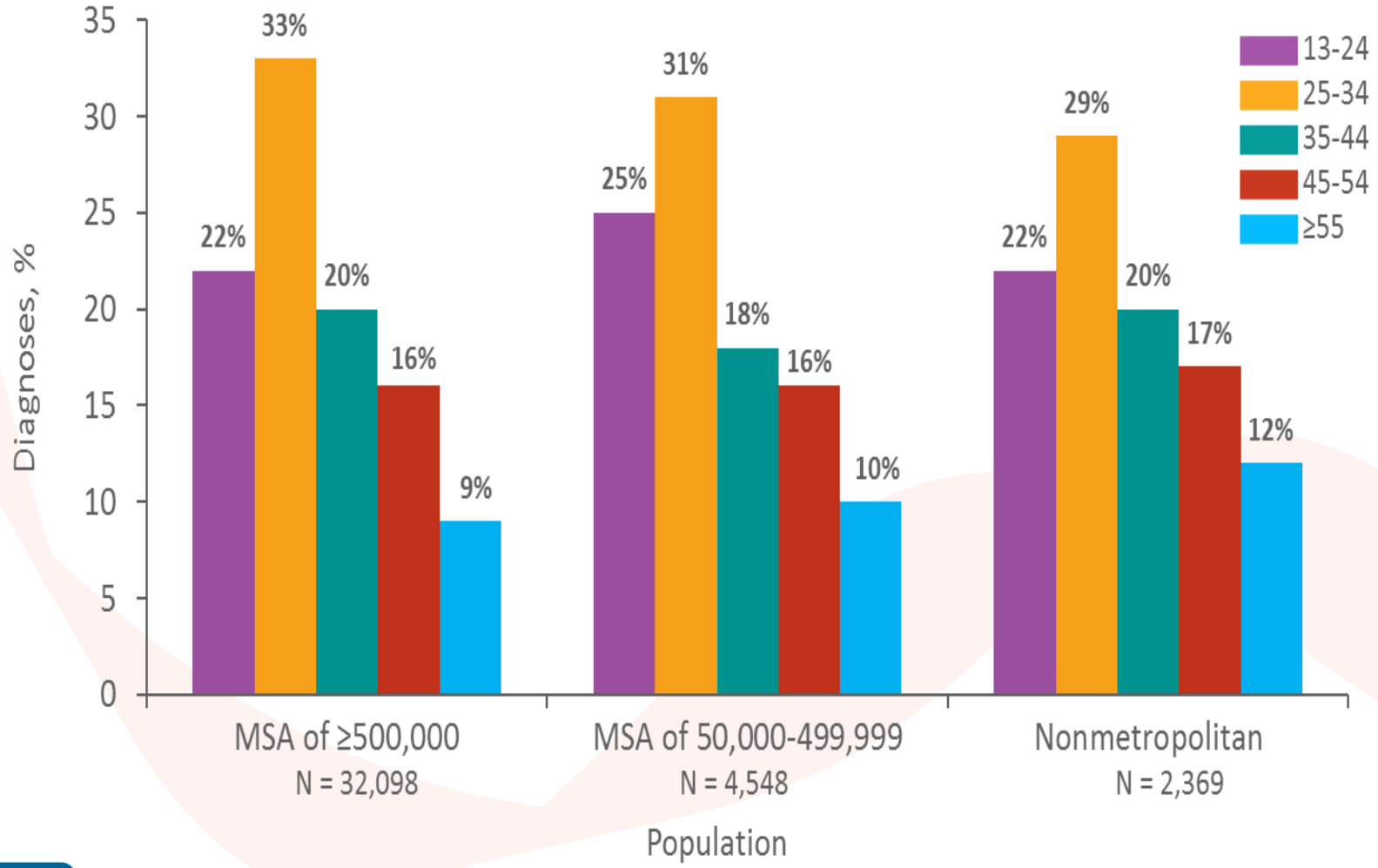

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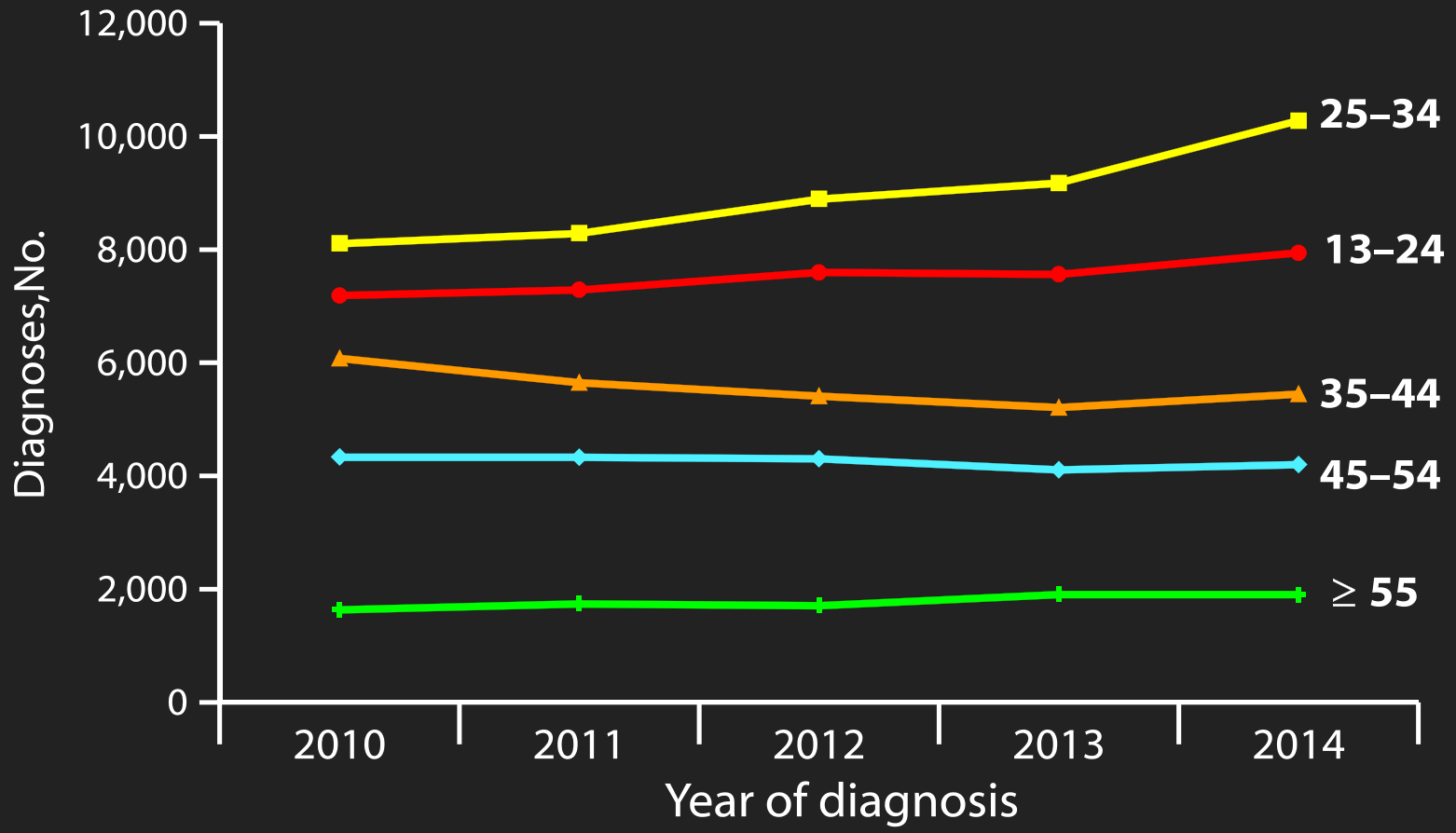
Diagnoses of HIV Infection among Men Who Have Sex with Men, by Age Group, 2010–2014—United States and 6 Dependent Areas



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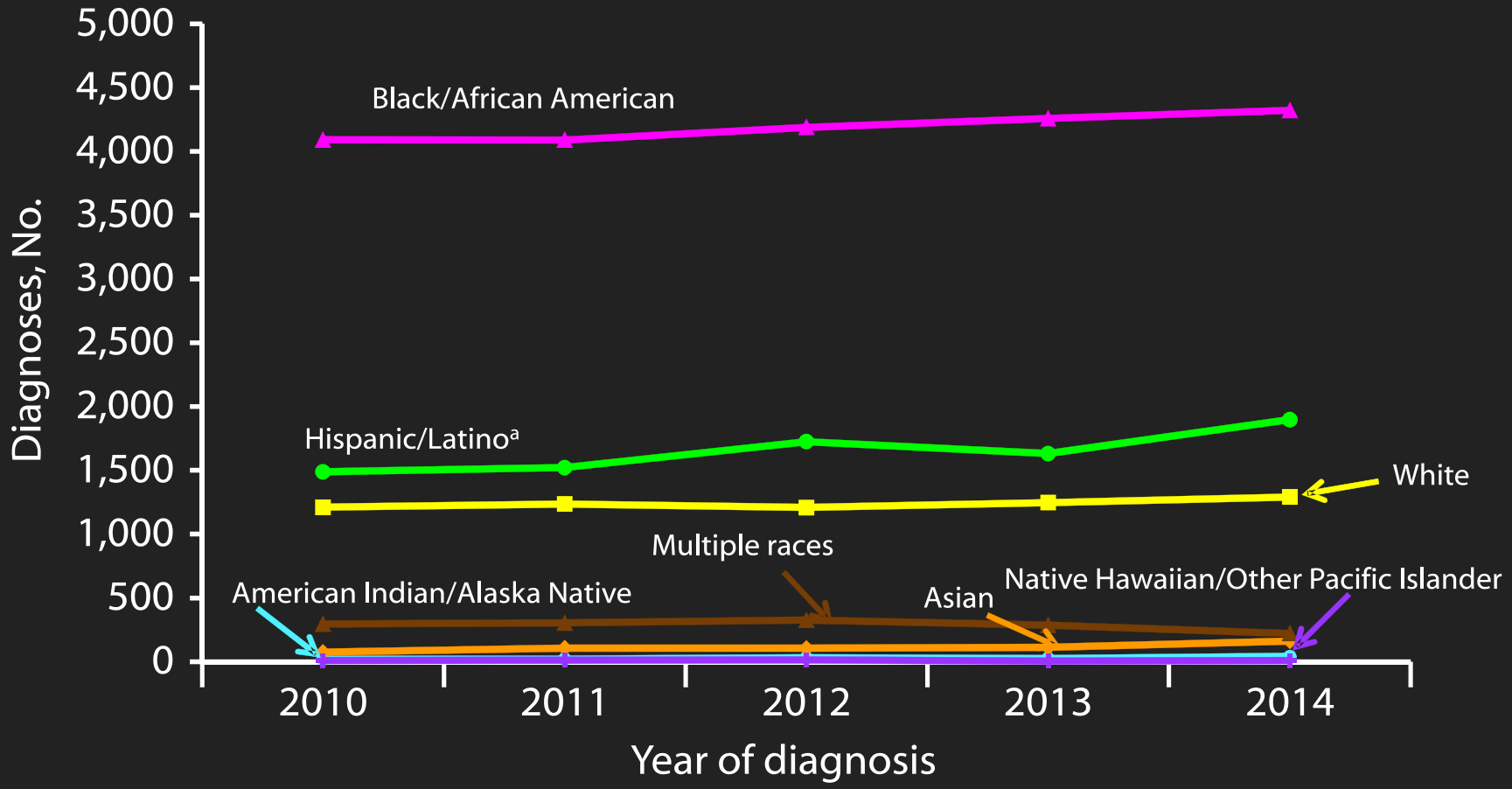
Diagnoses of HIV Infection among Men Who Have Sex with Men Aged 13–24 Years, by Race/Ethnicity, 2010–2014 United States and 6 Dependent Areas



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[a] Hispanics/Latinos can be of any race.

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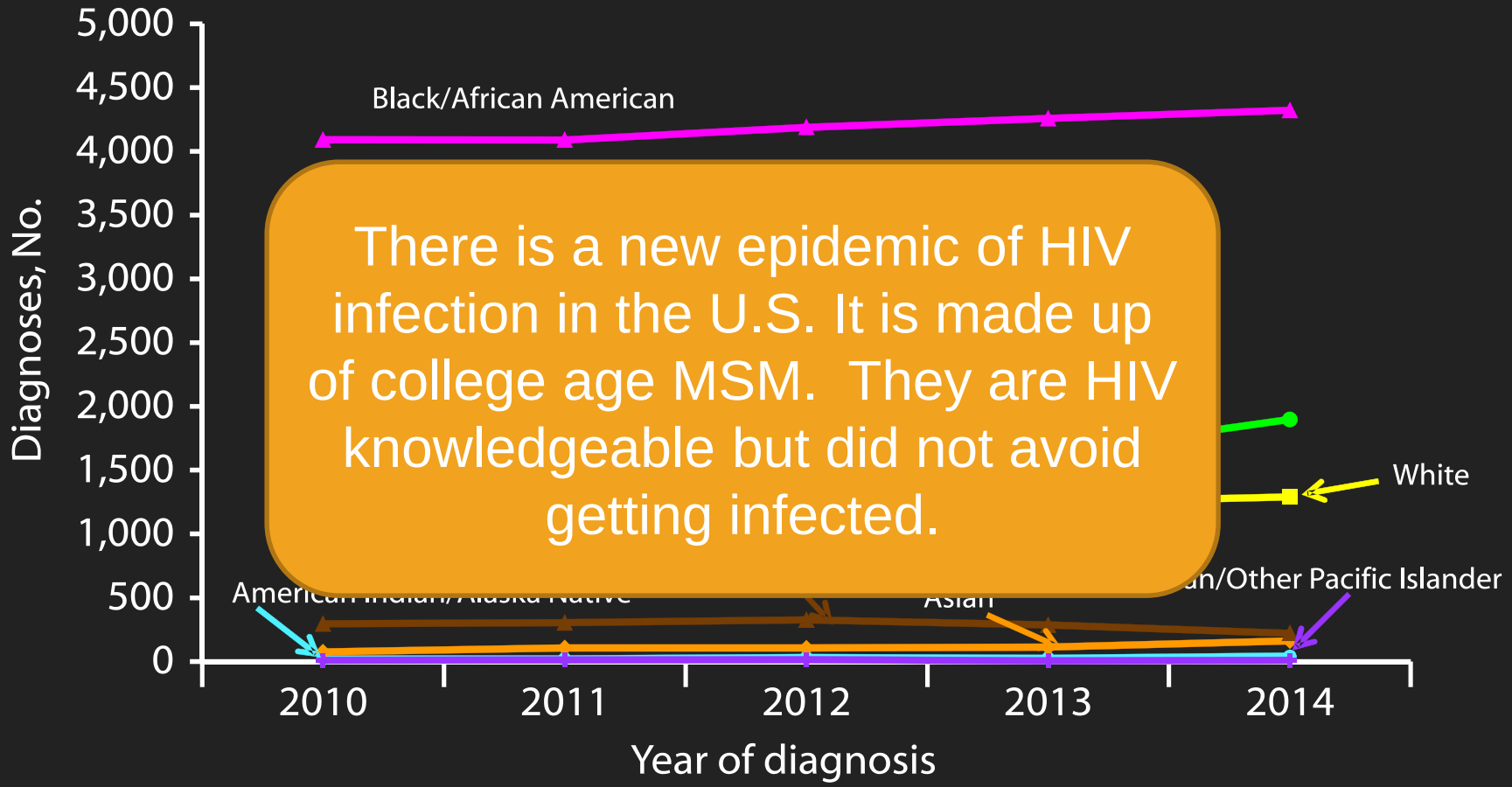

There is a new epidemic of HIV infection in the U.S. It is made up of college age MSM. They are HIV knowledgeable but did not avoid getting infected.

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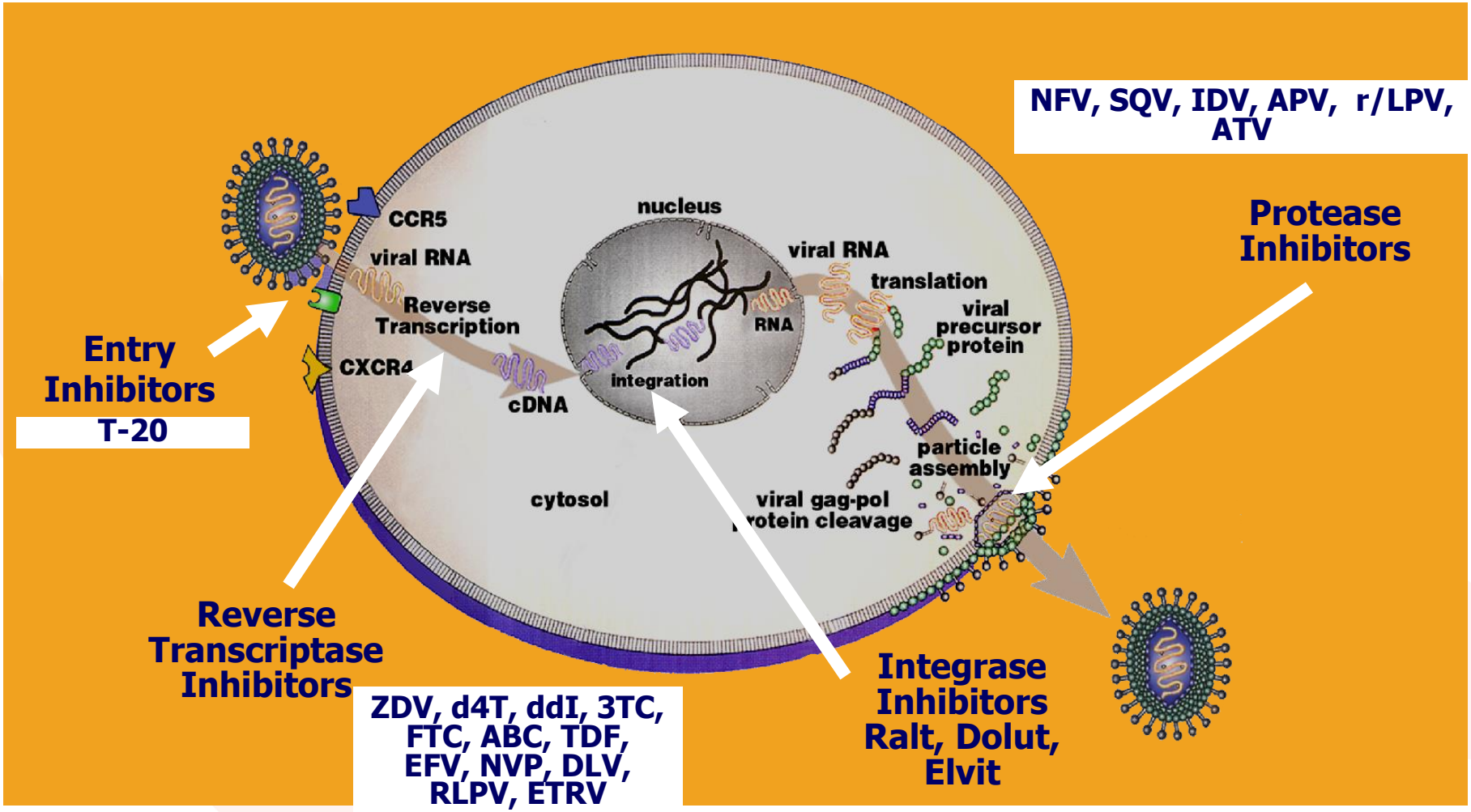
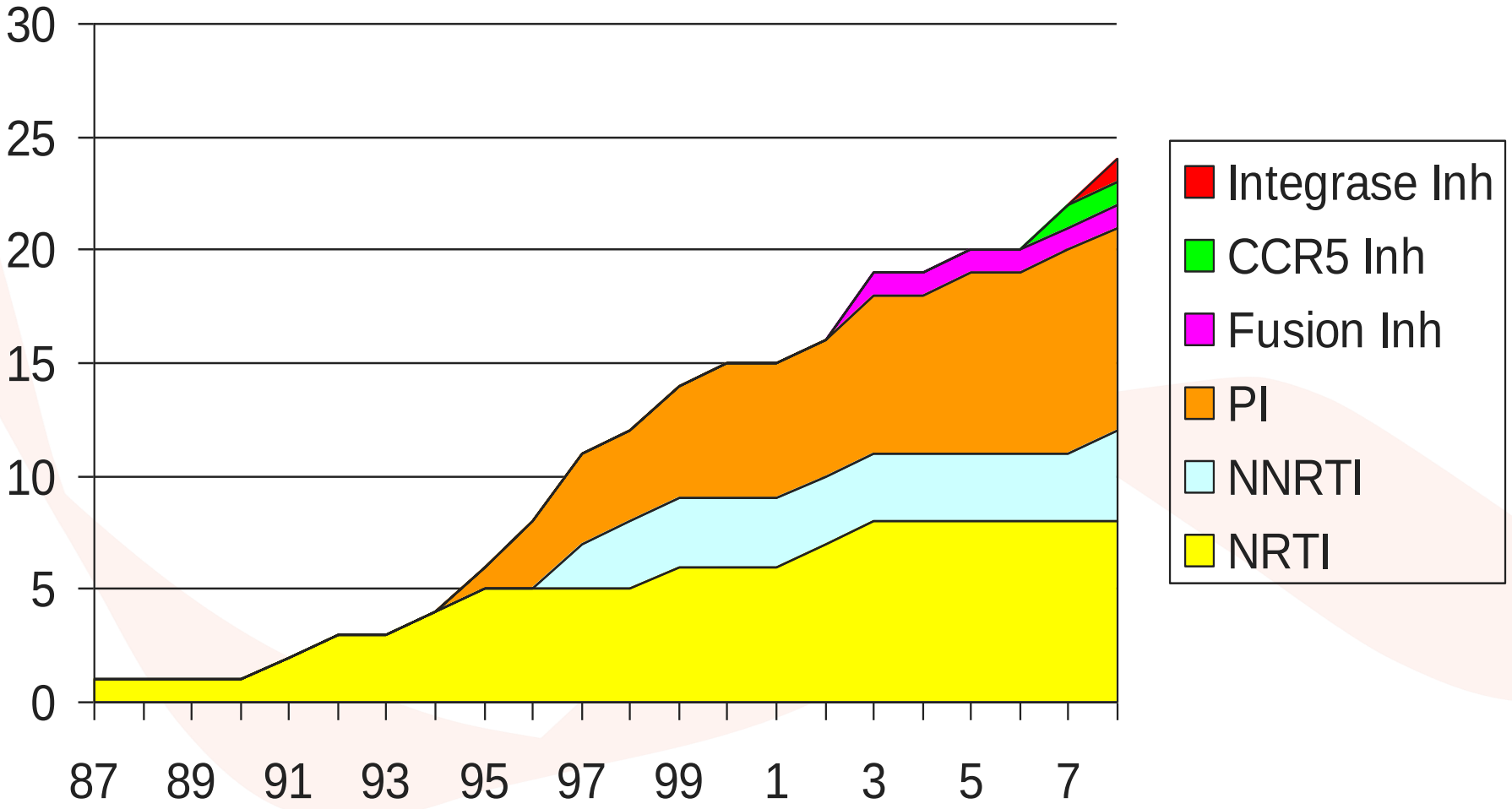
Targets for HIV Inhibition



22 current drugs, More in development

HIV Drug Approval



Current Available Medications

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

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

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- Treatin **may** delay p ne functio
- Treatin endent of immune function preservation.

Why Treat all patients?

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

A word about antiretrovirals…

- They are all experimental regardless of FDA approval.
- All have the potential to cause side effects.
- All possible drug-drug interactions have not been figured out.
- The impact of these medications on aging long term survivors of HIV is not known.

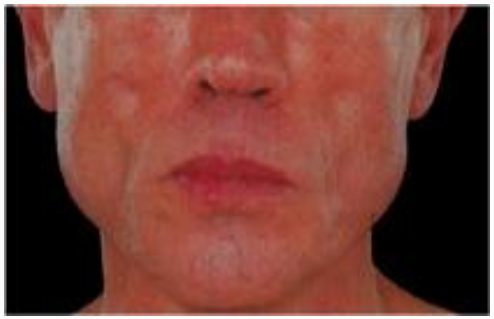
Risks of Treatment

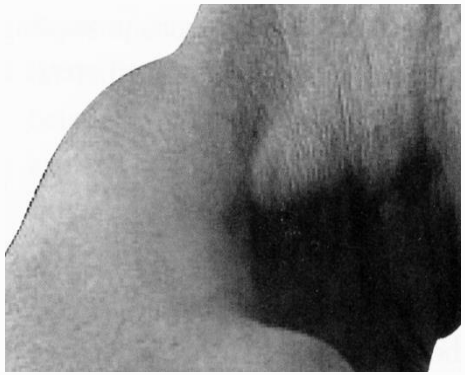
- Treatment with antiretrovirals carries with it the risk of short-term and long-term side effects.
- Some long term side effects may be irreversible.
- The longer a patient is treated, the greater the risk of side effects.
- Treatment promotes resistance.

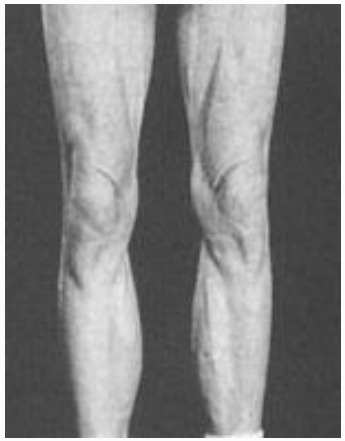
Risks of Treatment: Drug Toxicities/Tolerability

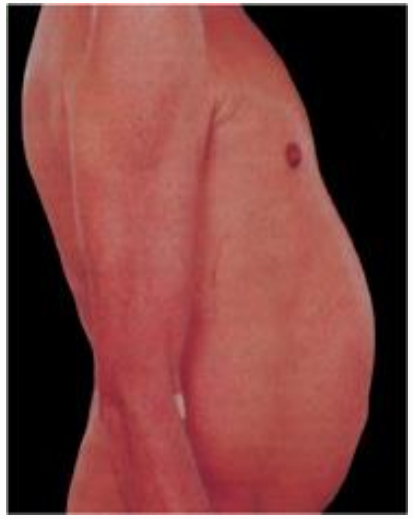
- Long-term toxicities: Now the major cause of treatment discontinuation and may have overlapping syndromes and pathways.
- Short-term toxicities are predictable, well known and relatively easy to manage.
- Risks of long term effects (cardiovascular, renal, etc.) can trigger regimen changes.

Physical Manifestations of HIV-Associated LD









New England Journal of Medicine (1998:339;1296);

International Journal of STD and AIDS (1198;9:596).

Body changes are not all there is to worry about…….

- Cardiovascular; increased with HIV (inflammatory issues), with PI exposure, increased dyslipidemias, increased CV risk factors, increased hypertension.
- Metabolic: increased insulin resistance, increased diabetes, increased fat redistribution, increased hepatosteatosis;
- Neurologic: increased neuropathy, increased cognitive disorders.
- Neoplasia: AIDS related malignancies, increased solid tumors except for receptor based tumors.
- Increased fragility and early aging.

Risks of Treatment: Resistance and "second generation" agents

- Resistance is measured by drug exposure, genotype and/or phenotype.
- Resistance is fairly well understood for older agents and some resistance crosses over to other agents.
- Second generation agents have been designed for people with HIV strains that have developed recognized resistance patterns.

Risks of Treatment: Drug Interactions

- All PI's and NNRTI's are metabolized by the P450 cytochrome system; each drug can be an inhibitor, inducer and a substrate.
- Ritonavir (and cobicistat) avidly bind the CYP34A enzyme causing extremely high levels of competing compounds.
- Important medications to remember include Versed®, statin drugs, cafergot, Rhythmol®, Viagra and rifampin.
- Drug-interactions are exploited to improve pK and dosing parameters of certain antiretrovirals.

Adherence in HIV

- Non-adherence leads to resistance and treatment failure.
- Non-adherence is extremely common and minimal missed doses can have serious consequences.
- Adherence is difficult to predict and measure.
- Some regimens may offer a better chance of adherence than others.

Adherence: A Case Study

- 51 year old male on a 5 pill regimen for 8 months. Dispensing log reveals late pick-up equivalent to 85% adherence. He denies any perceived toxicities.
- What factors might be involved to explain his non-adherence?
  - Educational level?
  - Insurance status?
  - Substance abuse?
  - Mental Illness?
  - Trust in provider?

Putting It All together

- How can all these factors be taken into account when designing a regimen?
  - Patient factors: concurrent diagnoses, tolerances, adherence, insurance status;
  - Viral factors: phenotype of current dominant strain, archived strains, viral fitness;
  - Medication factors: dosing, drug interactions, short and long term toxicities.

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 9,000 patients enrolled at 4 sites (3200 active);
  - Age range 16-81 years;
  - 24% female;
  - 38% African American;
  - 50% substance abuse;
  - 40% mental health;

VCCC Services

- Clinical and Laboratory Evaluation (Primary Care, Colposcopy, Obstetrics and HIV)
- High Resolution Anoscopy
- 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
- PreP Clinic
- Inpatient Care Direction
- On-call Services

VCCC Operations and Staff

- Over 9,000 patients enrolled
- Over 3,200 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

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.
- Research initiatives
  - Clinical trials (ACTG), epi-outcomes, repository, Vanderbilt BioVU

VCCC Outcomes

- 86% of patients seen at the VCCC in 2014 achieved undetectable virus
- 419 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 2014
- Joint Commission certified Primary Care Medical Home

How do we put it all together for the patient?

Comprehensive Care Center ART Conference

- All patients either starting, stopping or changing antiretroviral therapy;
- Presentation includes past regimens with labs, tolerances, genotypes, phenotypes;
- All co-morbidities included;
- Patient preferences included;
- Wide participation of clinical staff.

ART Conference Questions

- If the patient is naïve should HAART be initiated?
- If the patient is experienced is she failing therapy?
- Is the patient being presented to change a virologically successful regimen with toxicities?
- What are the goals of treatment?
- What other information is important before designing an effective regimen?
- What is the greatest obstacle to success?
- What should be done and in what order?

chart # 309 DOB # 51516

ART CASE CONFERENCE PATIENT SUMMARY

Patient Name: _____ **Date of Birth:** 11/23/58 **Provider:** Steve

Concurrent Diagnoses: Social Situation: Substance Abuse _____ Other _____
Hepatitis B/ Hepatitis C/ Esophageal Problems/ Colonic Problems/ CAD/ Hypertension/ Lipid Disorder/
CMV/ MAC/ TB/ Histoplasmosis/ Cryptococcosis/ KS/ Lymphoma/ PML/ Neuropathy/ Other: CHF '94
'94 pancreatitis, Diabetes, cute bacteremia

Presentation Date: 1-19-01
Recommendations: 3TC, ABC, NNRTI, LPV or T-20 ?
Influenced by: Exposures Y / N Intolerance Y / N Compliance Y / N Concurrent Dz. Y / N
Present: Clough, Haas, Mangialardi, McGowan, Raffanti
3TC ZIAJ SUSTIVA KALEIDA - called us 2/20/01

Presentation Date: _____
Recommendations:
Influenced by: Exposures Y / N Intolerance Y / N Compliance Y / N Concurrent Dz. Y / N
Present: Clough, Haas, Mangialardi, McGowan, Raffanti

Presentation Date: _____
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PCP '95
CMV '97
pancreatitis '96
CAD/CABG '01
Diabetes '94
TUPIDS '94
HTN '94

AZT anemia

AZT exposure prior to '94

Meds: ddI		
Start 4/94	Stop 9/94	
Date	CD4	Viral Load
NO meds		
10/95	2/1	
11/95	0/<1%	
3/96	5/1	
Comments: Stopped when CMV diagnosed		Genotype Y/N

Meds: AZT + 3TC		
Start 6/96	Stop 7/96	
Date	CD4	Viral Load
6/96	12/1	
Comments: D/cd 2° pancreatitis		Genotype Y/N

Meds: AZT + ddC		
Start 10/96	Stop 12/96	
Date	CD4	Viral Load
8/96		1,999,870
11/96		680,110
Comments: Admitted for AZT + Bactrim Related Anemia		Genotype Y/N

Meds: ddC + 3TC + Crixivan		
Start 1/97	Stop 6/97	
Date	CD4	Viral Load
1/97		370,100
2/97		334,267
3/97		21438
4/97	90/5	91224
5/97		39946
7/97		750,000
Comments: Recurrent pancreatitis		Genotype Y/N

Meds: D4T + 3TC + Viracept

Start 8/97 Stop 11/2000

Date	CD4	Viral Load
8/97		22435
10/97	510/17	286500
1/98	504/18	128,752
3/98	513/19	211,316
7/98	558/18	84276
10/98	486/27	141,480
12/98	525/25	112 028
1/99	567/27	33,972
4/99	560/28	105 360
6/99	648/27	170 481

Comments: Myalgias, Lactic Acid = 17 Genotype Y/N

Meds:

Start Stop

Date	CD4	Viral Load
8/99	570/30	181065
9/99	644/28	22807
10/99	580/29	255567
12/99	572/26	51615
4/00	360/30	23939
6/00	[illegible]	43466
8/00	484/22	53 847
10/00	275/25	40 949
11/00	385/35	122 778

Comments: Genotype Y/N

Meds: LPV/r + Efavirenz + ABAC + 3TC

Start 2/20/01 Stop

Date	CD4	Viral Load
3/01	429/33	1007
5/01	646/29	1842
8/01	720/30	815
11/01	680/34	<400
2/02	858/26	<400
12/03	486/27	61
3/03	728/28	227
6/03	672/24	213
9/03	756/28	1637
2/04	837/27	<50

Comments:

Meds: LPV/r + Efav + ABAC + 3TC

Start Stop

Date	CD4	Viral Load
12/04	713/31	232
8/05	848/27	<50
2/06	653/32	<50
9/06	917/28	<50
1/07	813/29	<50
4/07	909/30	
8/07	884/24	<48
11/07	984/23	<48
3/08	1175/25	<48
7/08	1078/28	<48

Comments: Need better lipid control Genotype Y/N

4/07
Chol 259
Trig 869
on Pravachol
Tricor
Omega 3
Niaspan

Meds:

Start Stop

Date	CD4	Viral Load

Comments: Genotype Y/N

Meds:

Start Stop

Date	CD4	Viral Load

Comments: Genotype Y/N

ART Recommendations

- Current virologically successful regimen:
  - Lopinavir/Ritonavir 2 tabs BID;
  - Efavirenz : 1 pill at night;
  - Abacavir/lamivudine: 1 pill a day
    - Total pill burden: 6 pills a day
- New recommendations:
  - Darunavir : 2 tabs BID
  - Ritonavir: 1 pill BID;
  - Etravirine : 2 pills BID;
  - Raltegravir: 1 pill BID;
    - Total pill burden: 10 pills a day

New HIV Treatment Regimens

- Most new patients coming into care for treatment of HIV infection are started on simple medication regimens:
  - **Triumeq** (lamivudine/dolutegravir/abacavir)
  - **Genvoya** (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide)
  - **Odefsey** (rilpivirine/emtricitabine/tenofovir alafenamide)
  - **Descovy** (tenofovir alafenamide) + Tivicay (dolutegravir)
- These regimens are well tolerated and extremely potent.
- Medications do not stop working unless the patient does not take them as prescribed.
- Data indicates that early treatment of HIV greatly reduces the impact of HIV infection on overall survival.

Special Programs

- Clinical Pharmacy Services
  - Started in 2009: 2 advanced practice RN's, pharmacist;
- Obstetrics Comprehensive Care Center
  - Started in 1999 by Bev Byram FNP: MFM MD, HIV FNP, 2 Case mgrs, 1 RN, 1 dietitian, mental health therapist
- High Resolution Anoscopy Clinic
  - Started in 2016 by Amen Eguakun FNP: training and protocols developed. Operations began in January 2017.
- Pathways Clinic
  - Started by Rob Nash Ph.D., ACNP in 2016. 3 RN case managers, psychiatric NP.
- PreP Clinic
  - Providing PreP and primary care to affected individuals

MAJOR ARTICLE

Pregnancy and HIV Disease Progression during the Era of Highly Active Antiretroviral Therapy

Jennifer H. Tai,[3,a] Mercy A. Udoji,[3,a] Gema Barkanic,[1] Daniel W. Byrne,[4] Peter F. Rebeiro,[1] Beverly R. Byram,[5] Asghar Kheshti,[5] Justine D. Carter,[1] Cornelia R. Graves,[2] Stephen P. Raffanti,[1,5] and Timothy R. Sterling[1,3]

[1]Division of Infectious Diseases, Department of Medicine, and [2]Department of Obstetrics and Gynecology, [3]Center for Health Sciences Research, and [4]Department of Biostatistics, [5]Vanderbilt University School of Medicine, and [6]Comprehensive Care Center, Nashville, Tennessee

(See the editorial commentary by Anastos, on pages 971–3.)

Background. Before the availability of highly active antiretroviral therapy (HAART), there was no clear effect of pregnancy on human immunodeficiency virus (HIV) disease progression. This has not been assessed during the HAART era.

Methods. We conducted an observational cohort study among HIV-infected women with ≥1 outpatient clinic visit between January 1997 and December 2004. HIV disease progression was defined as the occurrence of an AIDS-defining event or death.

Results. Of 759 women who met the inclusion criteria, 139 (18%) had had >1 pregnancy, and 540 (71%) had received HAART. There was no difference in HAART duration by pregnancy status. Eleven pregnant (8%) and 149 nonpregnant (24%) women progressed to AIDS or death. After controlling for age, baseline $CD4^+$ lymphocyte count, baseline HIV-1 RNA level, and durable virologic suppression in a Cox proportional hazards model that included propensity score for pregnancy, pregnancy was associated with a decreased risk of disease progression (hazard ratio [HR], 0.40 [95% confidence interval {CI}, 0.20–0.79]; $P = .009$]). In a matched-pair analysis of 81 pregnant women matched to 81 nonpregnant women according to age, baseline $CD4^+$ lymphocyte count, receipt of HAART, and date of cohort entry, pregnant women had a lower risk of disease progression both before (HR, 0.10 [95% CI, 0.01–0.89]; $P = .04$) and after (HR, 0.44 [95% CI, 0.19–1.00]; $P = .05$) the pregnancy event.

Conclusion. Pregnancy was associated with a lower risk of HIV disease progression in this HAART-era study. This finding could be the result of the healthier immune status of women who become pregnant or could possibly be related to a beneficial interaction between pregnancy and HAART.

Studies conducted before the availability of highly active antiretroviral therapy (HAART) showed that pregnancy either slightly increased the risk of HIV disease progression or had no effect. Early studies noted a possible association between pregnancy and accelerated disease progression [1–3]. Observational studies conducted in developing countries found that pregnancy was an independent predictor of increased HIV disease progression [4, 5]. Several studies conducted in the United States and Europe, however, did not demonstrate an increased risk of HIV disease progression in pregnant women [6–11]. All of the above studies were conducted in patient populations that received either no antiretroviral therapy (ART) or a single nucleoside reverse-transcriptase inhibitor, in accordance with treatment availability at that time. In a primarily pre–HAART-era study of HIV-infected women in the United States with 1 versus 2 pregnancies, there was little difference in $CD4^+$ lymphocyte counts, HIV-1 RNA levels, and time to class C events, but women with 2 pregnancies had a small survival advantage [12].

HAART provides greater virologic suppression and

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* J.H.T. and M.A.U. contributed equally to this study.

Reprints or correspondence: Dr. Timothy R. Sterling, 1161 21st Ave. South, A-2209 Medical Center North, Nashville, TN (timothy.sterling@vanderbilt.edu).

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Future Challenges

- The college age dilemma;
- Global Healthcare Disparity;
- Increasingly dysfunctional healthcare system:
  - Medicare “Donut Hole”;
  - Pay Up Front Policies
  - Increasingly high co-pays
  - Formulary pressures
  - Uncertain future
  - Complacency

HIV Medicine 2017

- HIV infection is a treatable, chronic illness;
- The US healthcare system is dysfunctional and consumes a considerable amount of resources that could be spent on patient care.
- All people with HIV should be treated;
- Significant advances in technology and our understanding of pathogenesis have translated into effective, life-long treatment;
- Treatment still carries with it a significant burden;
- Holistic, expert care in a “medical home” provides the best outcomes;
- We are seriously discussing “cure” strategies.
- PREP is standard of care.

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

Useful HIV Websites

www.vanderbilthealth.com/vccc
www.aidsinfonet.org
www.aidsetc.org
www.hivatis.org (DHHS, USPHS/IDSA Guidelines)
www.cdc.gov/nchstp/hiv_aids.htm
www.hiv-web.lanl.gov (Resistance mutations)
www.niaid.nih.gov
www.AIDS.medscape.com
www.hopkins-aids.edu
www.iapac.org
www.igm.gov
www.centerwatch.com
www.ucsf.edu/medical
www.virology.net