
CDC's Revised Recommendations for HIV Testing in Health Care Settings

Bernard M. Branson, M.D.

Associate Director for Laboratory Diagnostics
Divisions of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention



Presentation Outline

- Where we are now –
 - HIV epidemic and current testing
 - Previous recommendations and their effects
- Rationale for revised recommendations
- Examples of screening programs
- Paradigm for prevention



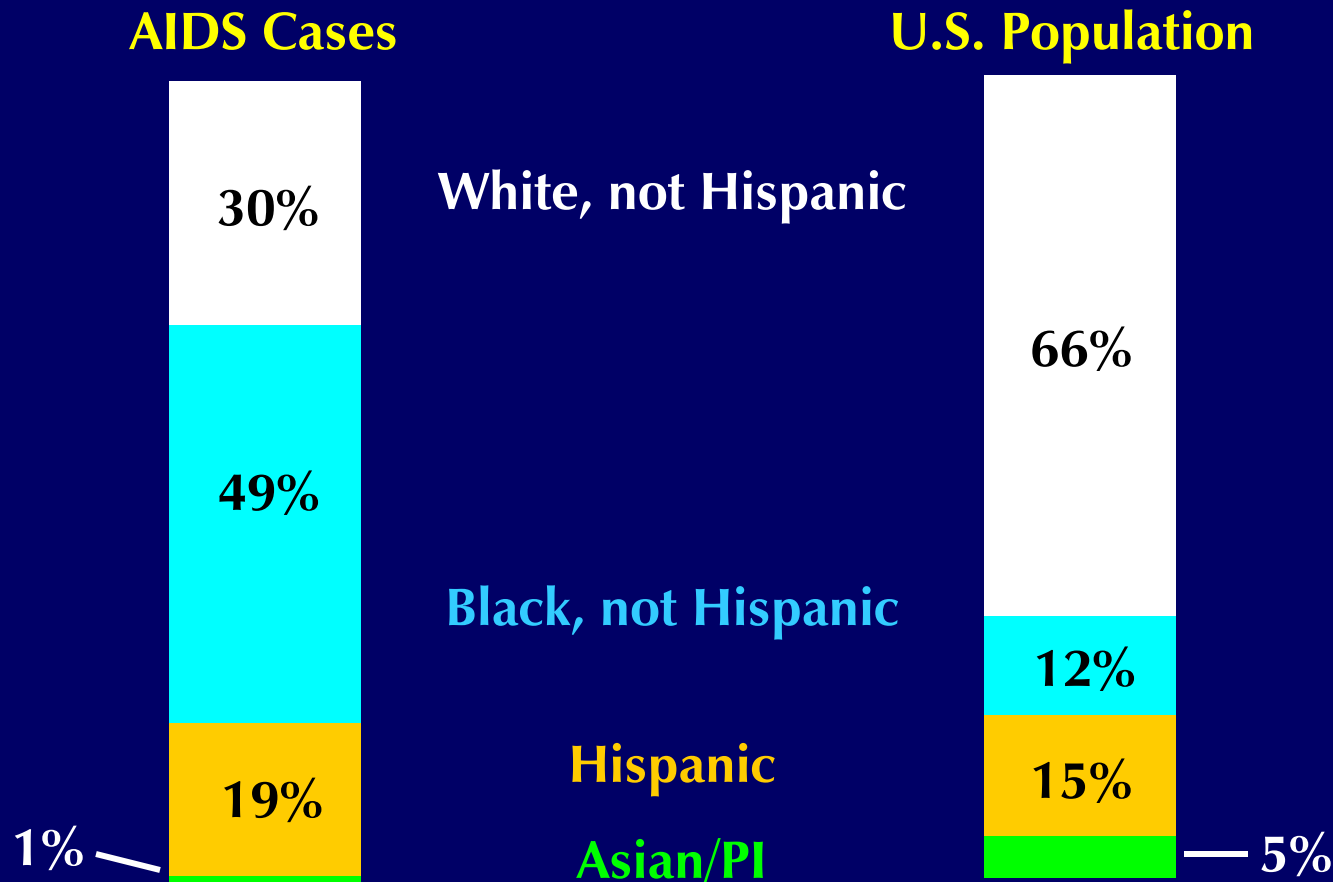
Dz dūhghvv#r i#K IY #/wōwv#ōp r qj#
Shuvr qv#z lk#K IY /#X q lwhg#/wōwhv

Number HIV infected	1,039,000 – 1,185,000
Number unaware of their HIV infection	252,000 - 312,000 (24%-27%)
Estimated new infections annually	56,300

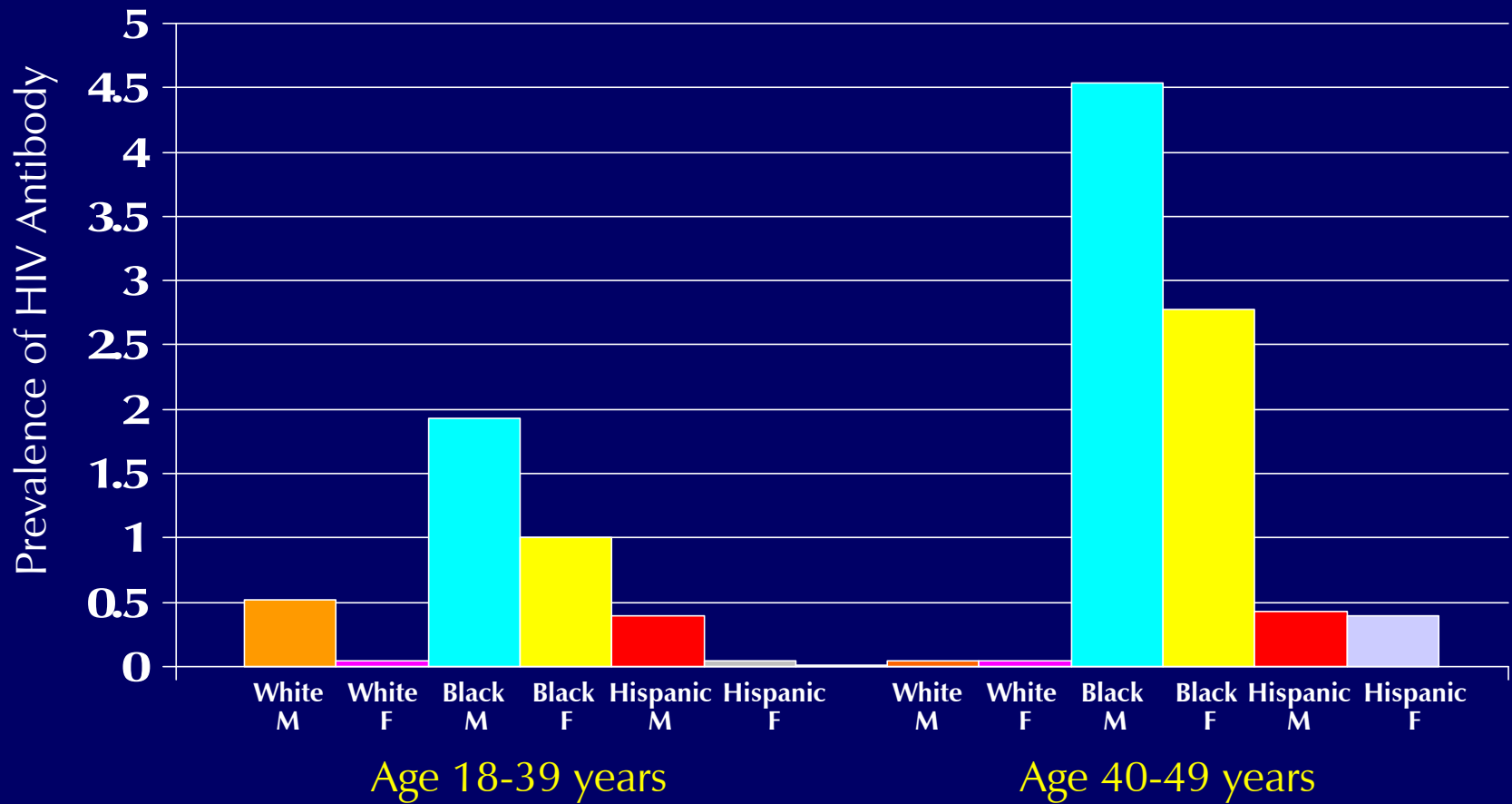
Glynn M, Rhodes P. 2005 HIV Prevention Conference



AIDS Diagnoses and U.S. Population by Race/Ethnicity, 2006



HIV Prevalence, NHANES 1999-2002

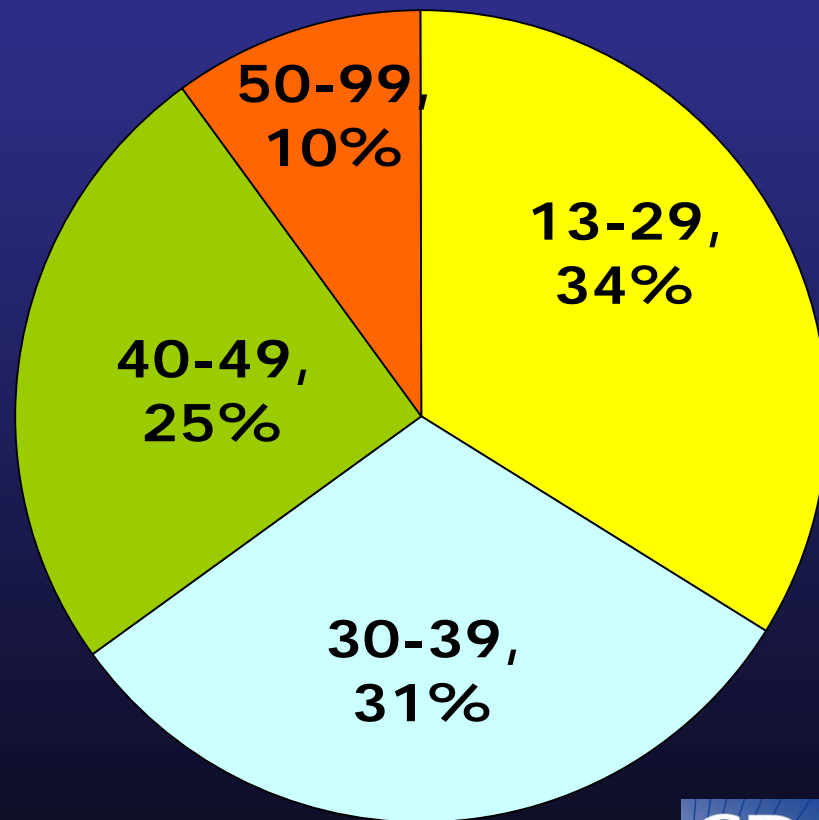
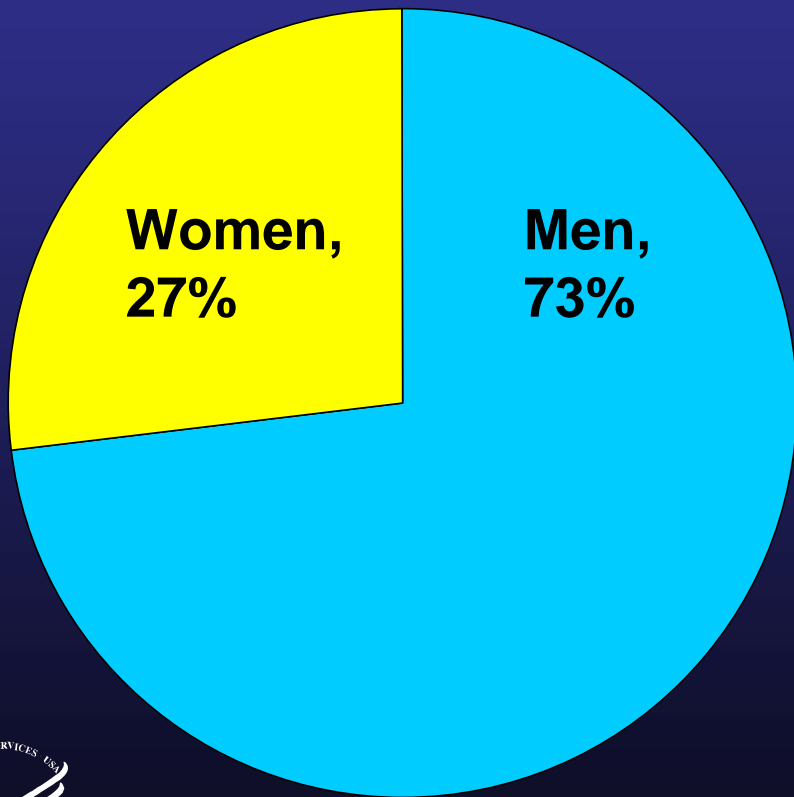


- McQuillan et al, NCHS: JAIDS April 2006



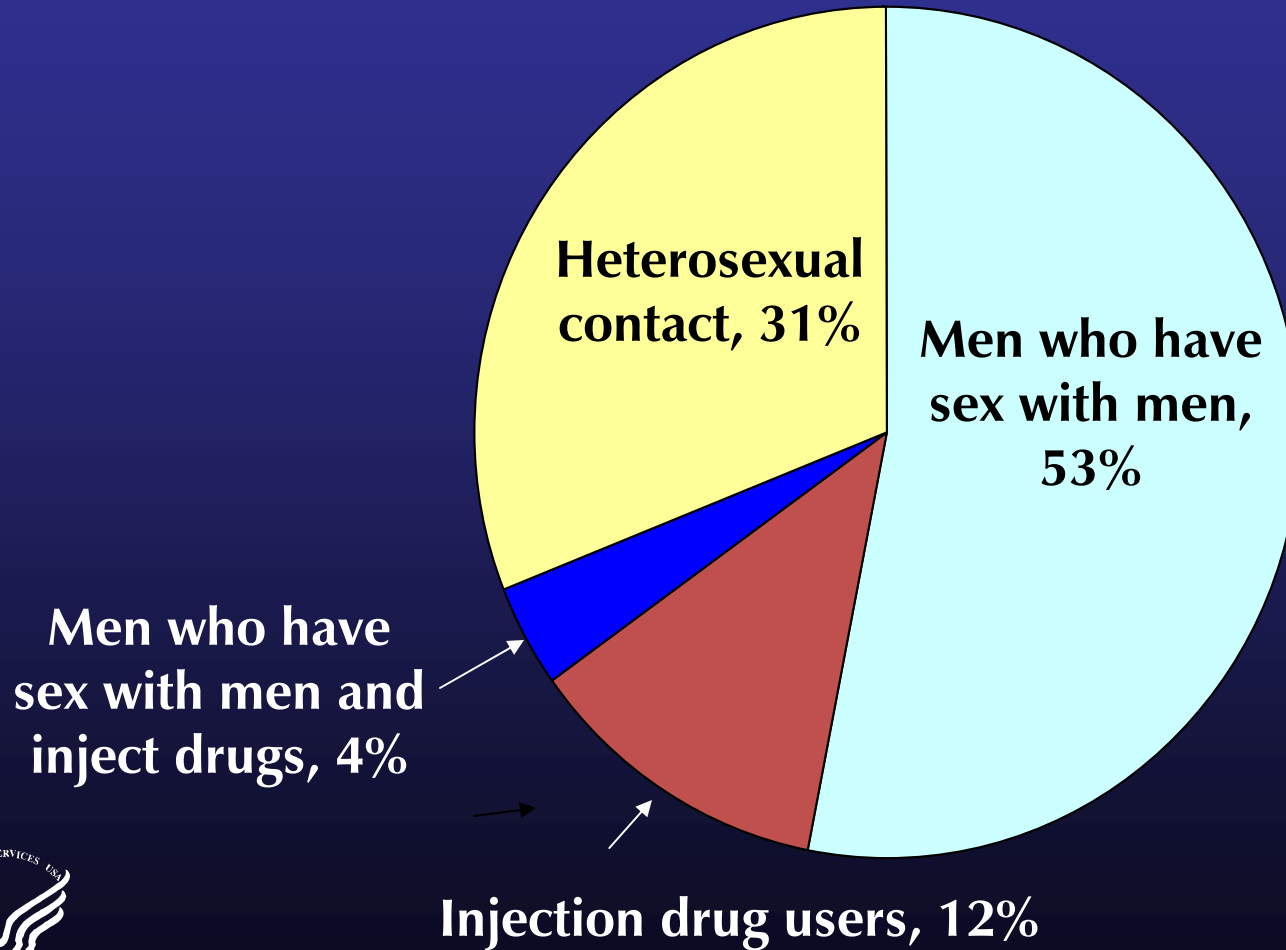
Estimated Percentage of New HIV Infections, by Sex and Age

50 U.S. States & DC, 2006

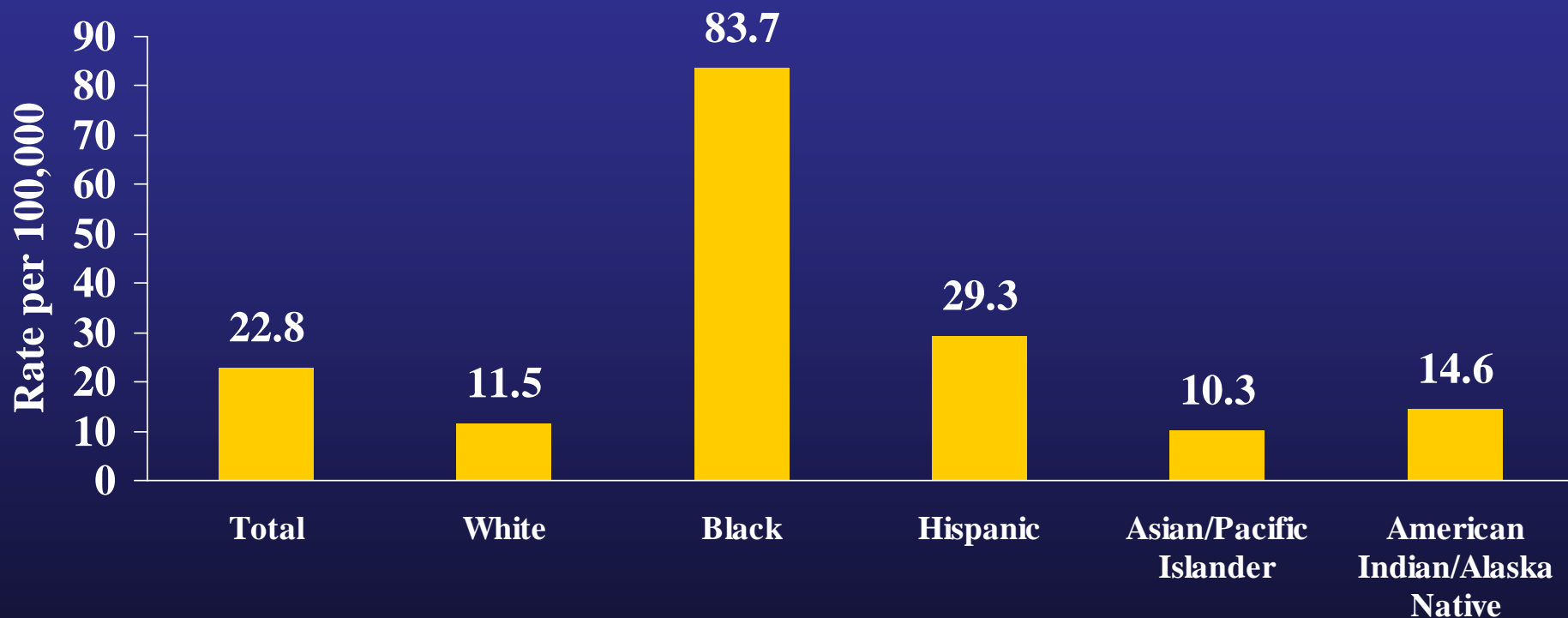


Estimated Percentage of New HIV Infections, by Transmission Category

50 U.S. States & DC, 2006



Estimated Rates of new HIV Infections by Race/ethnicity 50 U.S. States & DC, 2006



Total Male: 34.3 per 100,000
Total female: 11.9 per 100,000



Current HIV Testing



Terminology

- *Diagnostic testing:* performing an HIV test based on clinical signs or symptoms
- *Targeted testing:* performing an HIV test on subpopulations of persons at higher risk based on behavioral, clinical or demographic characteristics
- *Screening:* performing an HIV test for all persons in a defined population
- *Opt-out screening:* performing an HIV test after notifying the patient that the test will be done; consent is inferred unless the patient declines

Source of HIV Tests and Positive Tests

- 38% - 44% of adults age 18-64 have been tested
- 16-22 million persons age 18-64 tested annually in U.S.

	HIV tests*	HIV+ tests**
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 clinic	0.7%	2%

*National Health Interview Survey, 2002

**Suppl. to HIV/AIDS surveillance, 2000-2003



Late HIV Testing is Common

Supplement to HIV/AIDS Surveillance, 2000-2003

- Among 4,127 persons with AIDS*, 45% were first diagnosed HIV-positive within 12 months of AIDS diagnosis (“late testers”)
- Late testers, compared to those tested early (>5 yrs before AIDS diagnosis) were more likely to be:
 - Younger (18-29 yrs)
 - Heterosexual
 - Less educated
 - African American or Hispanic

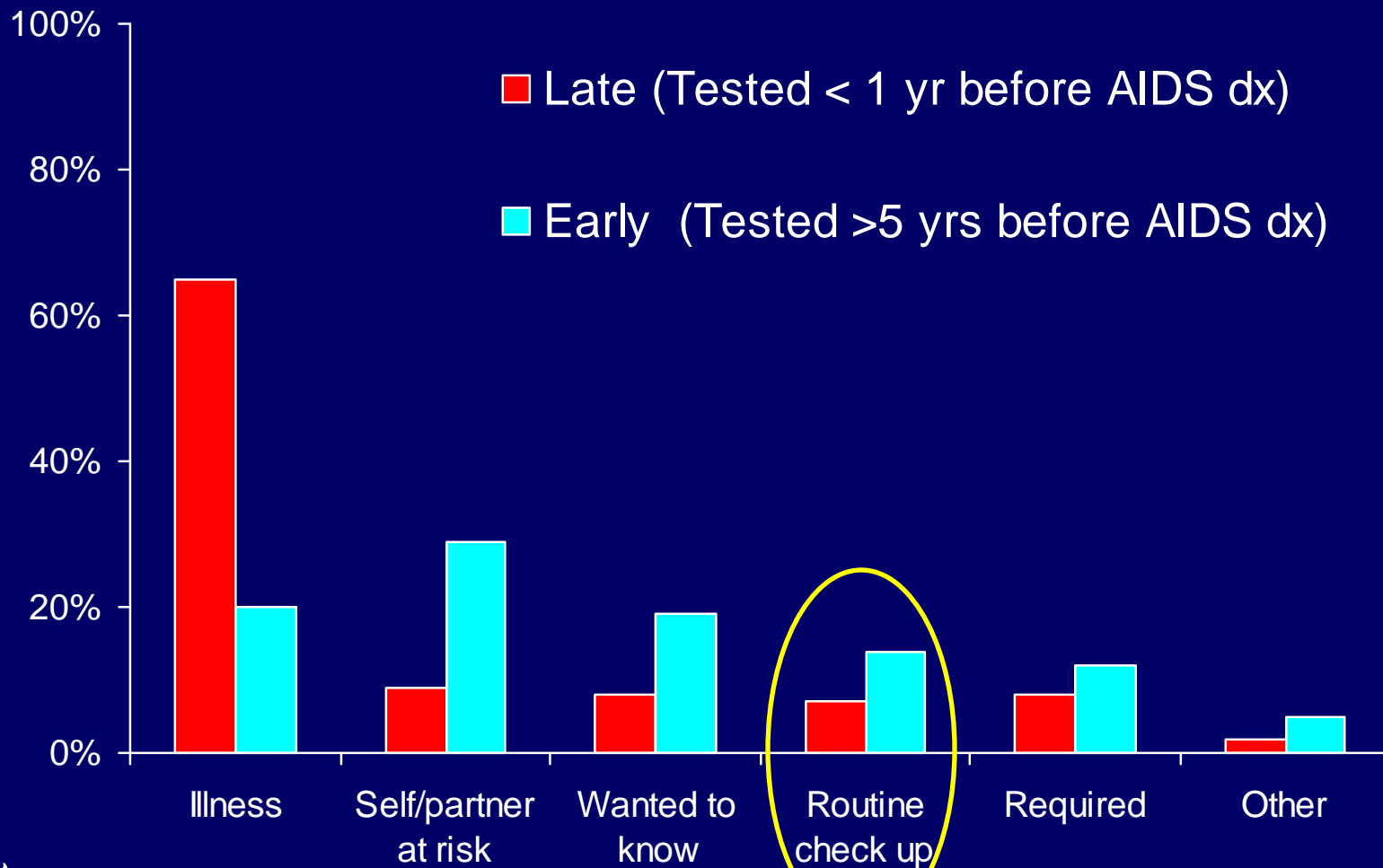
MMWR June 27, 2003

*16 states

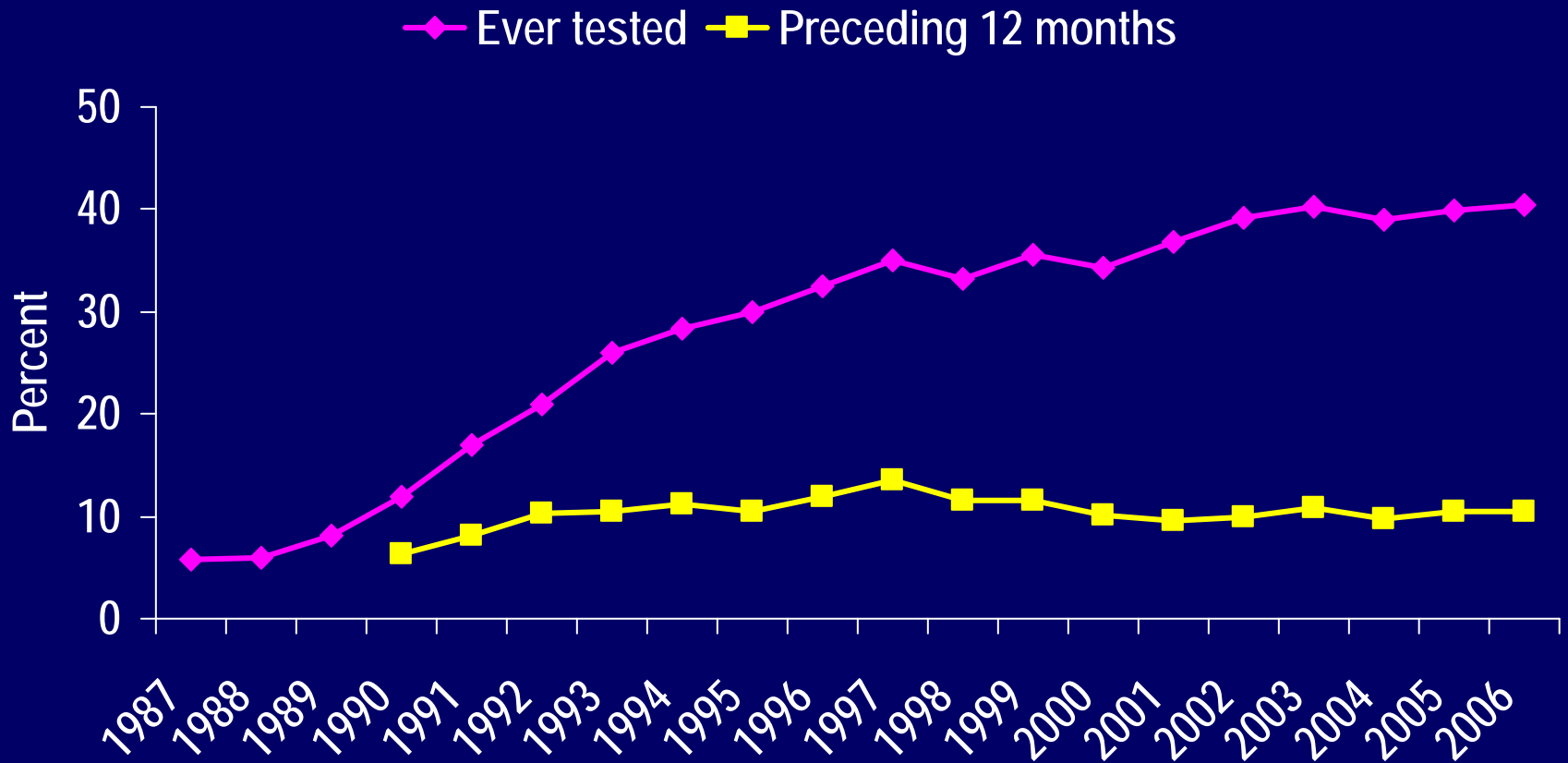


Reasons for testing: late versus early testers

Supplement to HIV/AIDS Surveillance, 2000-2003



Percent of Persons Ever Tested and Tested in the Preceding 12 Months- NHIS 2002-2006



Previous CDC Recommendations Adults and Adolescents

- Routinely recommend HIV screening in acute-care hospital settings with HIV prevalence $\geq 1\%$
- Targeted testing based on risk assessment in clinical settings with lower HIV prevalence



Recommendations Are Not Having Their Intended Effect in Acute Care Settings

- EDs account for 10% of all ambulatory care visits

	2002	2003	2004
ED visits	110 million	114 million	110 million
Age 15-64	69.6 million	71.6 million	71.5 million
HIV serology	163,000	239,000	268,000

*National Hospital Ambulatory Medical Care Survey,
National Center for Health Statistics*



Rapid HIV Screening in Acute Care Hospitals

<u>Study site</u>	<u>New HIV+</u>
Cook County ED, Chicago	2.3%
Grady ED, Atlanta	2.7%
Johns Hopkins ED, Baltimore	3.2%
King-Drew Med Center ED, Los Angeles	1.3%
Inpatients, Boston Medical Center	3.8%

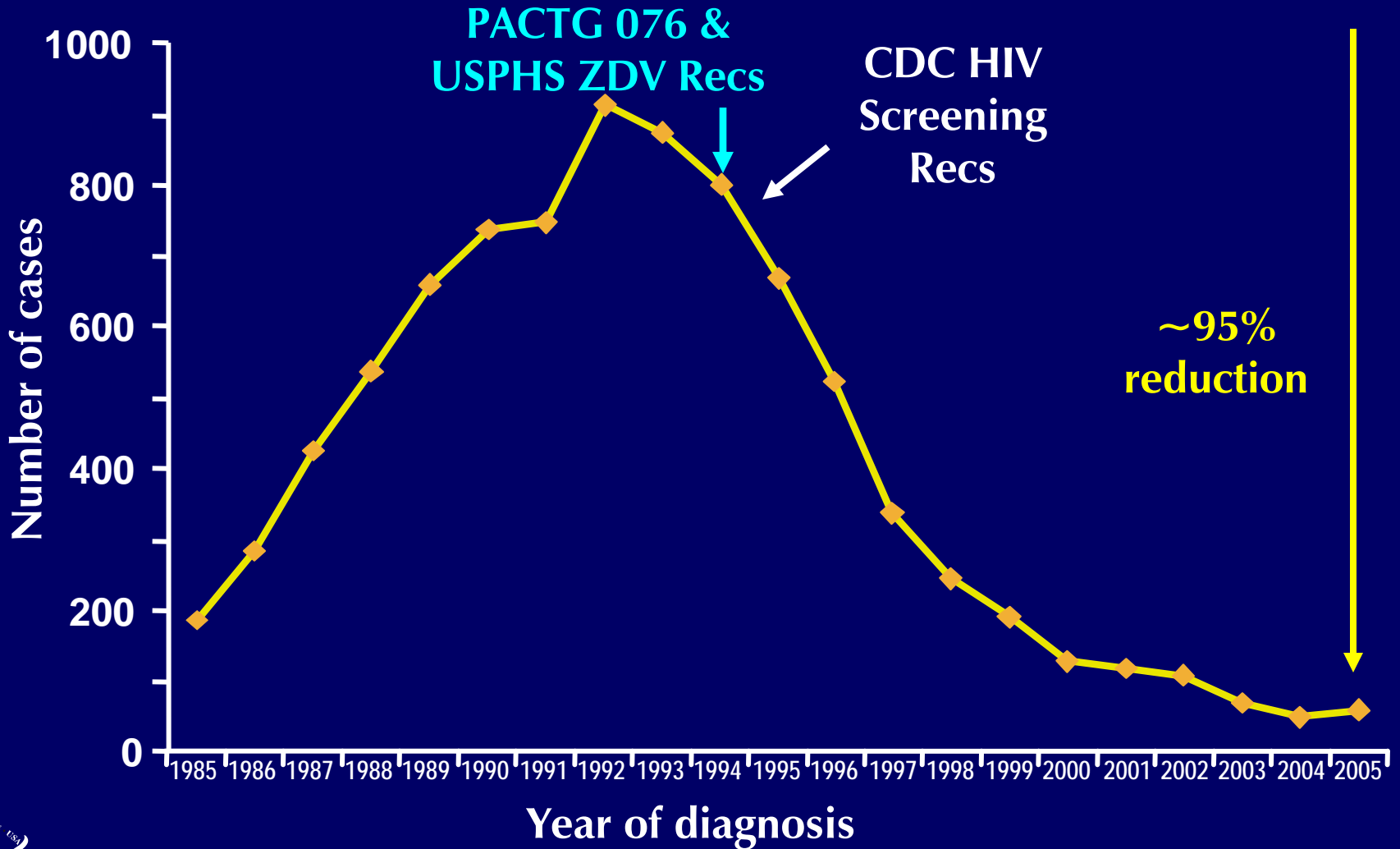


Previous CDC Recommendations Pregnant Women

- Routine, voluntary HIV testing as a part of prenatal care, as early as possible, for all pregnant women
- Simplified pretest counseling
- Flexible consent process



Estimated Number of Perinatally Acquired AIDS Cases, by Year of Diagnosis, 1985-2005 – United States



Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings

MMWR 2006;55(No. RR-14):1-17

Published September 22, 2006

<http://www.cdc.gov/mmwr/pdf/rr/rr5514.pdf>



Revised Recommendations Adults and Adolescents - I

- Routine, voluntary HIV screening for all persons 13-64 in health care settings, not based on risk
- All patients with TB or seeking treatment for STDs should be screened for HIV
- Repeat HIV screening of persons with known risk at least annually



Revised Recommendations Adults and Adolescents - II

- When acute retroviral infection is a possibility, use an RNA test in conjunction with an HIV antibody test
- Settings with low or unknown prevalence:
 - Initiate screening
 - If yield from screening is less than 1 per 1000, continued screening is not warranted

Revised Recommendations Adults and Adolescents - III

- Opt-out HIV screening with the opportunity to ask questions and the option to decline testing
- Separate signed informed consent should not be required
- Prevention counseling in conjunction with HIV screening in health care settings should not be required



Revised Recommendations Adults and Adolescents - IV

- Screening is voluntary
- Inform patients orally or in writing that HIV testing will be performed unless they decline.
- Arrange access to care, prevention, and support services for patients with positive HIV test results



Revised Recommendations Pregnant Women - I

- Universal opt-out HIV screening during each pregnancy
 - Include HIV in routine panel of prenatal screening tests
 - Consent for prenatal care includes HIV testing
 - Notification and option to decline testing
- Second test in 3rd trimester for pregnant women:
 - Known to be at risk for HIV
 - In jurisdictions with elevated HIV incidence
 - In high HIV prevalence health care facilities



Jurisdictions Where 2nd HIV Test in Third Trimester Is Recommended

- Alabama
- Connecticut
- Delaware
- District of Columbia
- Florida
- Georgia
- Illinois
- Louisiana
- Maryland
- Massachusetts
- Mississippi,
- Nevada
- New Jersey
- New York
- North Carolina
- Pennsylvania
- Puerto Rico
- Rhode Island
- South Carolina
- Tennessee
- Texas
- Virginia

- As of 2006



Revised Recommendations Pregnant Women - II

- Opt-out rapid testing with option to decline for women with undocumented HIV status in L&D
 - Initiate ARV prophylaxis on basis of rapid test result
- Rapid testing of newborn recommended if mother's status unknown at delivery
 - Initiate ARV prophylaxis within 12 hours of birth on basis of rapid test result

Rationale for Revising CDC Recommendations

- Many HIV-infected persons access health care but are not tested for HIV until symptomatic
- Effective treatment available
- Awareness of HIV infection leads to substantial reductions in high-risk sexual behavior
- Inconclusive evidence about prevention benefits from 'typical' counseling for persons who test negative
- Great deal of experience with HIV testing, including rapid tests



Criteria that Justify Routine Screening

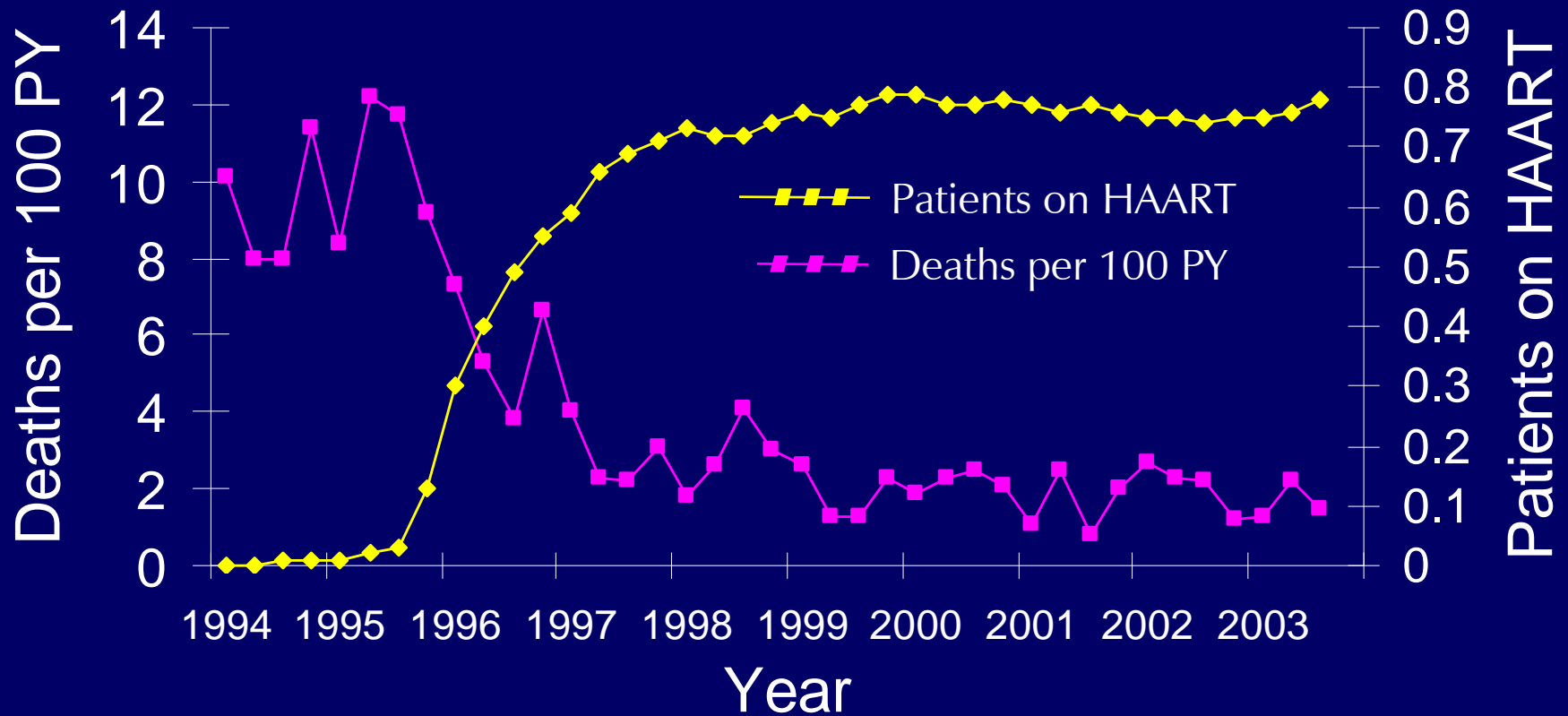
1. Serious health disorder that can be detected before symptoms develop
2. Treatment is more beneficial when begun before symptoms develop
3. Reliable, inexpensive, acceptable screening test
4. Costs of screening are reasonable in relation to anticipated benefits
5. Treatment must be accessible

Principles and Practice of Screening for Disease
-WHO Public Health Paper, 1968



Mortality and HAART Use Over Time

HIV Outpatient Study, CDC, 1994-2003



Patient Outcomes, ED vs Inpatient HIV Testing

	Rapid Test in ED N= 48	Conventional Test in Hospital N=55
Mean length of stay, days	6	13
ICU stay	5 (10%)	17 (31%)
Intubation required	1 (2%)	6 (11%)
Discharged before HIV test result	0	9 (16%)



- Lubelchek et al, Arch Int Med 2005



Knowledge of HIV Infection and Behavior

After people become aware they are HIV-positive, the prevalence of high-risk sexual behavior is reduced substantially.

Reduction in Unprotected Anal or
Vaginal Intercourse with HIV-neg partners:
HIV-pos Aware vs. HIV-pos Unaware **68%**

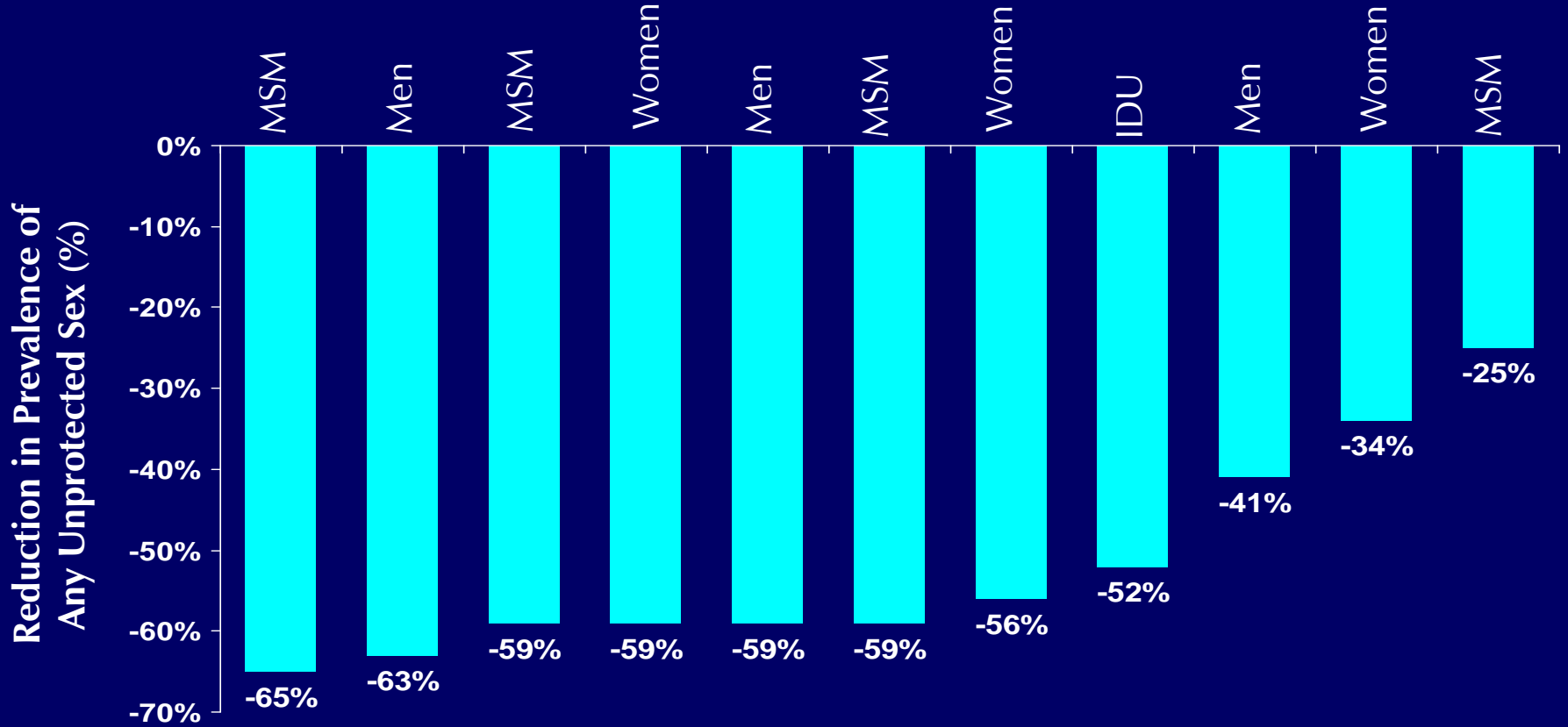
Meta-analysis of high-risk sexual behavior in persons aware and unaware they are infected with HIV in the U.S.

Marks G, et al. JAIDS. 2005;39:446



Reduction in Risky Sexual Behavior Among Persons Aware vs Unaware of Their HIV Infection

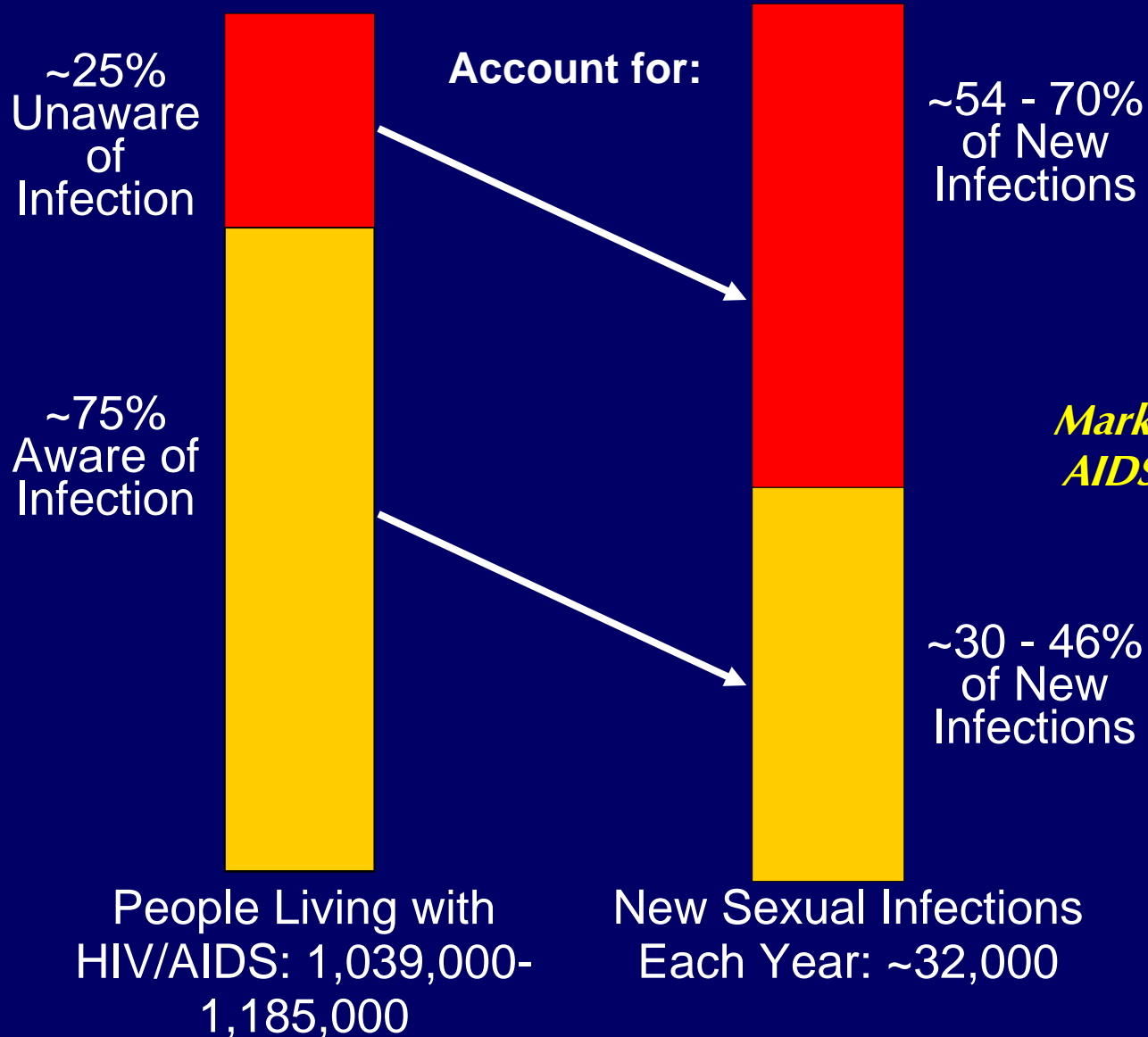
11 studies, 1986-2003



- Marks et al. JAIDS 2005



Awareness of Serostatus Among People with HIV and Estimates of Transmission



Opt-Out Screening

Prenatal HIV testing for pregnant women:

- RCT of 4 counseling models with opt-in consent:
 - *35% accepted testing*
 - *Some women felt accepting an HIV test indicated high risk behavior*
- Testing offered as routine, opportunity to decline
 - *88% accepted testing*
 - *Significantly less anxious about testing*

Simpson W, et al, BMJ June, 1999



Opt-Out: A New Paradigm?

- “Routine counseling and testing is defined as a policy to provide these services to all clients after informing them that testing will be done. Except where testing is required by law, individuals have the right to decline to be tested without being denied health care or other services.”

- *1987 CDC Recommendations*



Challenges: Traditional Counseling and Testing



Positive HIV Tests, 1989-2004

CDC Funded Testing Sites



- CDC, HIV Counseling and Testing at CDC-Supported Sites, 1989 - 2005



Expanded Testing Demonstration Projects

Site	Type	Annual Visits
Bronx-Lebanon Hospital Center	Emergency department	75,000+
Bronx-Lebanon Open Access Clinic	Walk-in, acute care	20,000+
LAC+USC Medical Center	Emergency department	100,000
Boston Medical Center	Outpatient, primary care	63,000
Boston Medical Center	Inpatient	28,000



Counselor-Based, Opt-In Screening

Site	Patients seeking care	Tested (%)	Confirmed Positive	Percent Positive
Bronx ED	158,150	2244 (1.4)	34	1.5%
Bronx Clinic	43,350	1687 (3.9)	42	2.5%
LAC+USC ED	72,000	2384 (3.8)	27	1.1%
BMC 1° care	63,000	1636 (2.6)	15	0.9%
BMC inpatient	28,000	2294 (8.2)	22	1.0%
TOTAL	364,400	10,245 (2.8)	140	1.4%

Testing period: April 2004-June 2006 (varies among sites)



Lessons Learned

- Difficult to obtain written consent and provide traditional counseling, yet still screen the large numbers of patients in acute care settings.
- Success will depend on streamlined systems, additional staff, and alternative approaches.



Lessons from the Field



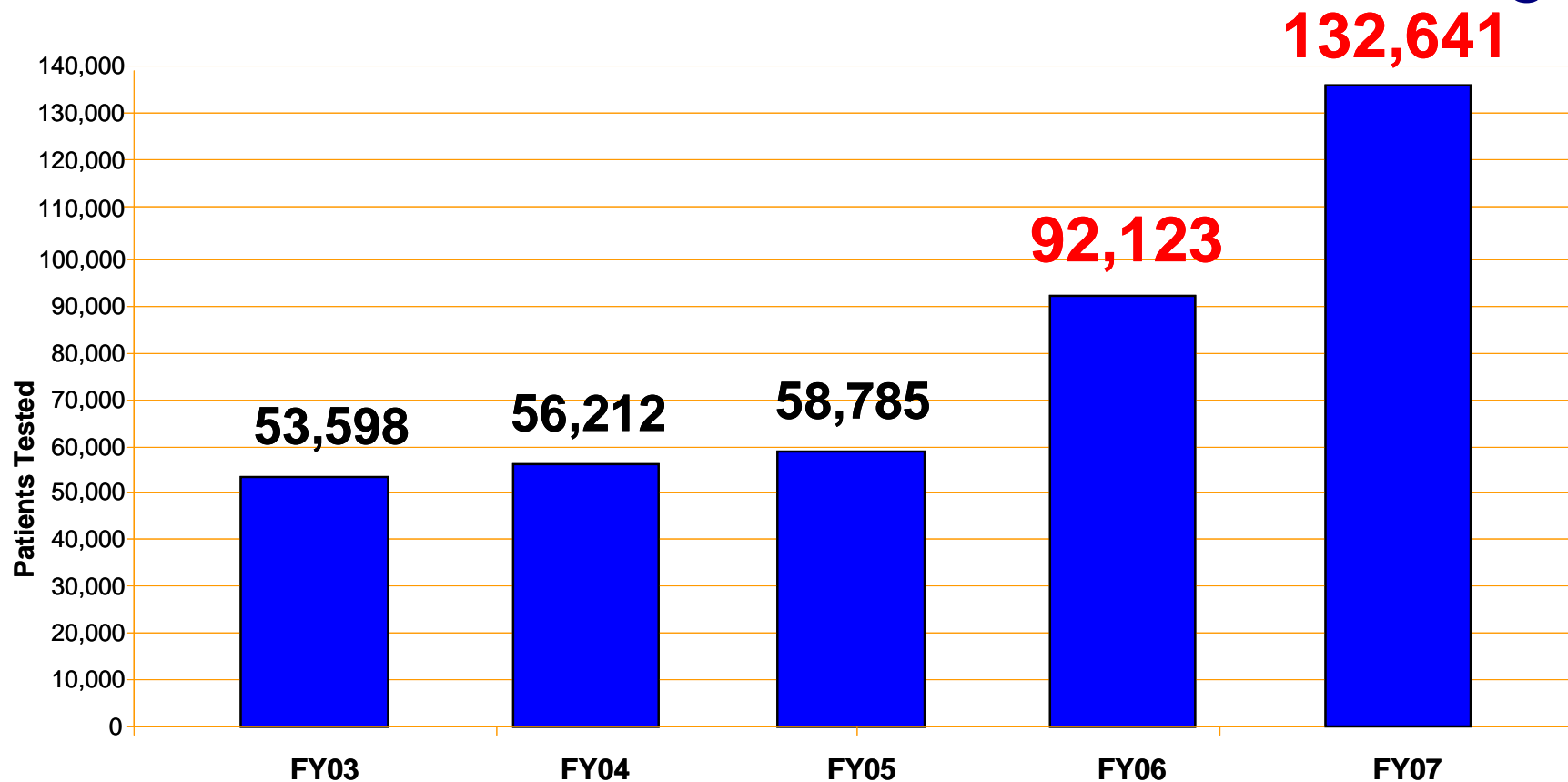
HIV Testing Expansion Initiative

New York City Health and Hospitals Corp

- Increase testing from baseline of ~55,000 per year (2003 – 2005)
- Increase the number of patients who know their HIV status
- Revised 2-part NY state signed informed consent form required



FY06-07: Continued Increase in HIV Testing

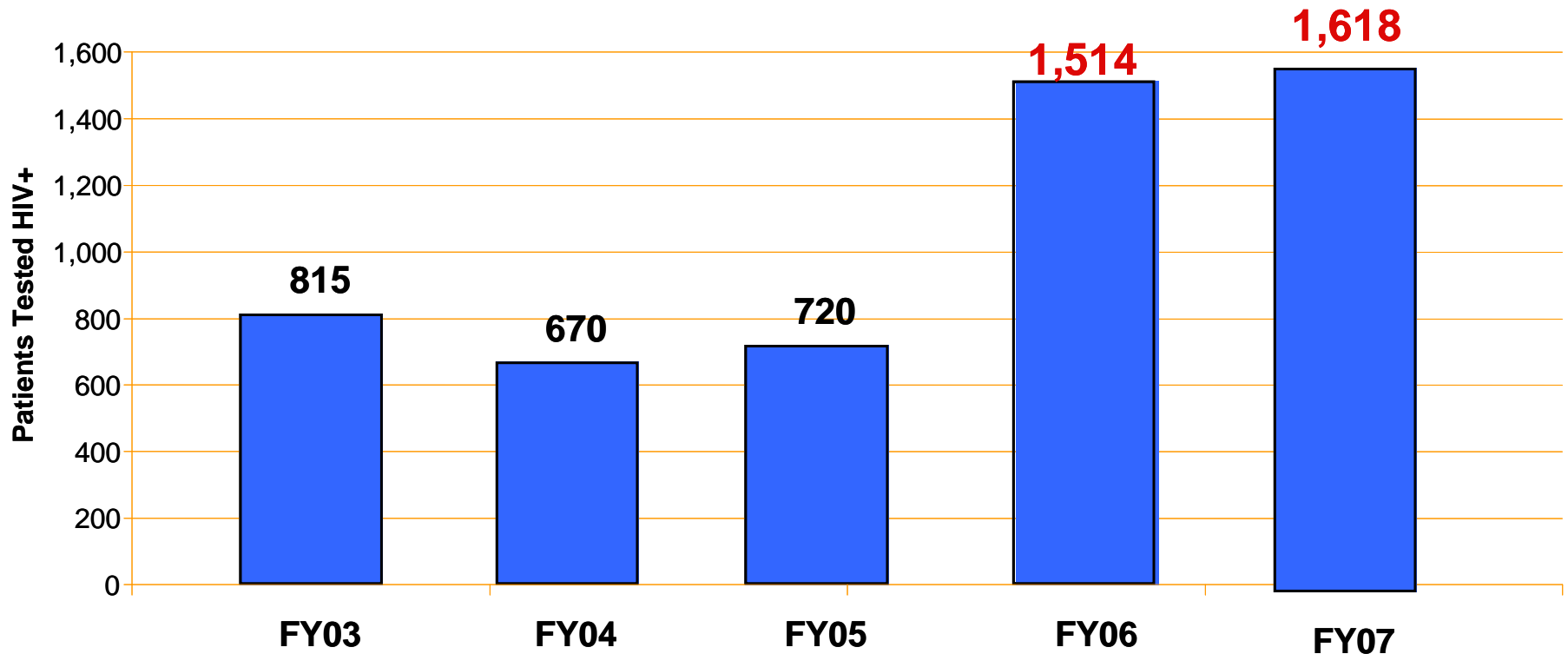


Unpublished data

FY03 – FY05 Outpatient Only (Source: PLM)

FY06-07 Outpatient, Inpatient and ED (Source: Facility Reports)

Number of HIV-Positive Persons Identified More than Doubled



Unpublished data

FY03 – FY04 Outpatient Only (Source: PLM)

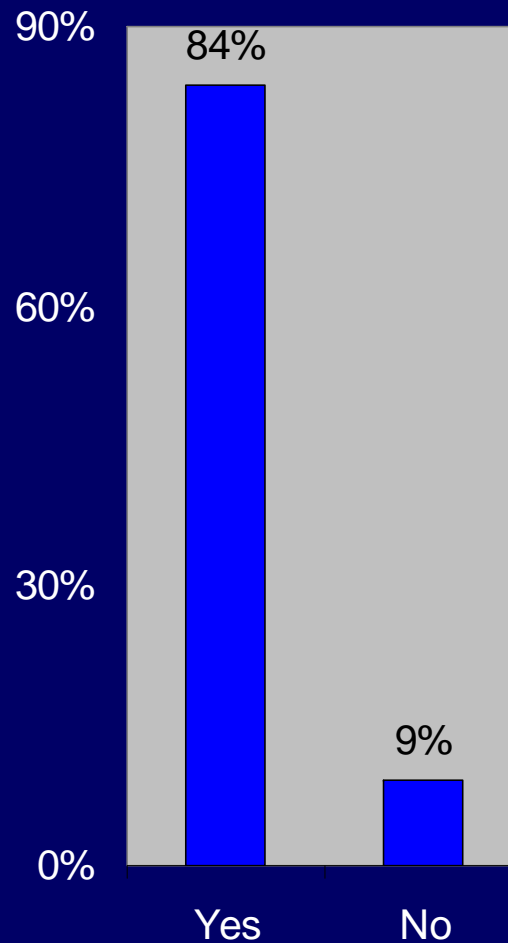
FY05 Outpatient and ED Pilot Sites Only (Source: PLM and RHT in ED Pilot Project Reports)

FY06-07 Outpatient, Inpatient and ED (Source: Facility Reports)

What do the patients think?

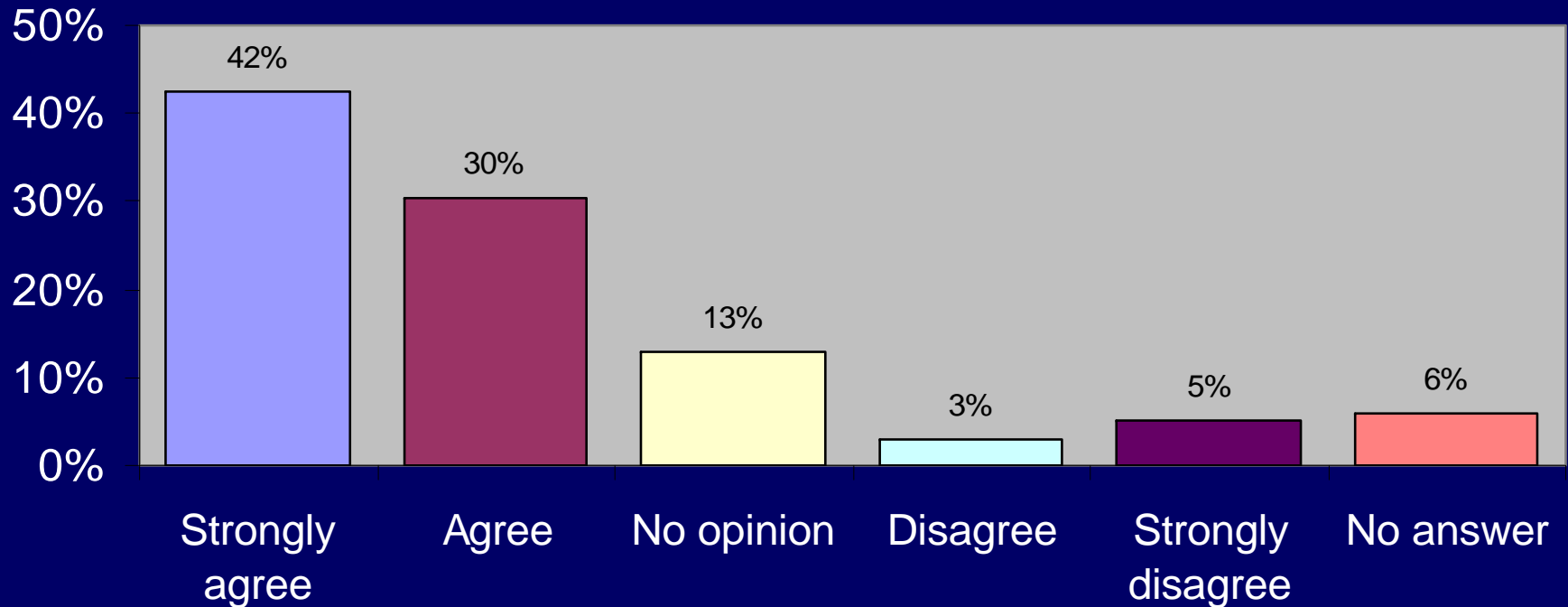
Would you recommend to a friend to get an HIV test if they went to the ED?

- Preliminary data, 680 pts
GW University Hospital ED



What do the patients think?

“The ED is a good place to perform HIV testing”



- Preliminary data, 680 pts, GW University Hospital ED

2006 Recommendations: New Paradigms

- Persons likely to be at high risk include injection-drug users and their sex partners, persons who exchange sex for money or drugs, sex partners of HIV-infected persons, and MSM or heterosexual persons who themselves or whose sex partners have had more than one sex partner since their most recent HIV test.
- Health-care providers should encourage patients and their prospective sex partners to be tested before initiating a new sexual relationship.



Sexual and Drug Behavior Patterns US Adolescents Age 18-26

- National Longitudinal Study of Adolescent Health (school based-survey) started in 1994-1995.
- Wave III follow-up 2001-02 interviewed 14,322 young adults (76% response rate)
- Biomarkers:
 - Urine collected for STDs
 - Oral fluid for HIV



- Hallfors et al, *AJPH* Jan 2007



Sexual and Drug Behavior Patterns US Adolescents Age 18-26

Risk Behavior Pattern

White

Black



- Hallfors et al, *AJPH* Jan 2007



Sexual and Drug Behavior Patterns US Adolescents Age 18-26

<i>Risk Behavior Pattern</i>	<i>White</i>	<i>Black</i>
Few partners, low ATOD	12.7%	37.6%



- Hallfors et al, *AJPH* Jan 2007



Sexual and Drug Behavior Patterns US Adolescents Age 18-26

<i>Risk Behavior Pattern</i>	<i>White</i>	<i>Black</i>
Few partners, low ATOD	12.7%	37.6%
Light alcohol and sexual activity	14.4%	14.7%



- Hallfors et al, *AJPH* Jan 2007



Sexual and Drug Behavior Patterns US Adolescents Age 18-26

<i>Risk Behavior Pattern</i>	<i>White</i>	<i>Black</i>
Few partners, low ATOD	12.7%	37.6%
Light alcohol and sexual activity	14.4%	14.7%
Low risk behavior	11.4%	12.0%



- Hallfors et al, *AJPH* Jan 2007



Sexual and Drug Behavior Patterns US Adolescents Age 18-26

<i>Risk Behavior Pattern</i>	<i>White</i>	<i>Black</i>
Few partners, low ATOD	12.7%	37.6%
Light alcohol and sexual activity	14.4%	14.7%
Low risk behavior	11.4%	12.0%
Binge drinking	9.8%	4.0%



- Hallfors et al, AJPH Jan 2007



Sexual and Drug Behavior Patterns US Adolescents Age 18-26

<i>Risk Behavior Pattern</i>	<i>White</i>	<i>Black</i>
Few partners, low ATOD	12.7%	37.6%
Light alcohol and sexual activity	14.4%	14.7%
Low risk behavior	11.4%	12.0%
Binge drinking	9.8%	4.0%
Substance use and sexual activity	9.0%	1.9%



- Hallfors et al, *AJPH* Jan 2007



Sexual and Drug Behavior Patterns US Adolescents Age 18-26

<i>Risk Behavior Pattern</i>	<i>White</i>	<i>Black</i>
Few partners, low ATOD	12.7%	37.6%
Light alcohol and sexual activity	14.4%	14.7%
Low risk behavior	11.4%	12.0%
Binge drinking	9.8%	4.0%
Substance use and sexual activity	9.0%	1.9%
Regret: AOD use with sex	8.0%	1.9%



- Hallfors et al, AJPB Jan 2007



Sexual and Drug Behavior Patterns US Adolescents Age 18-26

<i>Risk Behavior Pattern</i>	<i>White</i>	<i>Black</i>
Few partners, low ATOD	12.7%	37.6%
Light alcohol and sexual activity	14.4%	14.7%
Low risk behavior	11.4%	12.0%
Binge drinking	9.8%	4.0%
Substance use and sexual activity	9.0%	1.9%
Regret: AOD use with sex	8.0%	1.9%
Multiple partners	2.9%	3.0%



- Hallfors et al, *AJPH* Jan 2007



Sexual and Drug Behavior Patterns US Adolescents Age 18-26

<i>Risk Behavior Pattern</i>	<i>White</i>	<i>Black</i>
Few partners, low ATOD	12.7%	37.6%
Light alcohol and sexual activity	14.4%	14.7%
Low risk behavior	11.4%	12.0%
Binge drinking	9.8%	4.0%
Substance use and sexual activity	9.0%	1.9%
Regret: AOD use with sex	8.0%	1.9%
Multiple partners	2.9%	3.0%
Sex for money	1.1%	6.8%



- Hallfors et al, *AJPH* Jan 2007



STD and HIV Prevalences by Race US Adolescents Age 18-26

Risk Behavior Pattern

White

Black



- Hallfors et al, AJPH Jan 2007



STD and HIV Prevalences by Race US Adolescents Age 18-26

<i>Risk Behavior Pattern</i>	<i>White</i>	<i>Black</i>
Few partners, low ATOD	3.2%	20.3%



- Hallfors et al, *AJPH* Jan 2007



STD and HIV Prevalences by Race US Adolescents Age 18-26

<i>Risk Behavior Pattern</i>	<i>White</i>	<i>Black</i>
Few partners, low ATOD	3.2%	20.3%
Light alcohol and sexual activity	3.1%	17.4%



- Hallfors et al, AJPH Jan 2007



STD and HIV Prevalences by Race US Adolescents Age 18-26

<i>Risk Behavior Pattern</i>	<i>White</i>	<i>Black</i>
Few partners, low ATOD	3.2%	20.3%
Light alcohol and sexual activity	3.1%	17.4%
Low risk behavior	0.5%	12.4%



- Hallfors et al, AJPH Jan 2007



STD and HIV Prevalences by Race

US Adolescents Age 18-26

<i>Risk Behavior Pattern</i>	<i>White</i>	<i>Black</i>
Few partners, low ATOD	3.2%	20.3%
Light alcohol and sexual activity	3.1%	17.4%
Low risk behavior	0.5%	12.4%
Binge drinking	2.3%	15.6%



- Hallfors et al, AJPB Jan 2007



STD and HIV Prevalences by Race

US Adolescents Age 18-26

<i>Risk Behavior Pattern</i>	<i>White</i>	<i>Black</i>
Few partners, low ATOD	3.2%	20.3%
Light alcohol and sexual activity	3.1%	17.4%
Low risk behavior	0.5%	12.4%
Binge drinking	2.3%	15.6%
Substance use and sexual activity	3.4%	22.0%



- Hallfors et al, AJPB Jan 2007



STD and HIV Prevalences by Race

US Adolescents Age 18-26

<i>Risk Behavior Pattern</i>	<i>White</i>	<i>Black</i>
Few partners, low ATOD	3.2%	20.3%
Light alcohol and sexual activity	3.1%	17.4%
Low risk behavior	0.5%	12.4%
Binge drinking	2.3%	15.6%
Substance use and sexual activity	3.4%	22.0%
Regret: AOD use with sex	3.5%	19.2%



- Hallfors et al, AJPB Jan 2007



STD and HIV Prevalences by Race

US Adolescents Age 18-26

<i>Risk Behavior Pattern</i>	<i>White</i>	<i>Black</i>
Few partners, low ATOD	3.2%	20.3%
Light alcohol and sexual activity	3.1%	17.4%
Low risk behavior	0.5%	12.4%
Binge drinking	2.3%	15.6%
Substance use and sexual activity	3.4%	22.0%
Regret: AOD use with sex	3.5%	19.2%
Multiple partners	3.4%	9.7%



- Hallfors et al, AJPB Jan 2007



STD and HIV Prevalences by Race

US Adolescents Age 18-26

<i>Risk Behavior Pattern</i>	<i>White</i>	<i>Black</i>
Few partners, low ATOD	3.2%	20.3%
Light alcohol and sexual activity	3.1%	17.4%
Low risk behavior	0.5%	12.4%
Binge drinking	2.3%	15.6%
Substance use and sexual activity	3.4%	22.0%
Regret: AOD use with sex	3.5%	19.2%
Multiple partners	3.4%	9.7%
Sex for money	9.3%	23.2%



- Hallfors et al, *AJPH* Jan 2007



What are the Odds?

<i>Black vs. white adolescents</i>	<i>OR</i>	<i>AOR*</i>
Few partners, low ATOD	7.8	7.1
Light alcohol and sexual activity	6.3	5.8
Low risk behavior	28.9	24.9
Binge drinking	8.0	6.4
Substance use and sexual activity	9.7	8.7
Regret: AOD use with sex	7.8	7.2
Multiple partners	3.0	2.7
Sex for money	2.8	2.7

**Adjusted for gender, marital status, school dropout, functional poverty, age at first intercourse*



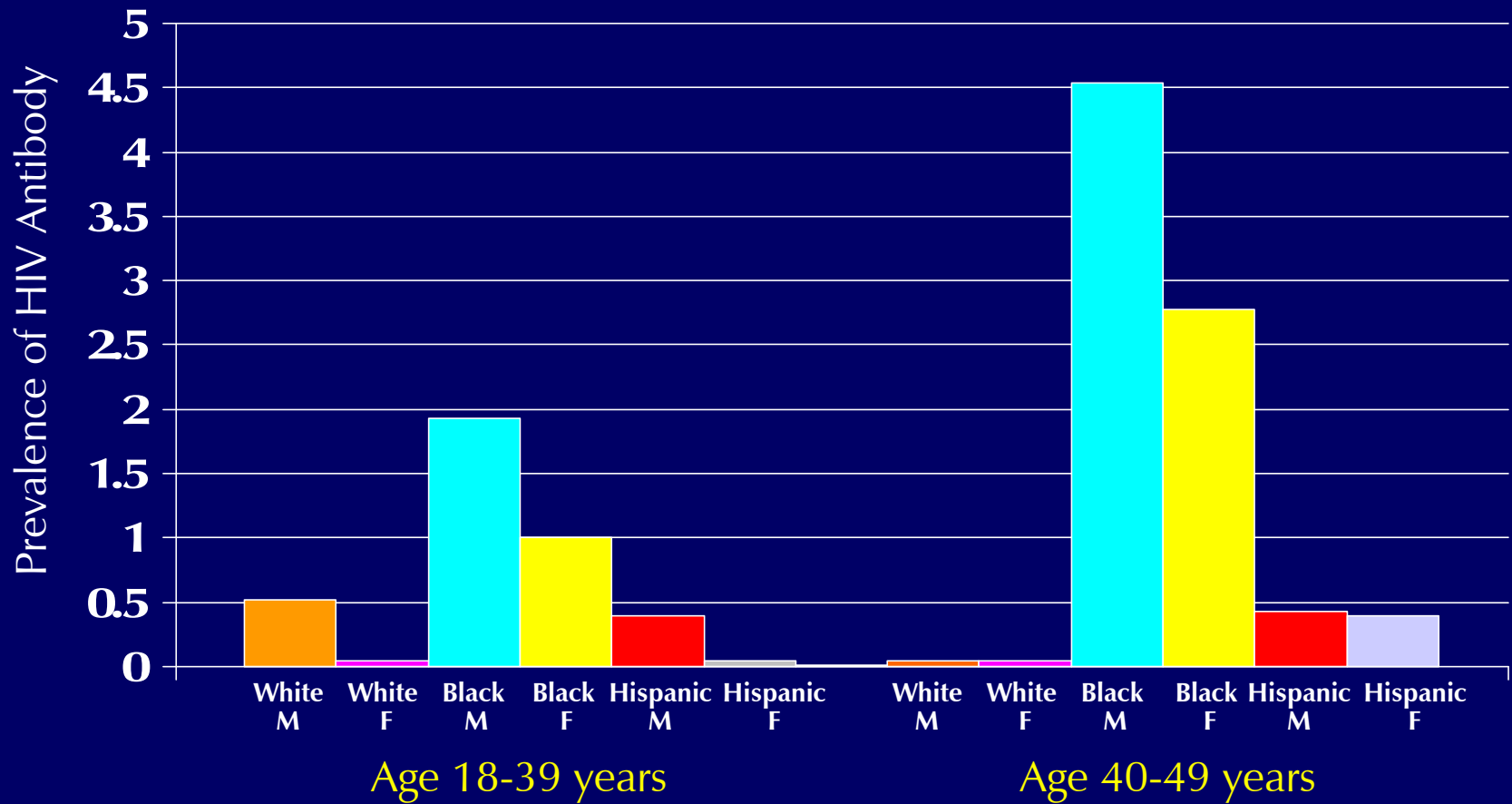
What are the Odds?

<i>Black vs. white adolescents</i>	<i>OR</i>	<i>AOR*</i>
Few partners, low ATOD	7.8	7.1
Light alcohol and sexual activity	6.3	5.8
Low risk behavior	28.9	24.9
Binge drinking	8.0	6.4
Substance use and sexual activity	9.7	8.7
Regret: AOD use with sex	7.8	7.2
Multiple partners	3.0	2.7
Sex for money	2.8	2.7

**Adjusted for gender, marital status, school dropout, functional poverty, age at first intercourse*



HIV Prevalence, NHANES 1999-2002



- McQuillan et al, NCHS: JAIDS April 2006



A “Perfect Storm” Effect

- *Assortative mixing*: sexual mating patterns are largely segregated according to race (like with like)
- *Dissortative mixing*: Blacks are more likely than Whites to cross high- and low-risk behavior groupings when choosing sexual partners

Per-Act Relative Risk of HIV Acquisition

- Choice of partner
- Type of sex act
- Condom Use



- Varghese et al, *Sex Transm Dis* 2002



Per-Act Relative Risk of HIV Acquisition: Choice of Partner, Sex Act, Condom Use

<u>Partner Status</u>	<u>RR</u>
-----------------------	-----------

1% prevalence

HIV-neg	1
Unknown	47
HIV-pos	4706

10% prevalence

HIV-neg	1
Unknown	43
HIV-pos	430



- Varghese et al, Sex Transm Dis 2002



Per-Act Relative Risk of HIV Acquisition: Choice of Partner, Sex Act, Condom Use

<u>Partner Status</u>	<u>RR</u>	<u>Sex Act</u>	<u>RR</u>
<u>1% prevalence</u>			
HIV-neg	1	Insertive fellatio	1
Unknown	47	Receptive fellatio	2
HIV-pos	4706	Insertive vaginal	10
<u>10% prevalence</u>			
HIV-neg	1	Insertive anal	13
Unknown	43	Receptive vaginal	20
HIV-pos	430	Receptive anal	100



- Varghese et al, Sex Transm Dis 2002



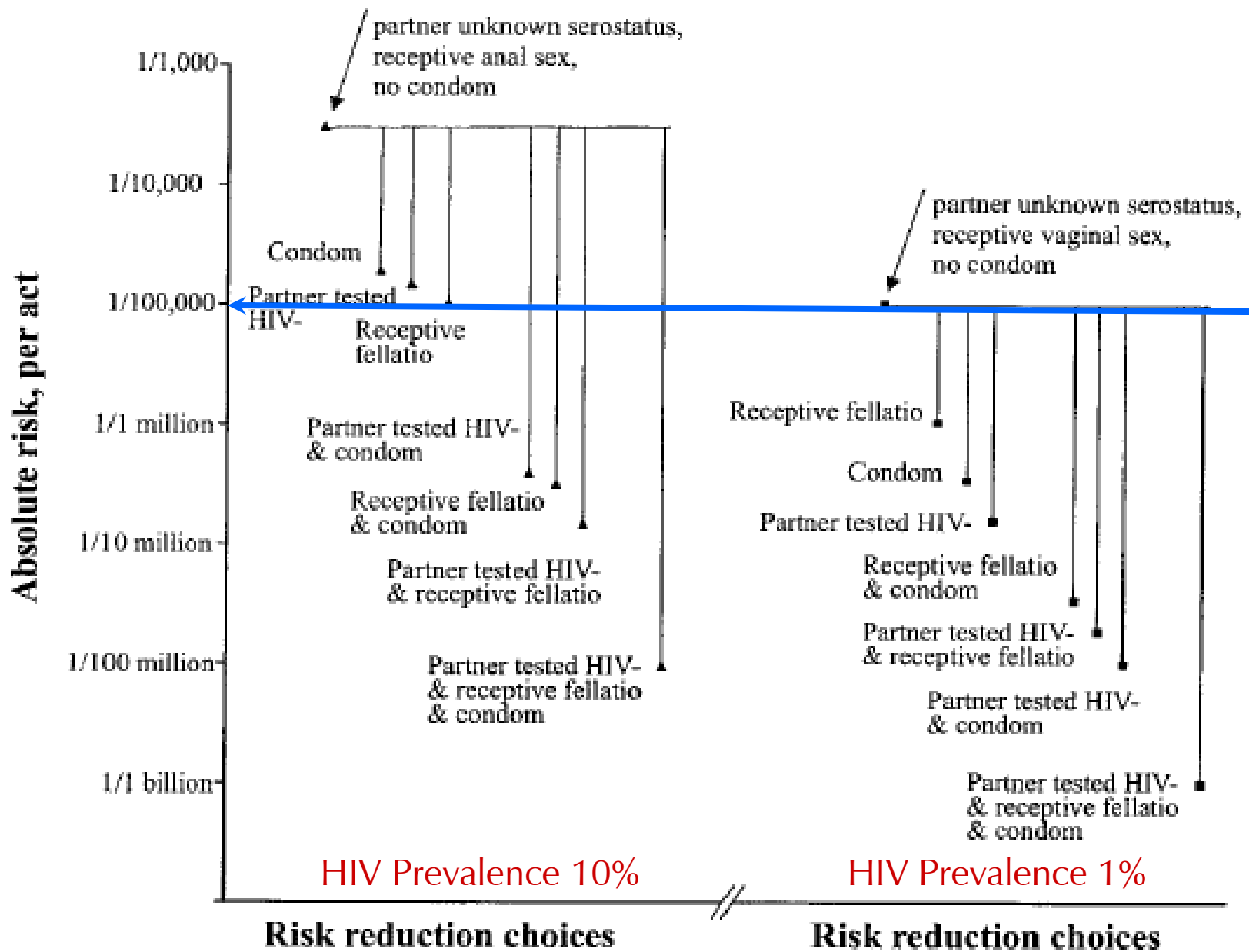
Per-Act Relative Risk of HIV Acquisition: Choice of Partner, Sex Act, Condom Use

<u>Partner Status</u>	<u>RR</u>	<u>Sex Act</u>	<u>RR</u>	<u>Condoms</u>	<u>RR</u>
<u>1% prevalence</u>					
HIV-neg	1	Insertive fellatio	1	Yes	1
Unknown	47	Receptive fellatio	2	No	20
HIV-pos	4706	Insertive vaginal	10		
<u>10% prevalence</u>					
HIV-neg	1	Insertive anal	13		
Unknown	43	Receptive vaginal	20		
HIV-pos	430	Receptive anal	100		



- Varghese et al, Sex Transm Dis 2002





- Varghese et al, Sex Transm Dis 2002

Conclusions

- The choice of partner is the most important factor determining the risk for HIV infection.
- People often rely on implicit theories about their partners to determine their level of HIV risk, and they do not ask about their partners' HIV status.
- Choosing a partner who has tested negative for HIV reduces risk 47-fold; using condoms reduces risk 20-fold.

2006 Recommendations: New Paradigm

- Health-care providers should encourage patients and their prospective sex partners to be tested before initiating a new sexual relationship.



Summary

- Health-care settings are important venues for HIV screening
- Routine testing offers immediate clinical benefits
- Expanded screening will require incremental and alternative approaches, such as
 - Increased physician referral
 - Adding HIV when other tests are ordered
 - Development of locally relevant screening criteria
- One size will not fit all

