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Overview

- Patient case study
- Epidemiology of HIV in the United States
- Current examples of sustainable HIV screening initiatives
- CDC opt-out HIV testing objectives and recommendations
- Awareness of HIV status and HIV transmission
- Data supporting HIV testing at various venues
- Recent legislative changes supporting HIV testing

Case Study: Patient Background and History

- Nancy is a 57-year-old African-American female
- Married for 29 years, has 3 children
- Works as a fifth-grade teacher in an urban public school
- Both she and her husband are active members of their community and local church
- BMI 32, TC 260, BP 145/90
- Nonsmoker, no known history of IV drug use, occasional alcohol consumption
- Diagnosed with diabetes in 2001
- Sees PCP and OB/GYN regularly, sees dentist annually, and specialists as needed
  - Husband sees the same PCP

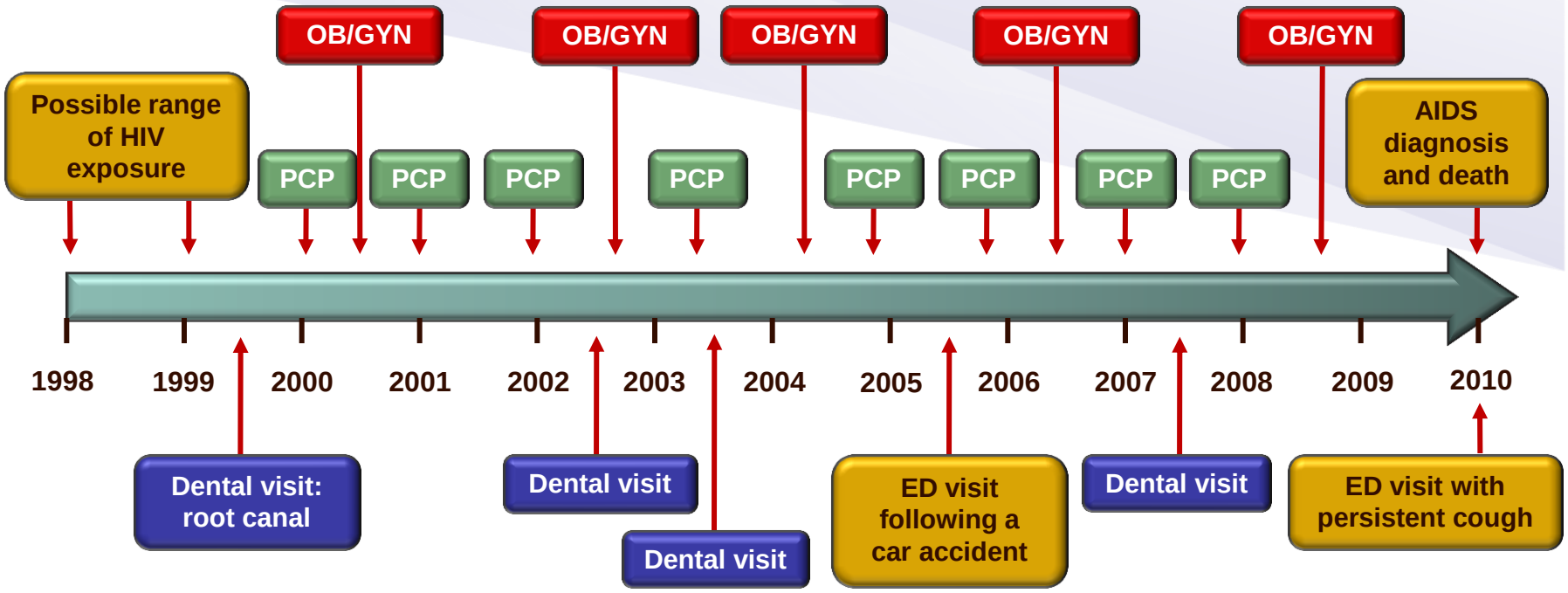
Case study for discussion purposes only.

Case Study (cont)

- Nancy comes into the ED on a Friday afternoon of a 3-day weekend because her PCP office is closed
  - She complains of severe, persistent cough accompanied by brown sputum, and difficulty breathing
  - A viral respiratory infection is suspected
  - She is kept overnight for observation
  - She is tested for HIV and respiratory infections on Saturday morning
  - Rapid HIV is positive, blood drawn for VL and CD4 counts
  - Condition continues to decline and Nancy expires Tuesday morning
  - Lab results post-mortem are:
    - 21 cells/mm^3 CD4
    - VL of 240,000 copies/mL
  - Husband also tested and found to be HIV+

Case study for discussion purposes only.

Nancy's Medical and Social History, 1998-2010: Other Opportunities for HIV Testing



Nancy attended church regularly on Sundays

Nancy volunteered at local community fairs

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Provider Barriers to HIV Testing: Prenatal, EDs, and Other Medical Settings

- Insufficient time
- Consent process
- Lack of knowledge/training
- Language
- Lack of patient acceptance
- Pretest counseling requirements
- Competing priorities
- Inadequate reimbursement

Estimated Rates for Adults and Adolescents Living With HIV Infection (Not AIDS)

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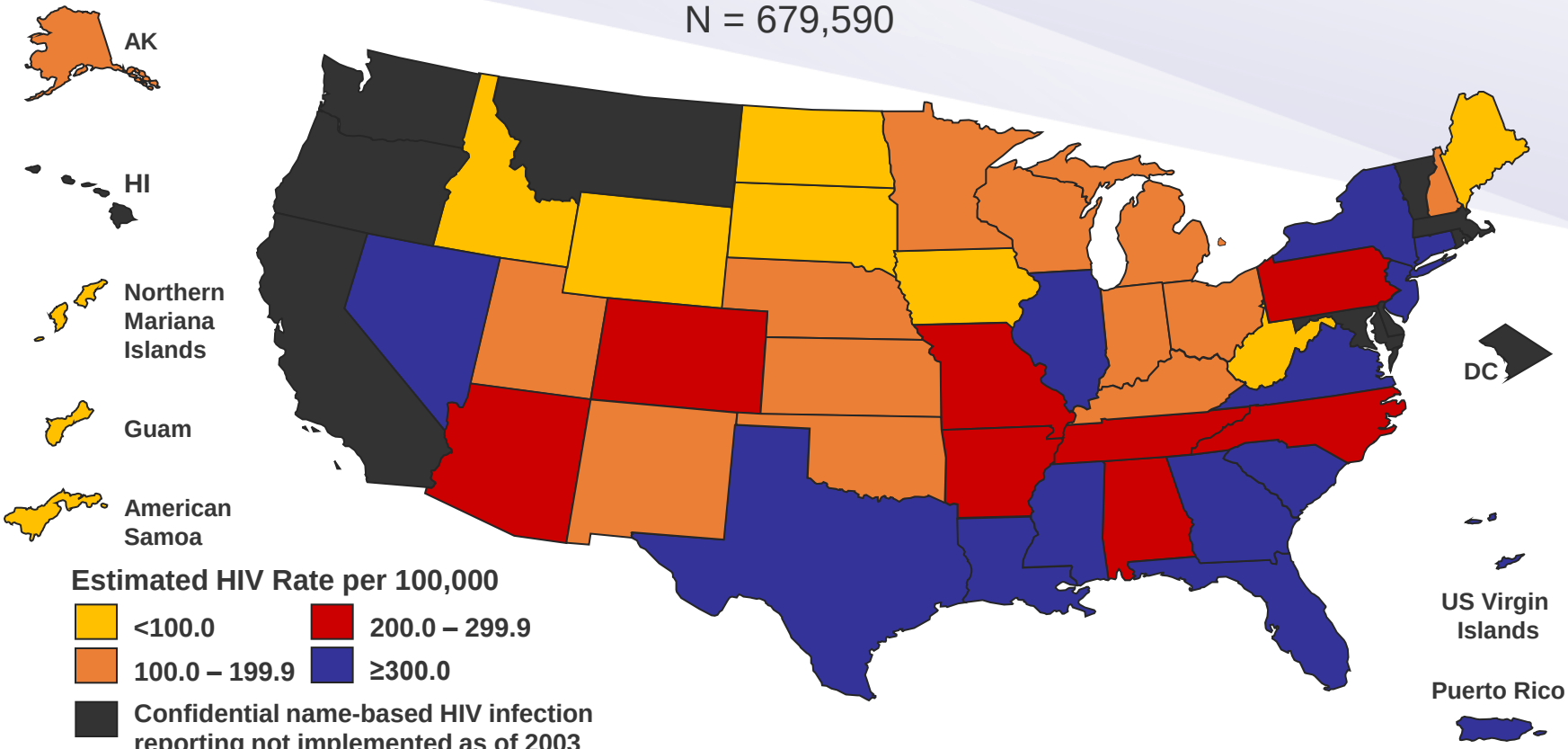
40 States and 5 US Dependent Areas, Year-end 2008

N = 679,590



Note: Rates have been adjusted for reporting delays. Inset maps not to scale.

Adapted from CDC. *HIV Surveillance Report.* 2011;21:Table 21.

Note: Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. Includes data from areas with confidential name-based HIV infection reporting since at least January 2006.

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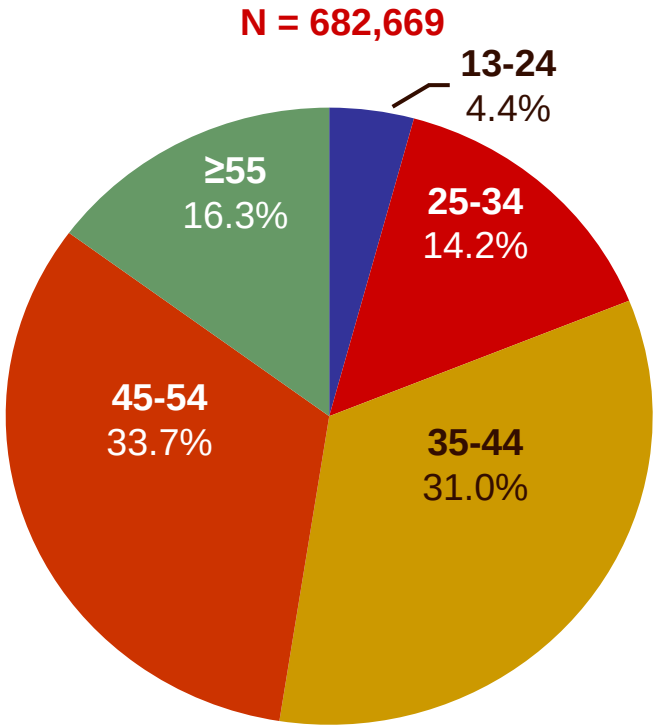
Estimated HIV Prevalence by Gender and Age in the United States (Through End of 2008, 40 States and 5 US Dependent Areas)

- Through end of 2008
  - 73% of all adults and adolescents living with a diagnosis of HIV infection were male and 27% were female

Estimated Persons Living With a Diagnosis of HIV Infection by Age



Adapted from CDC. *HIV Surveillance Report.* 2011;21:Table 15b.

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Distribution and Rates of Diagnoses of HIV Infection in Adults and Adolescents, by Race/Ethnicity and Sex (United States, 2009)

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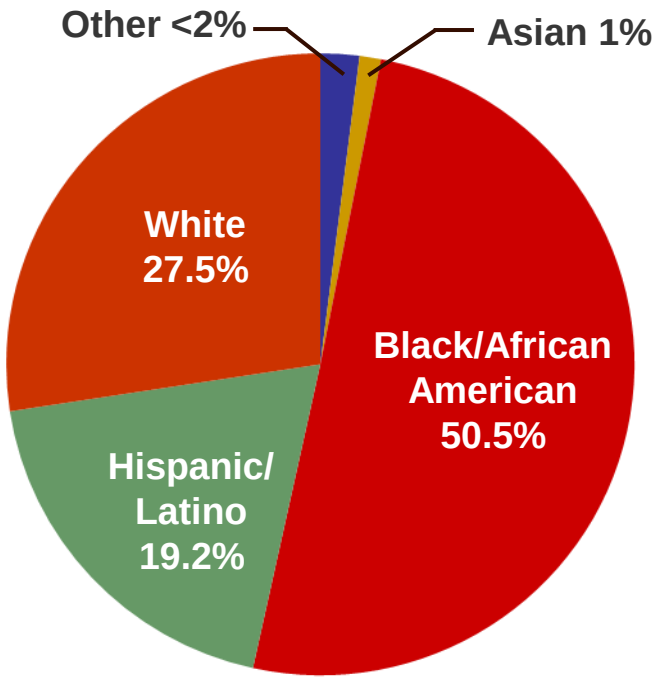
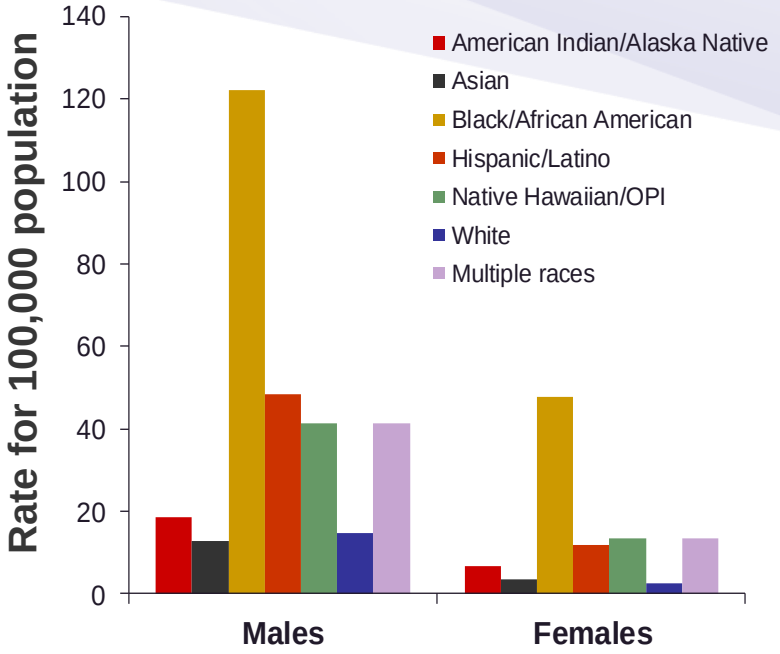
Estimated Distribution of Diagnoses of HIV Infection by Race/Ethnicity (2009)[1,a,b]

N = 42,959



Estimated Rates of Diagnoses of HIV Infection in Adults and Adolescents by Sex and Race/Ethnicity (2009)[2,b,c]

N = 42,011



[a] 40 states and 5 US dependent areas with confidential name-based HIV infection reporting.
[b] Estimated rates resulted from statistical adjustment that accounted for reporting delays, but not for incomplete reporting.
[c] 40 states with confidential name-based HIV infection reporting.
Hispanics/Latinos can be of any race.
Abbreviation: OPI, Other Pacific Islander.

[1]Adapted from CDC. *HIV Surveillance Report.* 2011;20:Table 1b. [2]CDC. *HIV Surveillance Report.* 2009;20:Table 3a.

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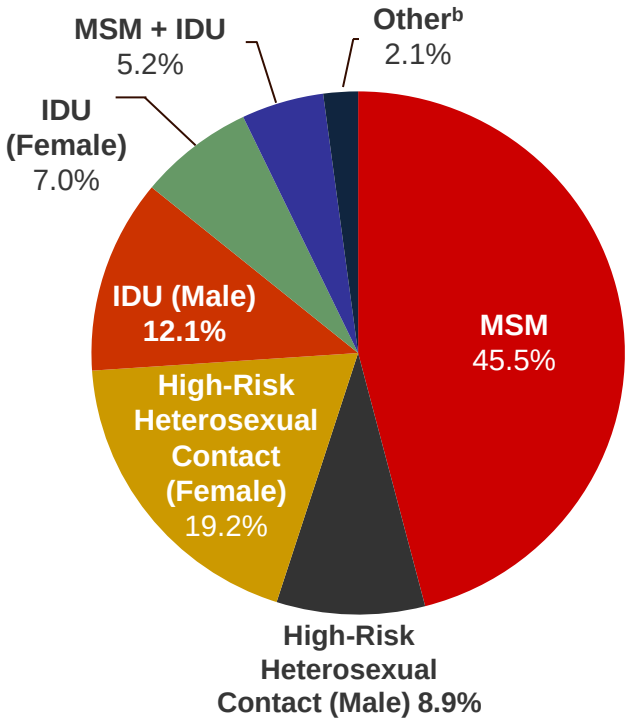
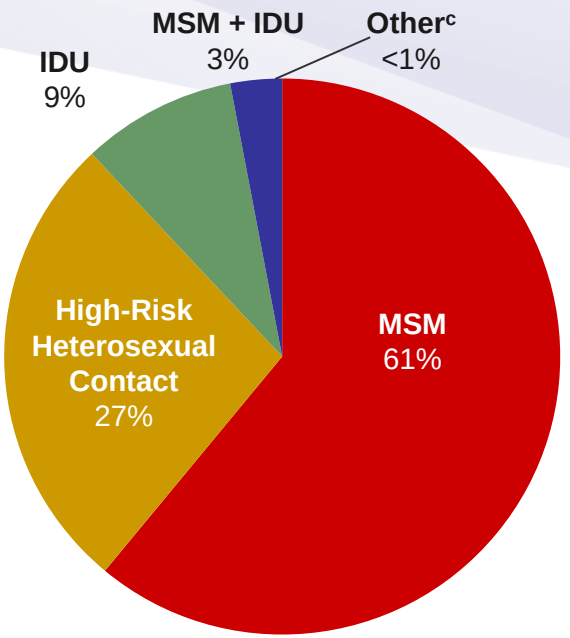
Estimated HIV/AIDS Prevalence and New Infections by Transmission Category in the United States

Estimated Prevalence of HIV/AIDS (Through End of 2008)[1,a]
N = 682,668



Estimated Incidence of New HIV Infections in 2009[2,b]
N = 48,100



[a] 40 states and 5 US dependent areas with confidential name-based HIV infection reporting.
[b] 50 states and the District of Columbia; 2009. Estimation based on incidence surveillance data from 16 states and 2 cities using the serologic testing algorithm for recent HIV seroconversion (STARHS).
[c] Includes hemophilia, blood transfusion, perinatal exposure, and risk factors not reported or not identified.

[1]Adapted from CDC. *HIV Surveillance Report.* 2011;21:Table 15b.
[2]Adapted from Prejean J et al. *Plos ONE*. 2011;6(8):e17502.

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Awareness of HIV Status in the United States

HIV estimated prevalence (2006)[1]	1,106,400 (95% CI 1,056,400-1,156,400)
Estimated undiagnosed (as of 2006)[1]	232,700
Estimated new annual infections (2006)[2]	56,300 (95% CI 48,200-64,500)

- From 2006 to 2009, the estimated number and rate of newly diagnosed HIV infection cases in the 40 states with confidential name-based HIV infection reporting remained stable[3]

[1]CDC. *MMWR.* 2008;57(39):1073-1076. [2]Hall HI et al. *JAMA*. 2008;300(5):520-529.
[3]CDC. *HIV surveillance report.* 2011;6.

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Where Do People Get Tested?

Site	All HIV Tests Performed (%)	Tests That Are Positive for HIV (%)
Private doctor/HMO	44	17
Hospital, ED, outpatient	22	27
Community clinic (public)	9	21
HIV counseling/testing	5	9
Correctional facility	0.6	5
STD clinic	0.1	6
Drug treatment facility	0.7	2

Janssen RS. *Topics HIV Med*. 2007;15(1):6-10.

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Examples of Sustainable HIV Screening Initiatives

- Routine testing programs with EDs

Yvette Calderon, MD
Jason Leider, MD
Jacobi Medical Center
Bronx, NY

Jeremy Brown, MD
George Washington University MFA
Washington, DC

Richard Rothman, MD, PhD
Johns Hopkins University
Baltimore, MD

- Routine testing programs in primary care settings

Ann Hinson
Christine Kerr, MD
Sophia McIntyre, MD
Nancy Dalessandro, RN (Women's Health)
Hudson River Health Care
Monticello, NY

Gebeyehu Teferi, MD
Unity Health Care
Washington, DC

Anish Mahajan, MD, MPH
University of California
Los Angeles, CA

Donna Futterman, MD
Albert Einstein College of Medicine
Bronx, NY

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Examples of Sustainable HIV Screening Initiatives (cont)

- Testing initiatives at dental offices

David Reznik, DDS
HIV Dental Alliance
Atlanta, GA

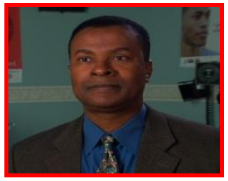
- Grassroots collaborations and faith-based initiatives

Jeannine Bookhardt-Murray, MD
Aisha Muhammad, MPH
Nelson Villegas
Harlem United
Bronx, NY

Derek Spencer, MS, CRNP
JACQUES Initiative
University of Maryland, School of Medicine
Baltimore, MD

Reverend Terrance Kennedy
New Hope for the World Ministries, Inc
New York, NY

Wayne A. Duffus, MD, PhD
S.C. Department of Health &
Environmental Control
Columbia, SC



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Other Examples of Sustainable HIV Screening Initiatives

- Additional examples of programs that may be considered and potentially supported include
  - Pharmacy-based testing initiatives
  - Training programs for healthcare providers
  - Correctional facilities (expanding testing services during incarceration/upon release)
  - Research/data evaluation in order to expand successful programs

National HIV/AIDS Strategy 2010

- Reducing new HIV infections
  - Intensify HIV prevention efforts in communities where HIV is most heavily concentrated
  - Expand targeted efforts to prevent HIV infection using a combination of effective, evidence-based approaches
  - Educate all Americans about the threat of HIV and how to prevent it

- Increasing access to care and improving health outcomes for people living with HIV
  - Establish a seamless system to immediately link people to continuous and coordinated quality care when they are diagnosed with HIV
  - Take deliberate steps to increase the number and diversity of available providers of clinical care and related services for people living with HIV
  - Support people living with HIV with co-occurring health conditions and those who have challenges meeting their basic needs, such as housing

Office of National AIDS Policy. *National HIV/AIDS Strategy for the United States, July 2010*. Available online at: http://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf. Accessed May 2, 2011.

National HIV/AIDS Strategy 2010 (cont)

- Reducing HIV-related health disparities
  - Reduce HIV-related mortality in communities at high risk for HIV infection
  - Adopt community-level approaches to reduce HIV infection in high-risk communities
  - Reduce stigma and discrimination against people living with HIV
- Achieving a more coordinated national response to the HIV epidemic in the United States
  - Increase the coordination of HIV programs across the federal government and between federal agencies and state, territorial, tribal, and local governments
  - Develop improved mechanisms to monitor and report on progress toward achieving national goals

Office of National AIDS Policy. *National HIV/AIDS Strategy for the United States, July 2010*. Available online at: http://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf. Accessed May 2, 2011.

2006 CDC Opt-Out HIV Screening Objectives

2006 CDC Opt-Out HIV Testing Objectives

Increase HIV screening of patients, including pregnant women, in healthcare settings
Foster earlier detection of HIV infection
Identify and counsel persons with unrecognized HIV infection and link them to clinical and prevention services
Further reduce perinatal transmission of HIV in the United States

- Opt-out screening
  - All patients are considered candidates for screening
  - Testing is part of standard panel of tests
  - All patients are offered the option to decline the test. The test is performed unless the patient specifically refuses

Branson BM et al; for the CDC. *MMWR*. 2006;55(RR-14):1-17.

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Selected 2006 CDC Opt-Out HIV Screening Guidelines

Testing Recommendations[a]

All patients aged 13 to 64 in all healthcare settings should be tested
Patients should be notified that testing will be performed, and can decline (“opt-out”)
Those at high risk should be tested at least annually
All patients at STD clinics should be screened routinely for HIV during each visit for a new complaint
Separate written consent should not be required; general consent for medical care is sufficient
Prevention counseling should not be required in HIV screening programs

[a]Recommendations for nonpregnant adults and adolescents.

Branson BM et al; for the CDC. *MMWR*. 2006;55(RR-14):1-17.

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Adults and Adolescents: CDC Recommendations for HIV-Screening Locations

- All primary care settings
- Emergency departments, in-patient services, and urgent care clinics
- Public health settings
  - Tuberculosis clinics
  - STD clinics
  - Substance abuse treatment centers
  - Correctional facility treatment centers

Branson BM et al; for the CDC. *MMWR*. 2006;55(RR-14):1-17.

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Why Offer Routine HIV Testing?

- Best possible patient care includes HIV testing
- Early detection and linkage to care result in better long-term outcomes
- Public health benefit: reduced HIV transmission
- Routine HIV testing reduces stigma and increases acceptance by patients and HCPs
- Awareness of HIV status results in changes in risk behavior

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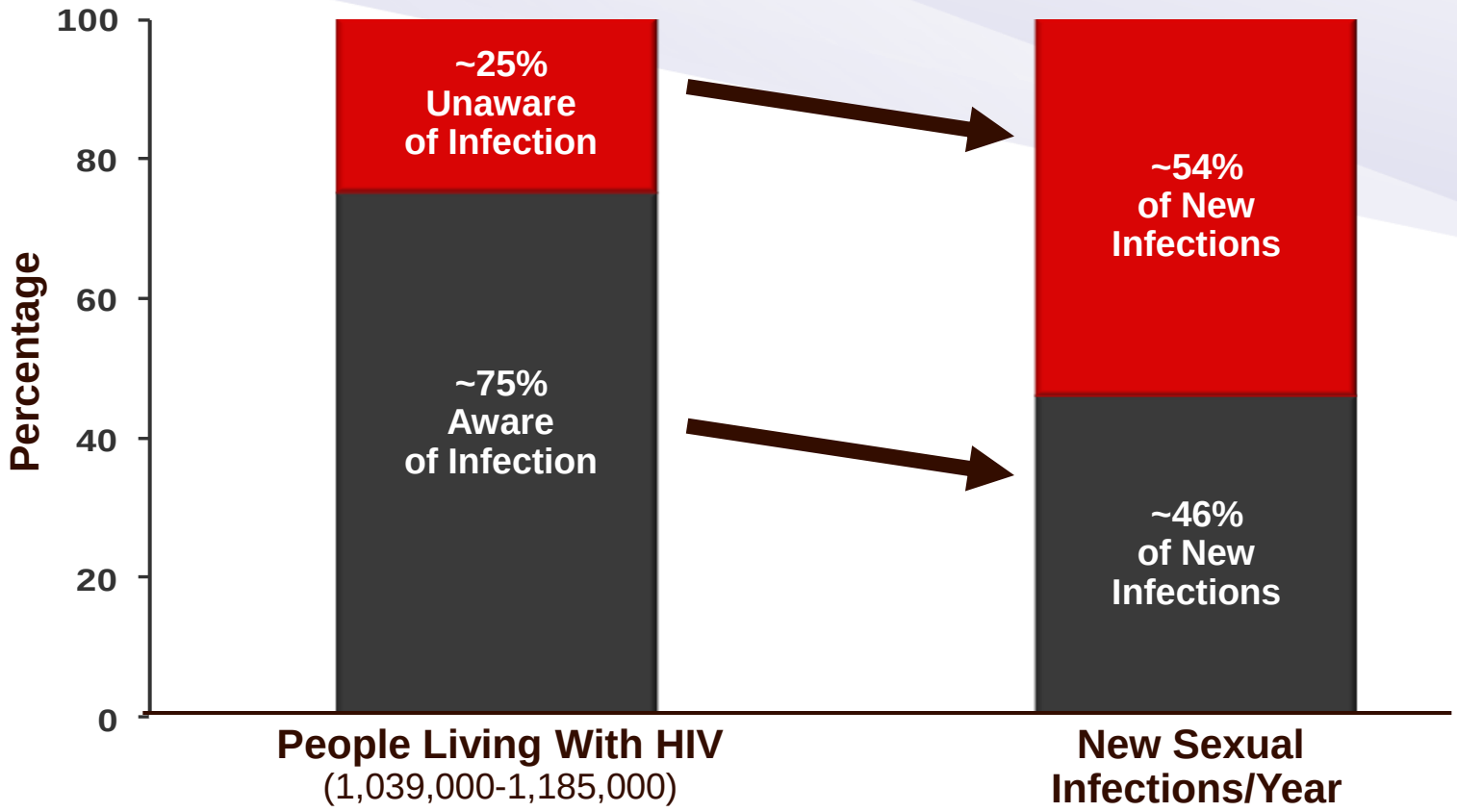
Awareness of HIV Serostatus: Estimate of Transmission



Adapted from Marks G et al. *AIDS*. 2006;20(10):1447-1450.

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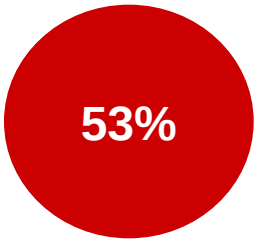
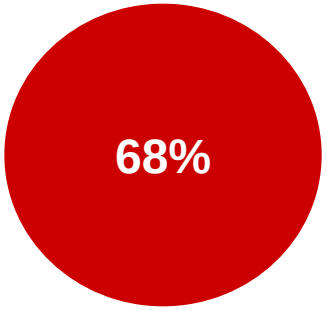
Unsafe Sex and HIV Status Awareness

- Unsafe sexual behavior is reduced substantially after people become aware they are HIV-positive
  - Meta-analysis of 11 published US studies (1988 through 2003)



Reduction in unsafe sex in HIV persons aware of their status relative to persons unaware



Reduction in unsafe sex of HIV persons aware of their status (adjusted data*) relative to persons unaware when sexual partners were HIV-negative

*Adjustment factor focused the analysis on behavior with partners at risk for HIV infection and accounted for unsafe sexual behavior with partners who were not already HIV+.

Marks G et al. *J Acquir Immune Defic Syndr*. 2005;39(4):446-453.

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Change in Policy Has Significant Impact: San Francisco Department of Public Health Medical Care System

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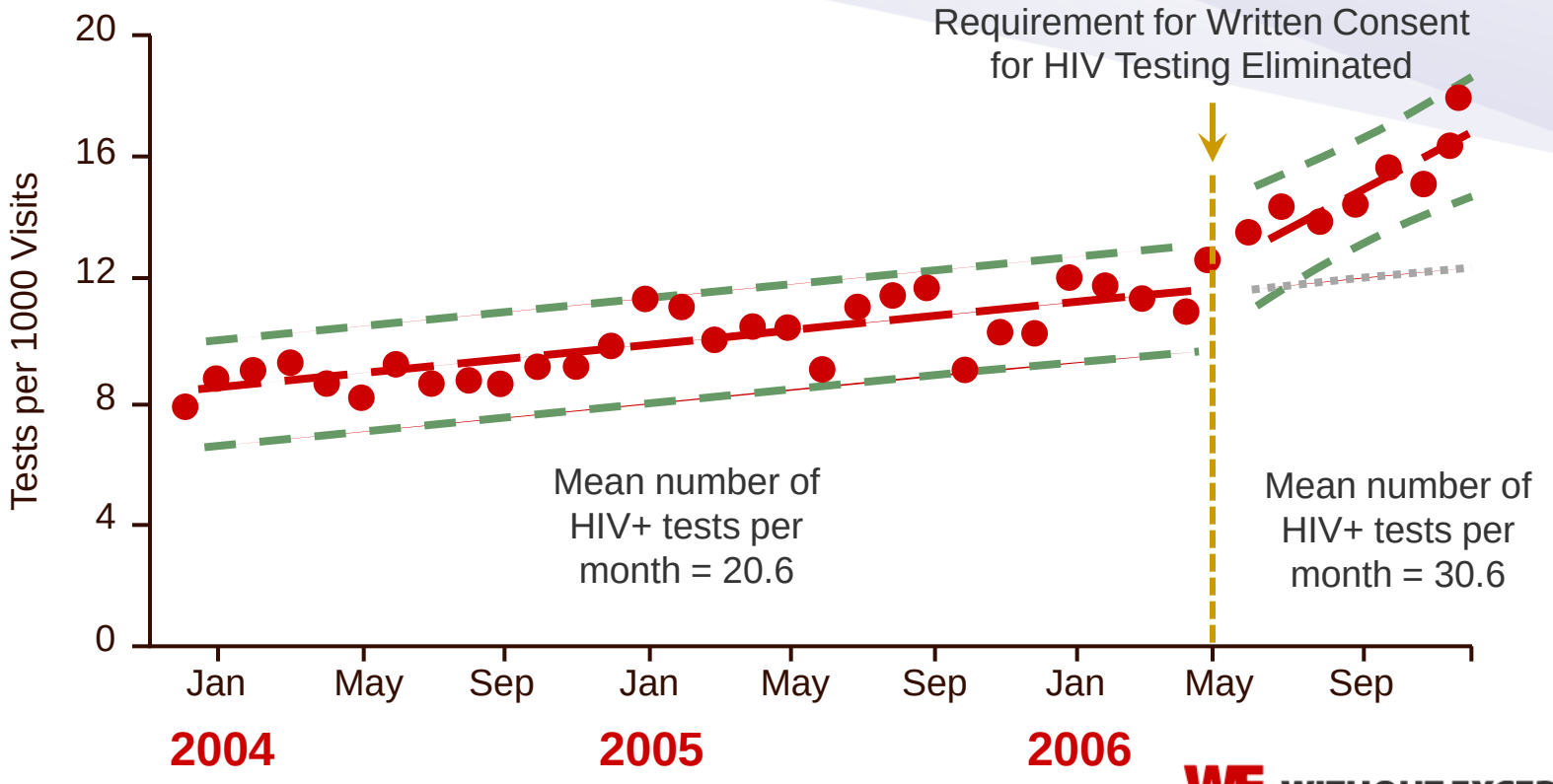
Mean Rate of HIV Tests per 1000 Patient Visits in Persons Aged 18 Years or Older (Dec 2003 – Dec 2006)



Zetola NM et al. *JAMA*. 2007;297(10):1061-1062.

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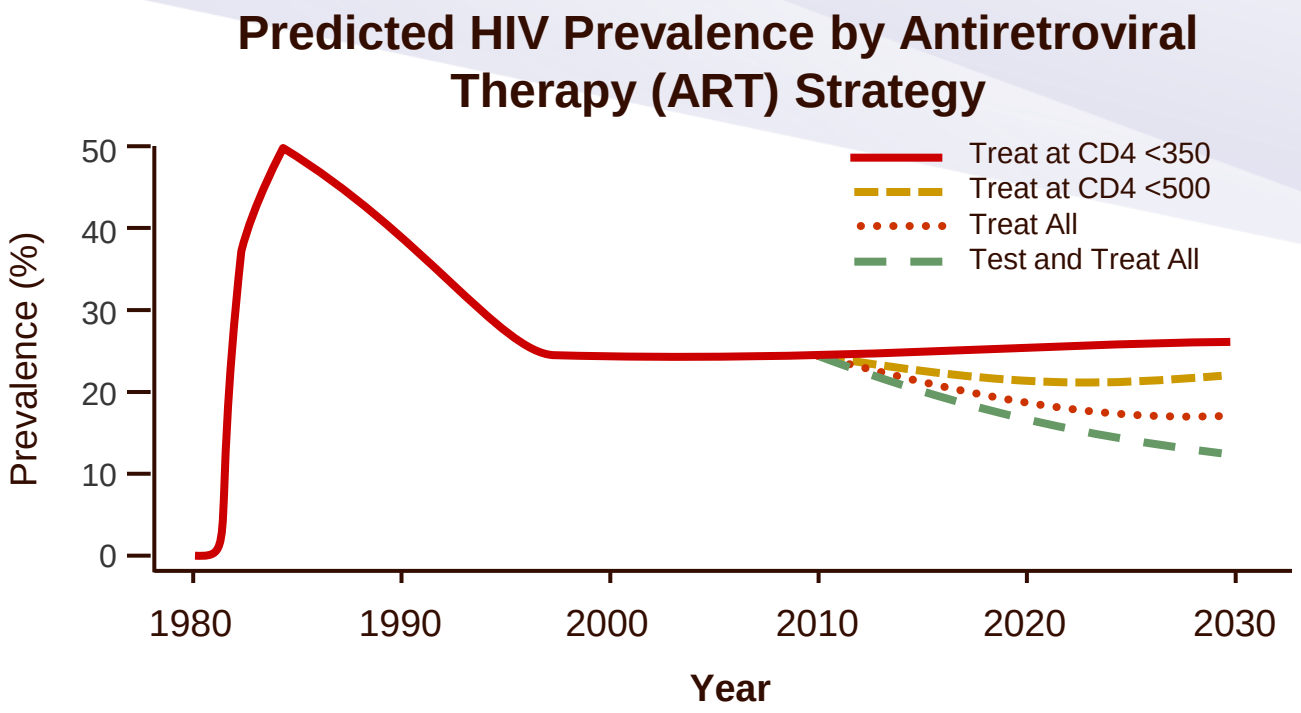
San Francisco: Predicted HIV Prevalence and % Reduction in New HIV Infections Among MSM by Specific Test and Treat Strategy

GILEAD



- If a test-and-treat strategy is used in San Francisco, it is estimated that 81% of all new HIV infections would be averted by 2019

Charlebois et al. 17th CROI; 2010; San Francisco. Abstract 996.

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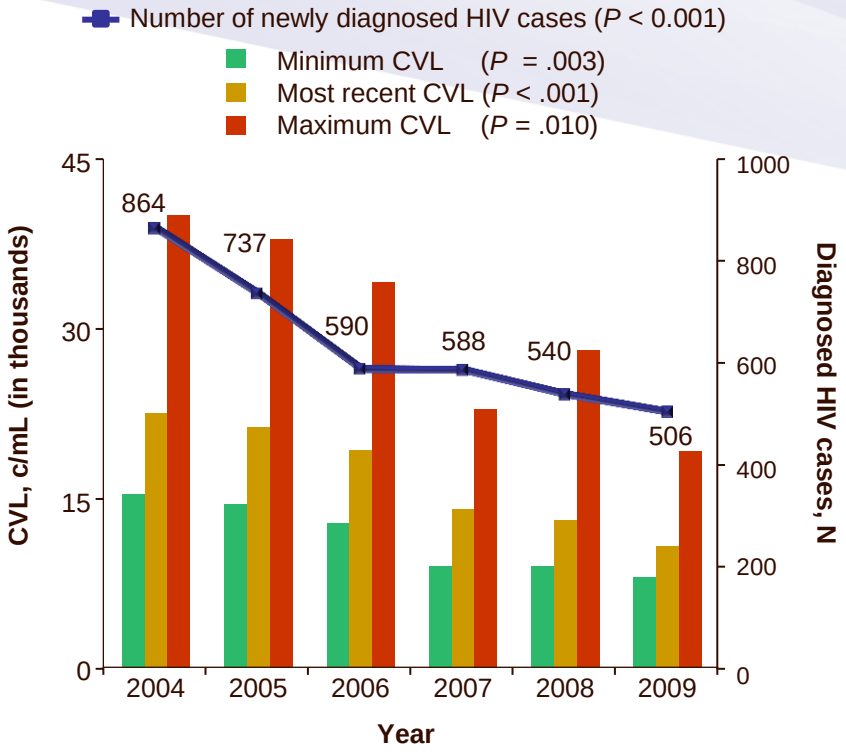
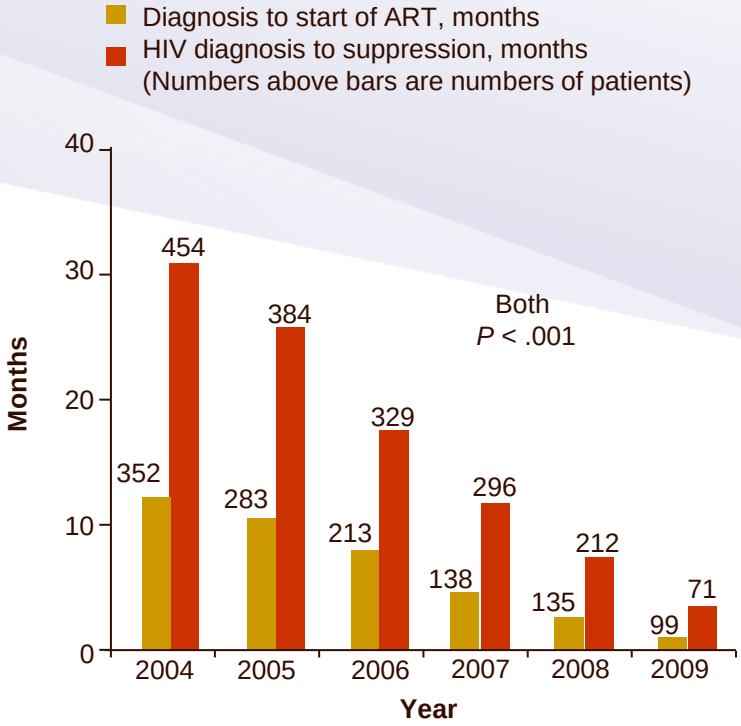
San Francisco Department of Public Health: Earlier HIV Diagnosis and Initiation of Therapy Associated with Lower Community Viral Load (CVL) and Reduced Transmission



Irrespective of CVL measure the number of diagnosed HIV cases decreased over time (*P* < .001)



Mean CD4 at Initiation: 2007: 357 2009: 445

Time from ART initiation to virologic suppression decreased from a mean of 18.8 months in 2004 to a mean of 2.8 months in 2009 (*P* < .001)

Das M, et al. 18th CROI; 2011; Boston. Abstract 1022.

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DSMB Stops Major Trial 4 Years Early Because of the Associated Benefits With Earlier Initiation of ART[1,2]

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HPTN 052: Multicenter, international, randomized, NIH-funded phase 3 study[1]

HIV serodiscordant adult couples
ART-naive, HIV-infected partner
Screening CD4 count: 350-550

N = 1763 couples

- Early arm (886 couples): Start ART when CD4 count is 350-550
- Delayed arm (877 couples): Start ART when CD4 is ≤200-250, or AIDS diagnosis

- **96% reduction** in HIV transmission risk to uninfected partner with earlier vs delayed ART (median follow-up, 1.7 years)
  - New linked HIV infections: Early ART (n = 1) vs Delayed ART (n = 27); *P* < .001 (primary prevention endpoint)
- **41% reduction** in clinical events when treatment was started early*
  - Significantly greater number of extrapulmonary TB cases in Delayed ART arm; *P* = .002

"The early initiation of antiretroviral therapy reduced rates of sexual transmission of HIV-1 and clinical events, indicating both personal and public health benefits from such therapy."[1]

"The results are the first from a major randomized clinical trial to indicate that treating an HIV-infected individual can reduce the risk of sexual transmission of HIV to an uninfected partner."[2]

*Clinical events included death, World Health Organization stage 4 events, severe bacterial infections, and pulmonary tuberculosis for index partners.

[1]Cohen MS et al. *N Engl J Med*. 2011;365(6):493-505. [2]National Institute of Allergy and Infectious Diseases [Press release]. May 12, 2011.

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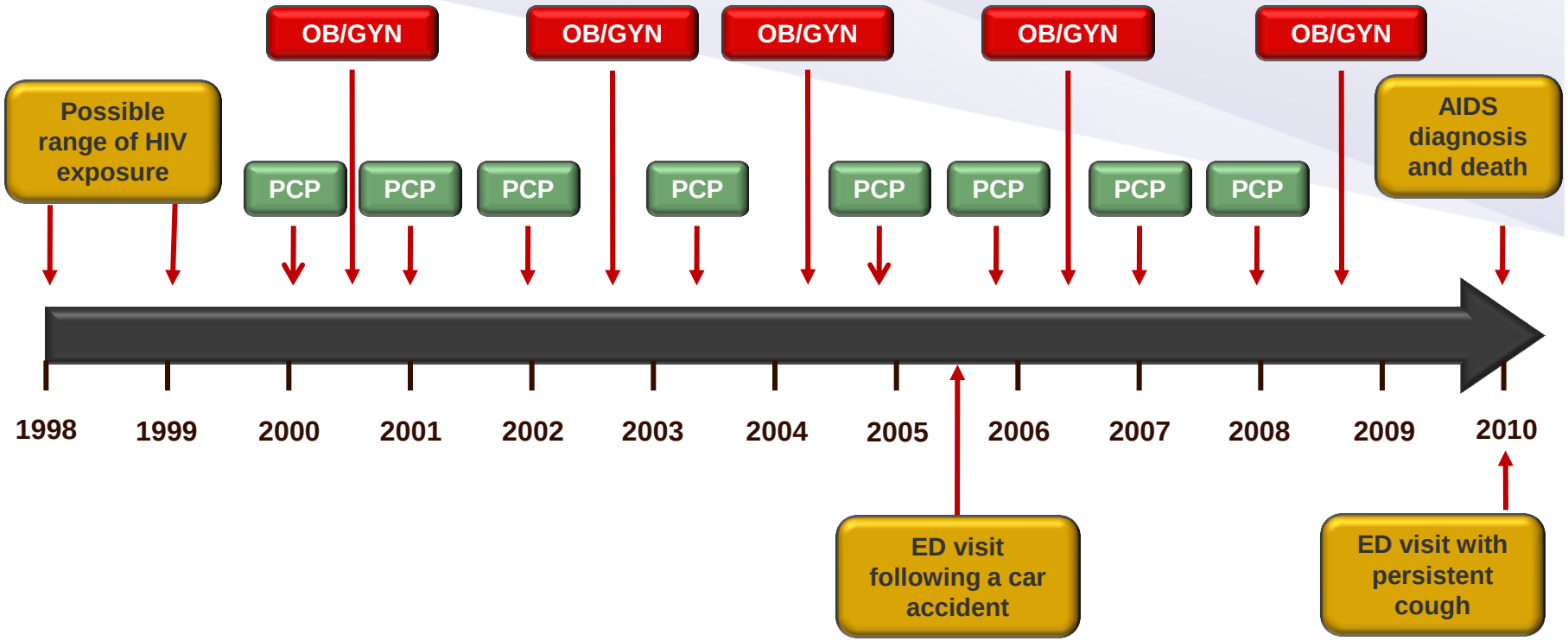
Nancy's Medical History, 1998-2010: Primary Care and OB/GYN Visits



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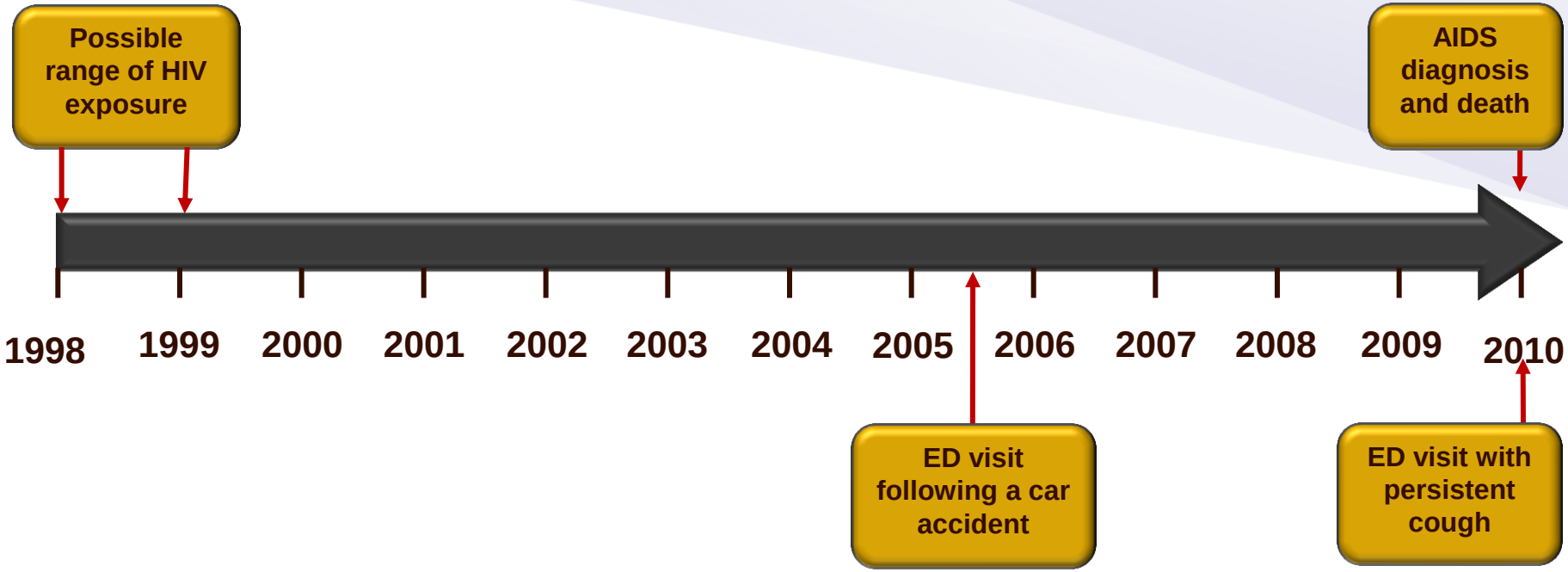
Nancy's Medical History, 1998-2010: Emergency Department Visits



Case study for discussion purposes only.

HIV Screening by Potential AIDS-Defining Event

Review of 8 US Health Plans

(N = 7451; 2006 Calendar Year)

Potential AIDS-Defining Event	n	Screening Rate
Burkitt's or immunoblastic lymphoma or primary lymphoma of brain	2980	3.0%
Encephalopathy	2066	5.0%
Invasive cervical cancer	958	4.4%
Candidiasis of bronchi, trachea, lung, or esophagus	542	7.0%
Histoplasmosis, disseminated or extrapulmonary	370	2.2%
Wasting/cachexia	350	4.3%
Disseminated herpes or herpes meningitis	94	13.8%
M. avium or *M. kansasii*, disseminated or extrapulmonary	67	13.4%
Pneumocystis carinii pneumonia	48	10.4%
Kaposi's sarcoma	35	8.6%
Progressive multifocal leukoencephalopathy	20	0.0%
CMV pneumonia or retinitis	16	25.0%
Coccidioidomycosis, disseminated or extrapulmonary	13	7.7%
Cryptococcosis, extrapulmonary	11	9.1%
Misc (toxoplasmosis of brain, chronic isosporiasis, salmonella septicemia, chronic cryptosporidosis)	5	20.0%

- **4.3% (n = 320) patients with any potential AIDS-defining event screened for HIV**
- **12.5% (n = 15) patients with multiple potential AIDS-defining events screened for HIV**

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Chen JY et al. 16th CROI; 2009; Montreal. Abstract #1044.

HIV Screening in Commercially Insured Patients Screened or Diagnosed With Sexually Transmitted Diseases or Blood-Borne Pathogens

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Receipt of HIV Screening by Risk, Compiled From Administrative Claims Data From Health Plans Across 6 States

(N = 270,423; Jan 2007 to Oct 2007)

Risk	Sample size	HIV Screening Rate (%)
Total	270,423	32.7
Hepatitis	126,490	46.9
Hepatitis B[a]	111,031	48.4
Diagnosis	2289	11.4
Screening tests	108,742	49.2
Hepatitis C[a]	89,814	41.3
Diagnosis	4952	10.0
Screening tests	84,862	43.1
STD	143,933	20.3
Syphilis[a]	99,160	65.3
Diagnosis	263	26.2
Screening tests	98,897	65.4
Chlamydial or gonorrhea infection	98,422	46.9
Diagnosis	15,469	33.6
Screening tests	82,953	49.4

Risk	Sample size	HIV Screening Rate (%)
STD counseling, screening	66,774	43.8
Human papillomavirus	23,343	11.0
Trichomonaisis[a]	17,018	22.8
Diagnosis	3714	21.1
Screening tests	13,304	23.3
Genital herpes	10,365	21.4
Epididymitis	8653	3.1
Condyloma	6392	13.3
Pelvic inflammatory disease	1389	10.8
Other nongonococcal urethritis	501	22.2
Chancroid, granuloma inguinale, and lymphogranulmoa venereum	213	19.7

[a]Stratified HIV screening rate for a risk category by the method the category was captured (ie, diagnosis codes vs screening laboratory tests).

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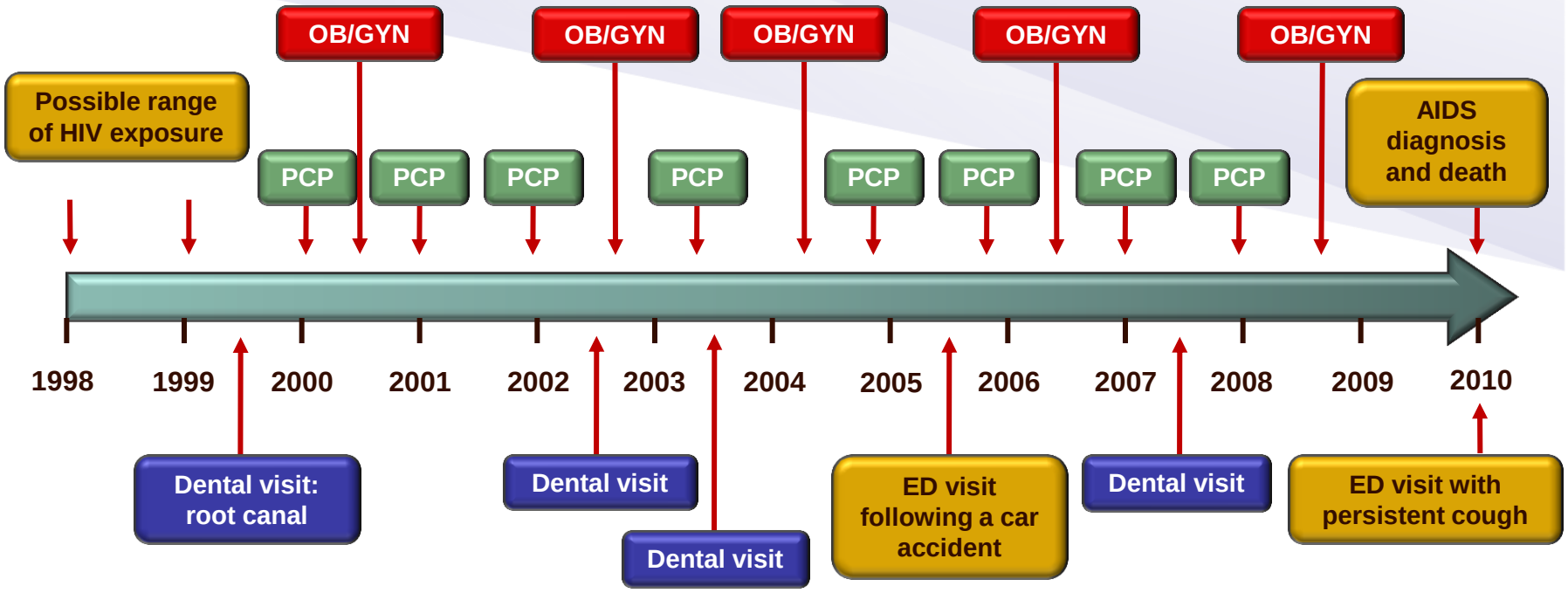
Chen JY et al. *Sex Transm Dis*. 2011;38(6):522-527.

Nancy's Medical and Social History, 1998-2010: Other Opportunities for HIV Testing



Nancy attended church regularly on Sundays

Nancy volunteered at local community fairs

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Support Grows for Routine Testing

- Medicare covers HIV tests for pregnant women and persons at increased risk for infection, including anyone who asks for the test[1]
- Ryan White 2009 reauthorization establishes a goal of 5 million HIV tests annually through federal programs[2]
- The VA, the nation's largest provider of HIV care, adopts routine verbal opt-out HIV testing[3]
- California law is first in the United States to require private insurers to cover routine HIV testing[4]
- 24 states have modified their laws since the 2006 CDC recommendations[5]
  - Only 3 states still require specific written informed consent for HIV testing

1. www.medicare.gov/(S(iftfep24utll4knes5k2xv55))/navigation/manage-your-health/preventive-services/hiv-screening.aspx.
2. energycommerce.house.gov/Press_111/20091013/Ryan_White_Section.pdf.
3. www.hiv.va.gov/vahiv?page=prtop02-va-00.
4. www.nytimes.com/2008/10/02/us/02hiv.html.
5. Neff S et al. *JAMA.* 2011;305(17):1767-1768.

Implementation of CDC Opt-Out HIV Testing Guidelines

STATE POLICIES ON HIV TESTING

Compatibility of Consent and Counseling Laws With 2006 CDC Recommendations (as of January 2011)

PARAMETER AND SUBPARAMETER	COMPATIBLE STATES	INCOMPATIBLE STATES
Consent	AL, AK, AZ, AR, CA, CO, CT, DC, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MI, MN, MS, MO, MT, NV, NH, NJ, NM, NC, ND, OH, OK, OR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WI, WV, WY	MA, NE, NY, PA
Opt-in vs opt-out	AL, AK, AZ, AR, CA, CO, CT, DC, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY	MA
Specific vs general	AL, AK, AZ, AR, CA, CO, CT, DC, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MI, MN, MS, MO, MT, NV, NH, NJ, NM, NY,[a] NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WI, WV, WY	MA, NE
Written vs oral or written	AL, AK, AZ,[b] AR, CA, CO, CT, DC, DE, FL, GA, HI, ID, IL,[c] IN, IA, KS, KY, LA, ME, MD, MI, MN, MS, MO, MT, NV, NH, NJ, NM, NC, ND, OH, OK, OR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WI, WV, WY	MA, NE, NY,[a] PA
Counseling	AL, AK, AZ, AR, CA, CO, CT, DC, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO,[d] MT, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, SC, SD, TN, TX, UT, VT, VA, WA, WI, WV, WY	PA, RI
Prevention vs testing counseling	AL, AK, AZ, AR, CA, CO, CT, DC, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO,[d] MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY	RI
In-person vs discretionary notification/ counseling	AL, AK, AZ, AR, CA, CO, CT, DC, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY	PA

Abbreviation: CDC, Centers for Disease Control and Prevention.

[a]In New York, written consent is required except in cases of rapid testing (oral consent is sufficient) and may be incorporated into the general medical consent; the consent form must have a clearly marked place adjacent to the signature where the test participant has the opportunity to decline HIV-related testing in writing.

[b]In Arizona, compatibility for written vs oral or written consent differs by healthcare setting (consent in nonhospitals may be oral or written; consent in hospitals must be written), as well as type of healthcare professional (consent to testing by physicians, registered nurse practitioners, and physician assistants may be oral or written).

[c]In Illinois, compatibility for written vs oral or written consent differs between the compiled statutes and administrative code; administrative code has not been updated since statutory amendments passed to be more compatible.

[d]In Missouri, compatibility for counseling differs by healthcare professional (laws for physicians are compatible; those for others are not).

Source: Neff S, Goldschmidt R. Centers for Disease Control and Prevention 2006 human immunodeficiency virus testing recommendations and state testing laws. *JAMA*. 2011;305(17):1767-1768.

*Written informed consent required, except that general consent to medical care is sufficient if the general consent form provides an express opportunity for the patient to decline the test. Documented oral informed consent is a permitted alternative method of consent for oral rapid testing.

WE WITHOUT EXCEPTION
when HIV testing is routine, we all win

Breaking Down Barriers to HIV Testing

- Financial resources and staff resources to make routine testing seamless and fully integrated into standard care will help address
  - Insufficient time
  - Competing priorities
- Increased education and training will help address lack of knowledge/training
- Increased patient education will help address lack of patient acceptance
- Making HIV testing routine will help destigmatize HIV among providers and patients
- Having a mechanism to reimburse for testing is vital to its widespread adoption and will help address inadequate reimbursement

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If you have further questions regarding HIV or this presentation, please visit the Gilead booth.

Thank you!

GILEAD