

HIV Screening in Health-Care Settings: New Approaches and New Paradigms

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Presentation Outline

- Where we are now –
 - HIV epidemic
 - Current testing
 - Previous recommendations and their effects
- The case for increased HIV testing
- New Recommendations
- Implications for women and infants



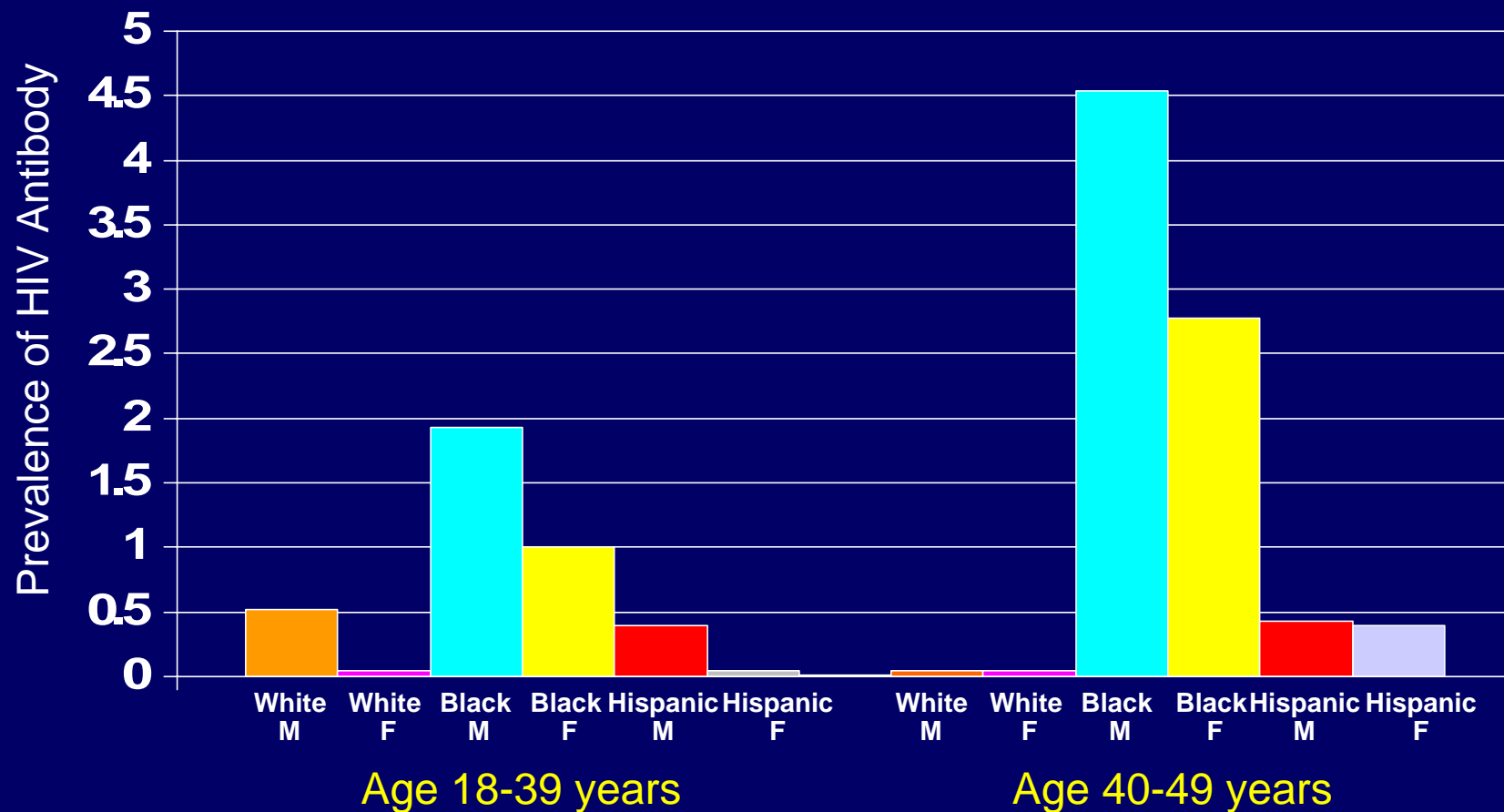
Awareness of HIV Status among Persons with HIV, United States

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	40,000

Glynn M, Rhodes P. 2005 HIV Prevention Conference



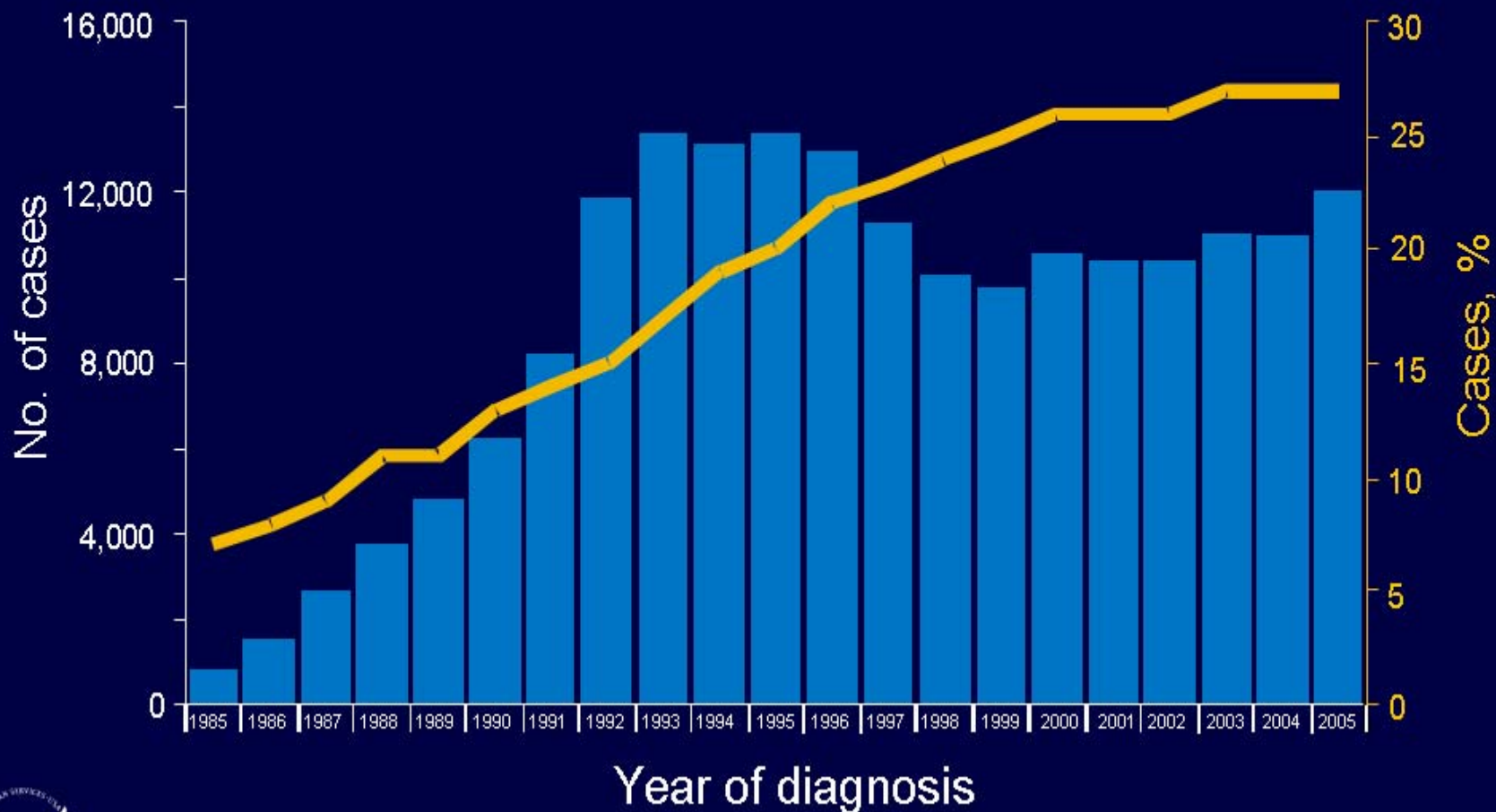
HIV Prevalence, NHANES 1999-2002



- McQuillan et al, NCHS: JAIDS April 2006



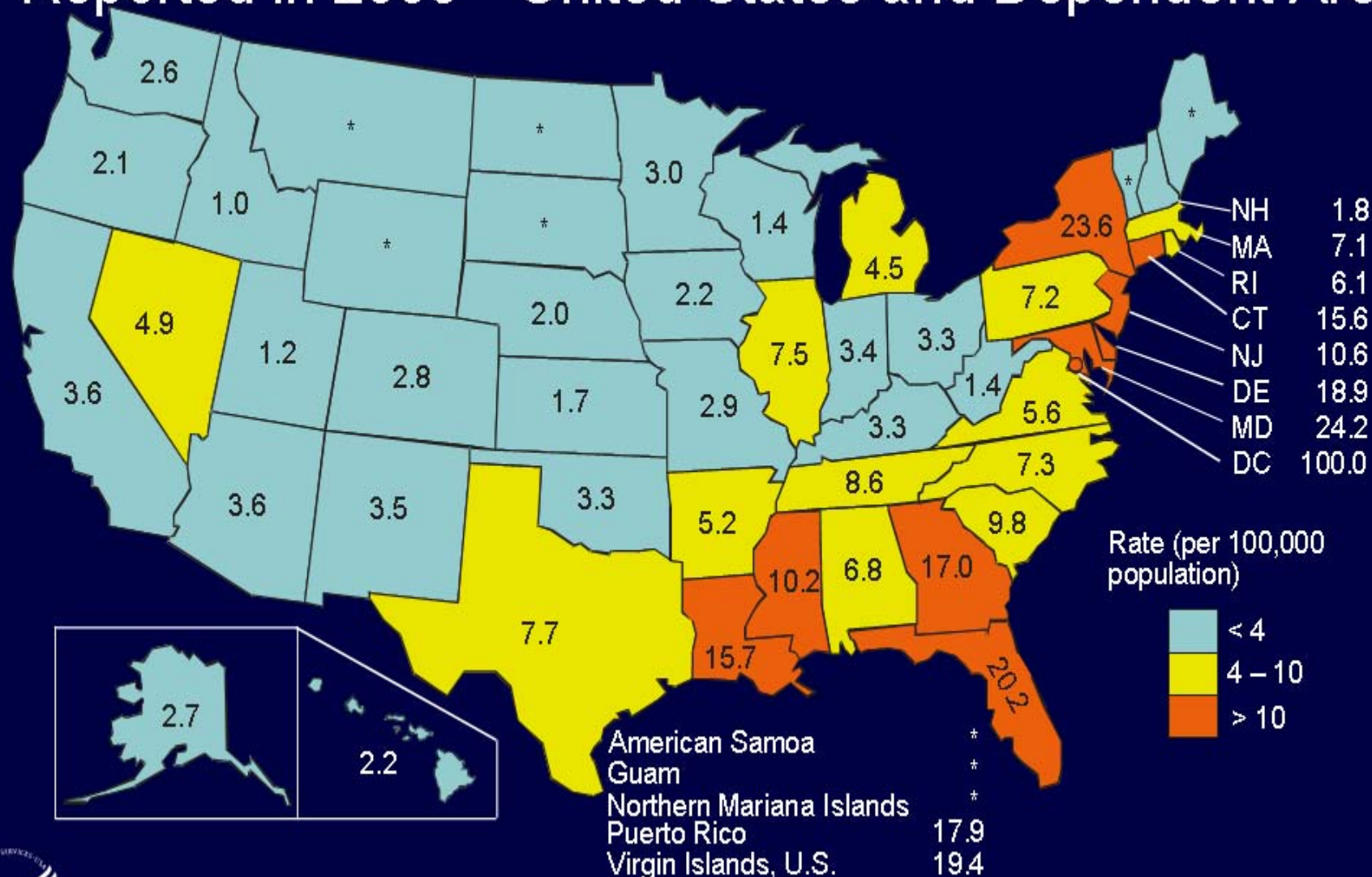
Estimated Number and Proportion of AIDS Cases among Female Adults and Adolescents 1985–2005—United States and Dependent Areas



Note. Data have been adjusted for reporting delays.



AIDS Rates for Female Adults and Adolescents Reported in 2005—United States and Dependent Areas



* Rates were not calculated for areas reporting fewer than 5 AIDS cases in females in 2005.



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.

	<u>HIV tests*</u>	<u>HIV+ tests**</u>
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

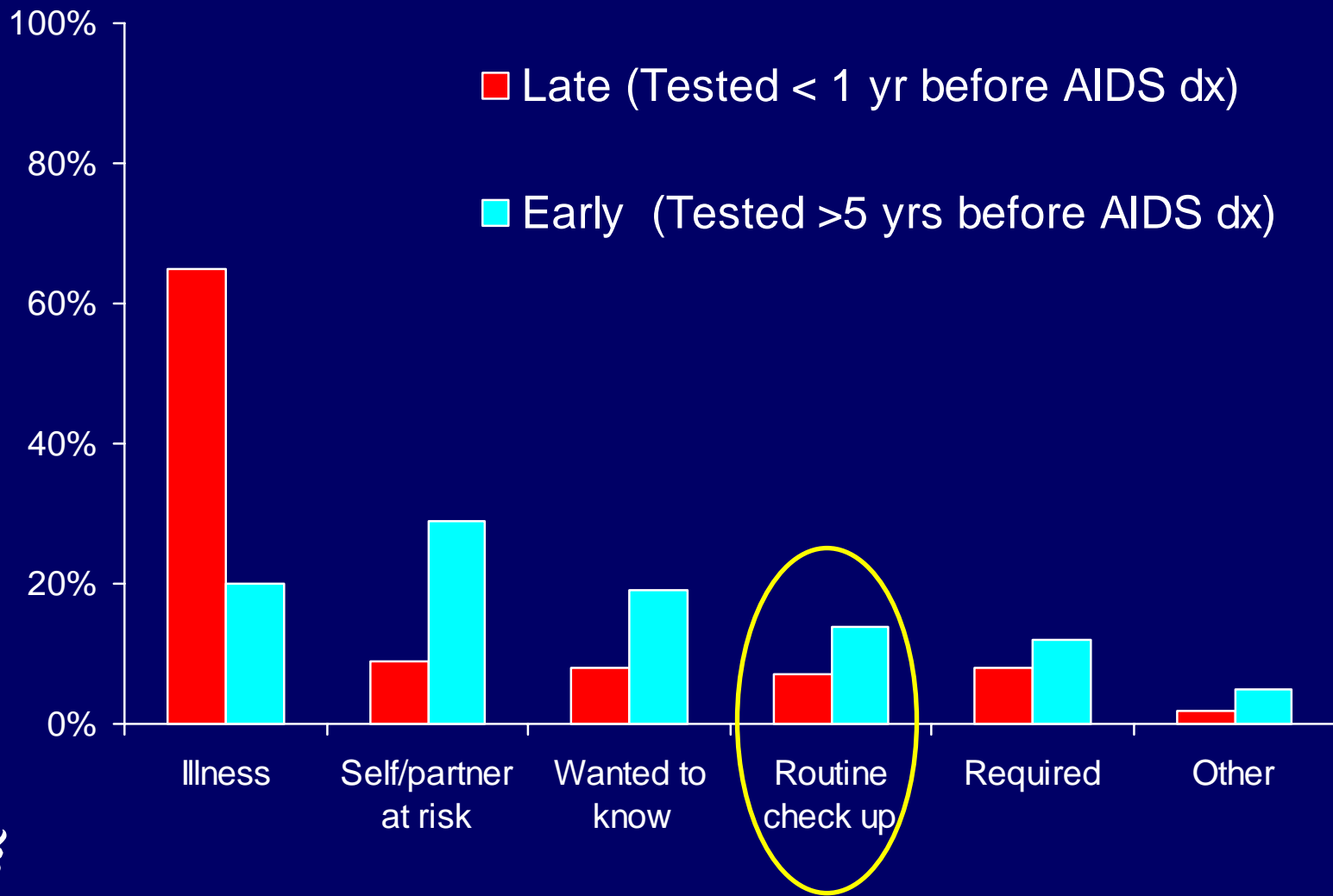
MMWR June 27, 2003

*16 states



Reasons for testing: late versus early testers

Supplement to HIV/AIDS Surveillance, 2000-2003



Missed Opportunities: South Carolina

- All reported cases of HIV, 2001 - 2005
- Confidentially matched with registry of health care visits:
 - 60 emergency departments
 - 62 inpatient facilities
 - 63 ambulatory surgery facilities
 - 19 free medical clinics



MMWR 55:47, December 1, 2006



Missed Opportunities: South Carolina

- 4,315 reported HIV cases
 - 3,157 (73%) made 20,271 health-care visits prior to their first positive HIV test
 - Diagnosis codes at 15,648 (77%) of prior visits would not have prompted an HIV test



MMWR 55:47, December 1, 2006



Missed Opportunities: South Carolina

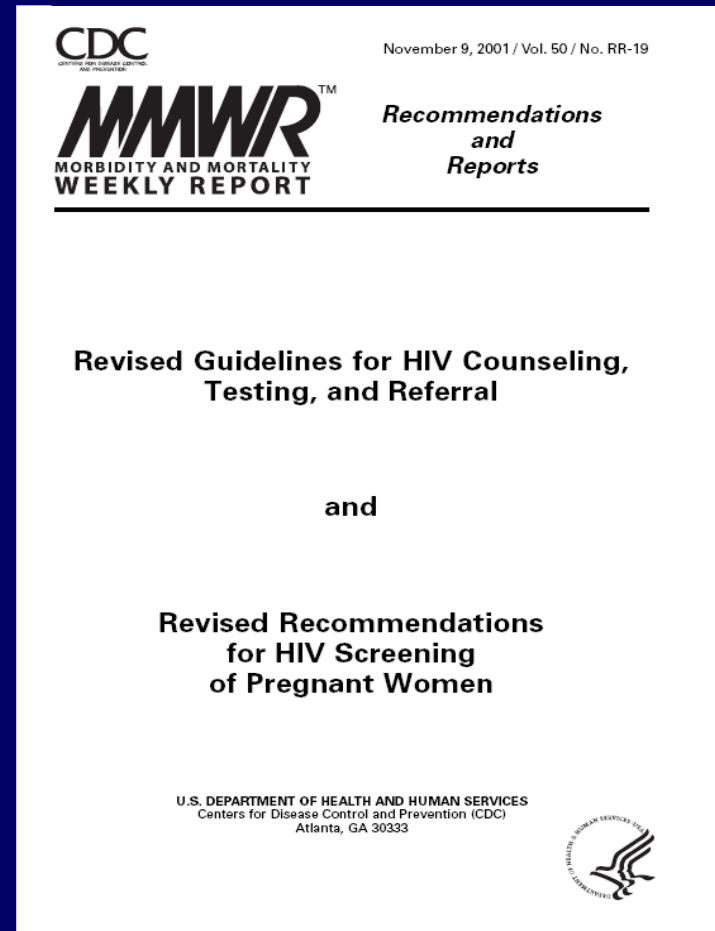
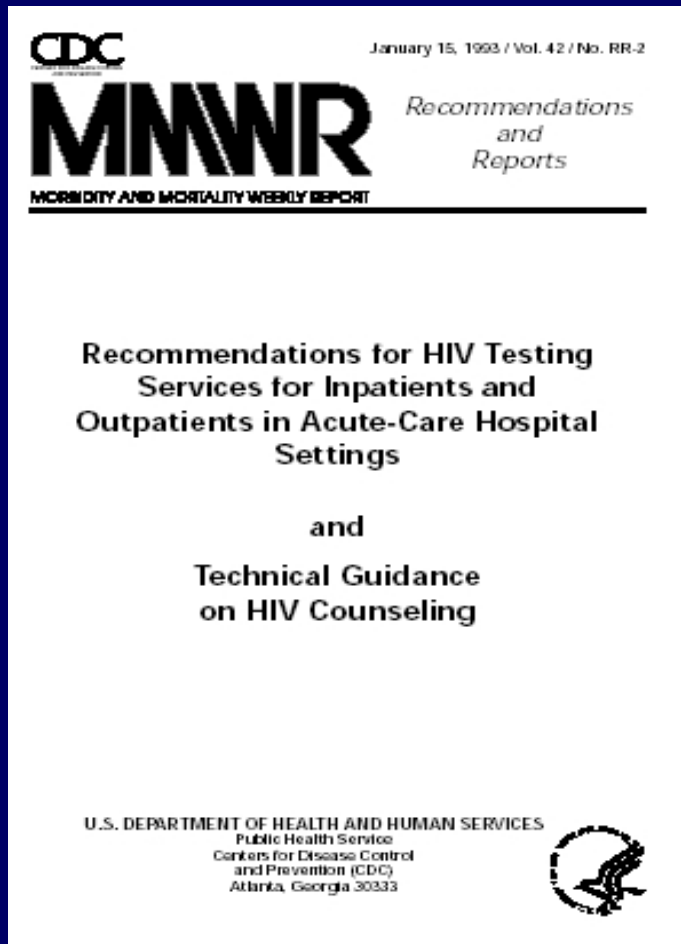
- 1,784 (42%) developed AIDS within 1 year
- 1,302 (73%) made 7,988 previous health-care visits (*median 4 per patient*) but were not tested for HIV
- 6,303 (79%) were visits to emergency departments
- Diagnosis codes for 6,277 (79%) of prior visits would not have prompted an HIV test



MMWR 55:47, December 1, 2006



Previous Recommendations



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



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%



Are Recommendations Having Their Intended Effect?

Advance Data

From Vital and Health Statistics



Number 340 • March 18, 2004

National Hospital Ambulatory Medical Care Survey: 2002 Emergency Department Summary

by Linda F. McCaig, M.P.H., and Catharine W. Burt, Ed.D., Division of Health Care Statistics



HIV Testing Practices in EDs

- Survey of 154 ED providers
 - Average: 13 STD patients per week
 - Only 10% always recommend HIV test
- Reasons for not testing for HIV:
 - 51% concerned about follow up
 - 45% not a “certified” counselor
 - 19% too time-consuming
 - 27% HIV testing not available

-Fincher-Mergi et al, 2002: AIDS Pat Care STDs

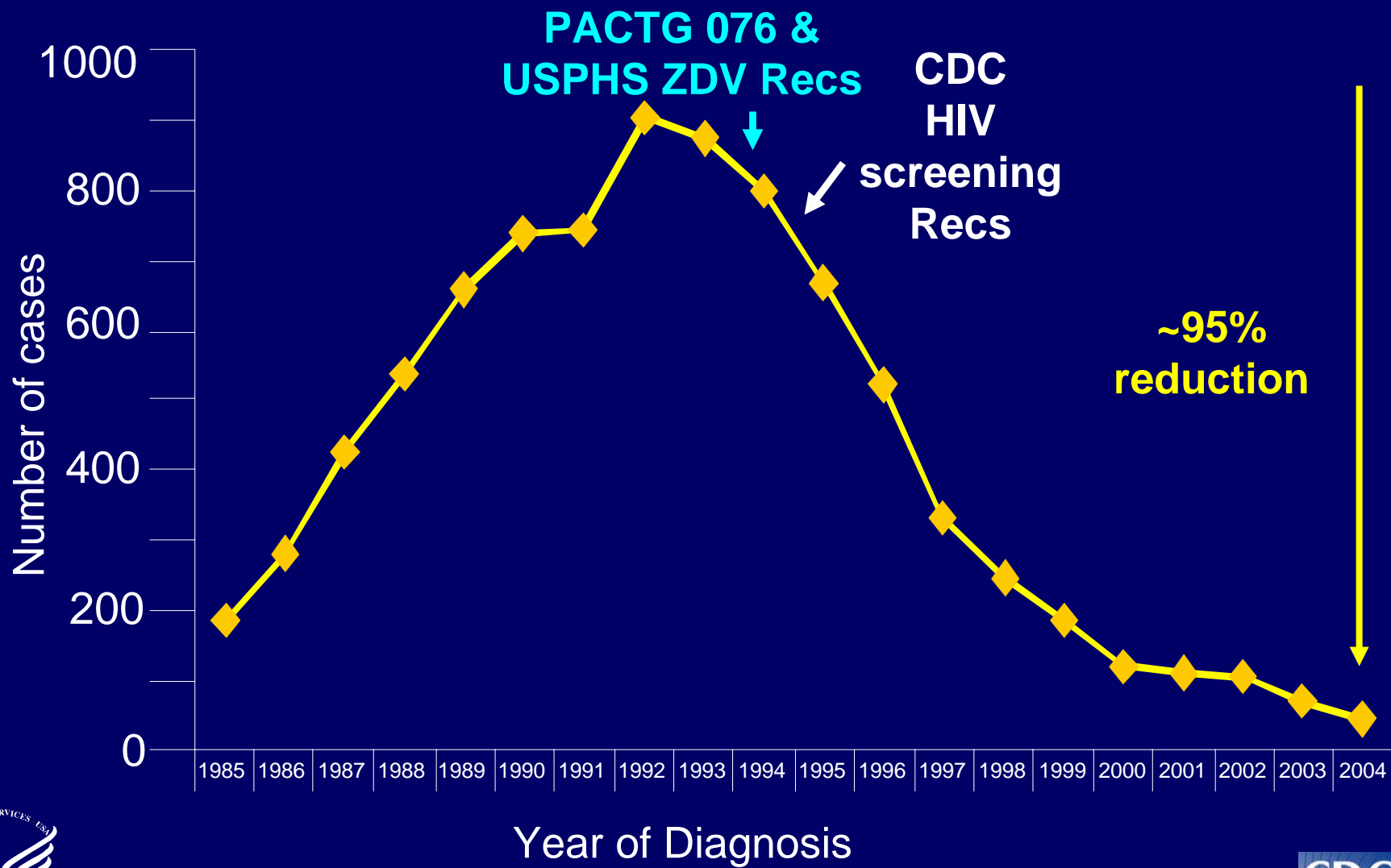


Previous CDC Recommendations Pregnant Women

- 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, 1985-2004 – United States





MMWRTM

Morbidity and Mortality Weekly Report

Recommendations and Reports

September 22, 2006 / Vol. 55 / No. RR-14

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



<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
- When acute retroviral infection is a possibility, use an RNA test in conjunction with an antibody test



Revised Recommendations Adults and Adolescents - II

- Opt-out HIV screening with the opportunity to ask questions and the option to decline testing
- Separate signed informed consent not recommended
- Prevention counseling in conjunction with HIV screening in health care settings is not required
- Communicate test results in same manner as other diagnostic/screening tests



Revised Recommendations Adults and Adolescents - III

- Settings with low or unknown prevalence:
 - Initiate screening
 - If yield from screening is less than 1 per 1000, continued screening is not warranted
- May need to resolve conflicts between the recommendations and state or local regulations

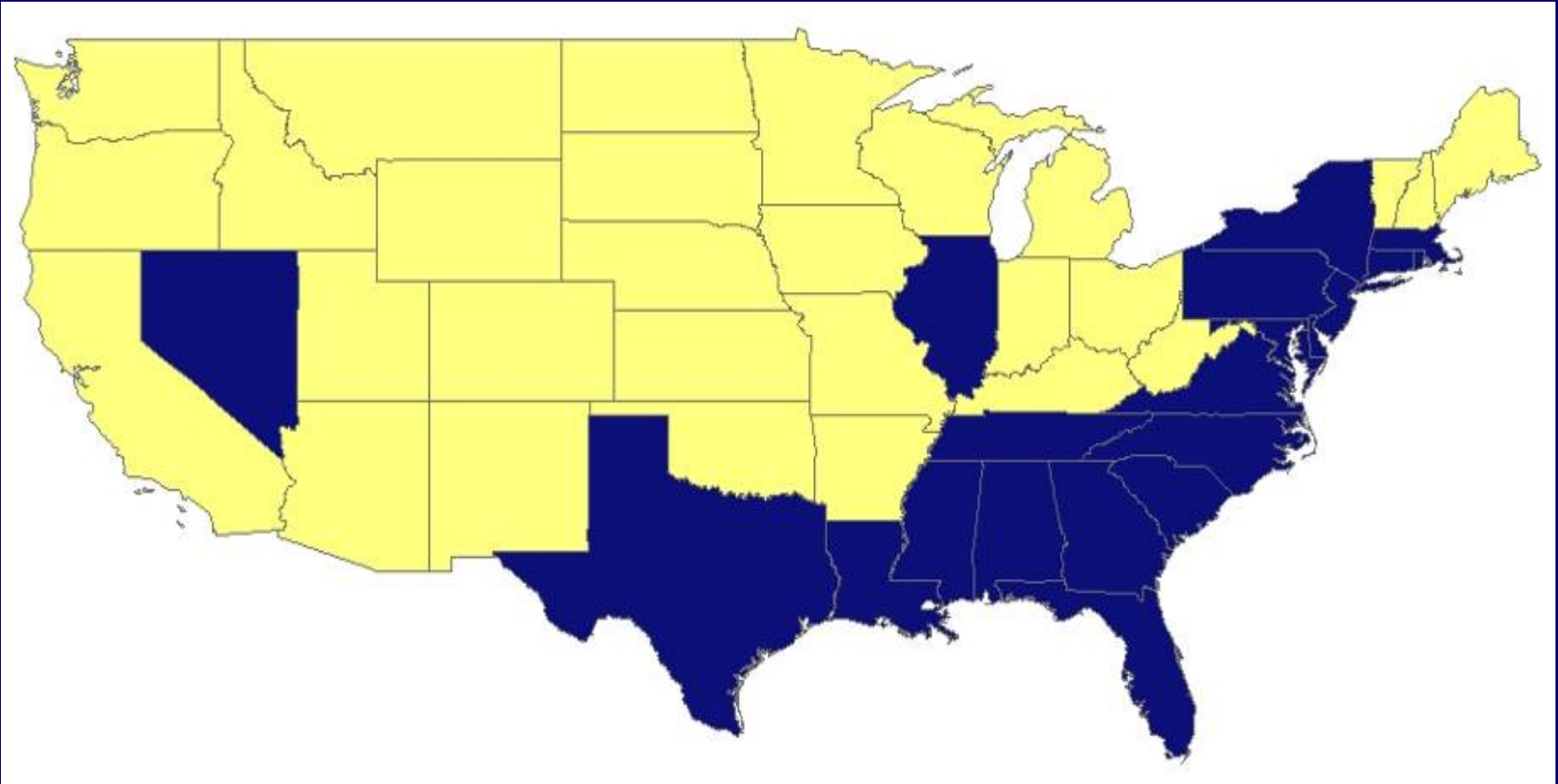



CDC Revised Recommendations Pregnant Women - I

- Universal opt-out HIV screening
 - Include HIV in routine panel of prenatal screening tests during each pregnancy
 - Consent for prenatal care includes HIV testing
 - Notification and option to decline
- 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



22 Jurisdictions with elevated HIV or AIDS Case Rates Among Women aged 15-45, 2004*



 ≥ 7 HIV cases or ≥ 9 AIDS cases per 100,000 women
*includes Puerto Rico (not shown)



Revised Recommendations Pregnant Women - II

- Opt-out rapid testing 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



Revised Recommendations

Special Considerations for Adolescents

- Discuss HIV screening with ALL adolescents
- Info and counseling on HIV infection and testing part of primary care for adolescents
- Parental involvement not typically required but laws concerning consent and confidentiality **differ among states**



Revised Recommendations Communicating HIV Test Results

- Negative results can be conveyed without direct personal contact
 - High risk offered prevention counseling and advised to retest periodically
- Positive results should be communicated confidentially, through personal contact
 - Friends and family members should not be used as interpreters
 - Linked to counseling, clinical care, and prevention services



Rationale for Revising 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

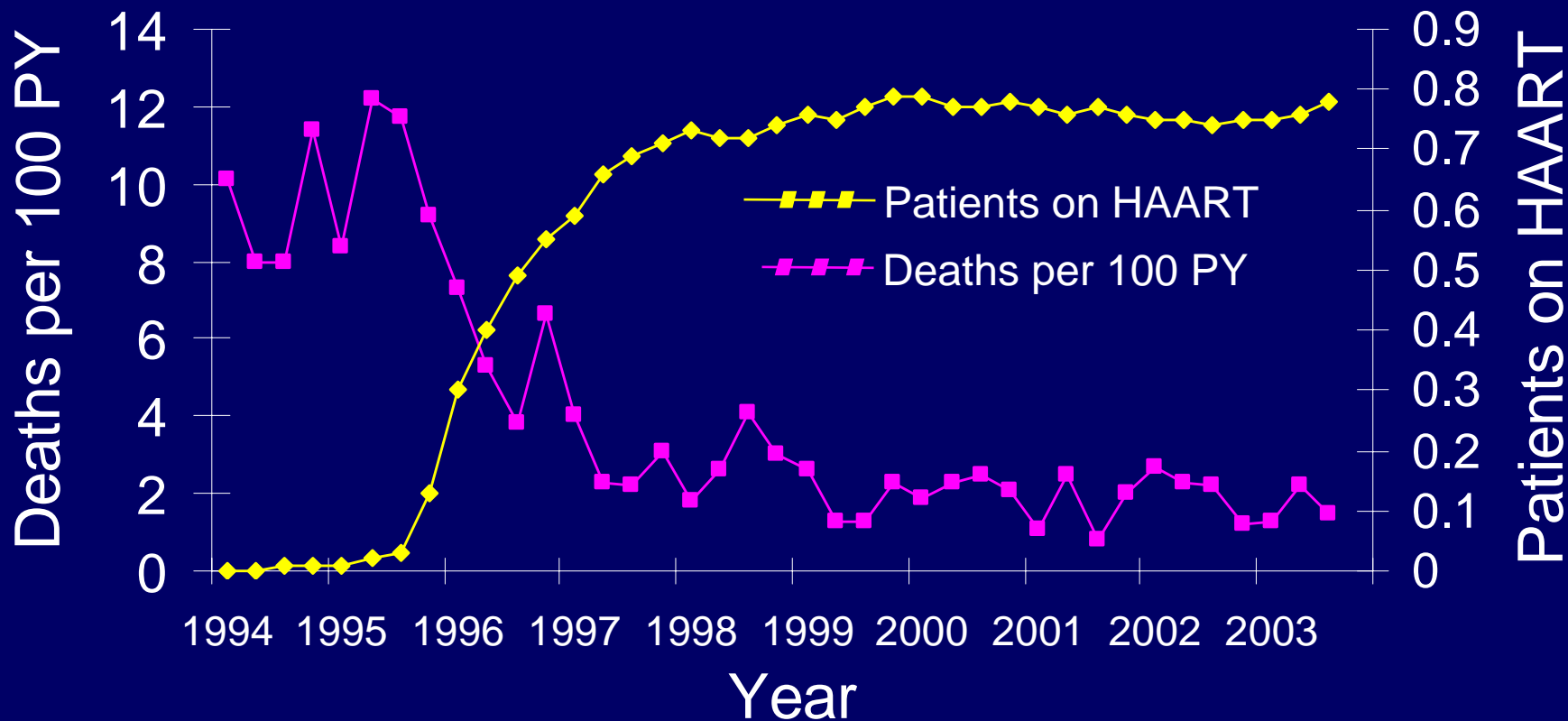
1. Serious health disorder that can be detected before symptoms develop
2. Treatment is more beneficial when begun before symptoms develop
3. Reliable, inexpensive, acceptable screening test
4. Costs of screening are reasonable in relation to anticipated benefits
5. Treatment must be accessible

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



Mortality and HAART Use Over Time

HIV Outpatient Study, CDC, 1994-2003



Knowledge of HIV Infection and Behavior

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

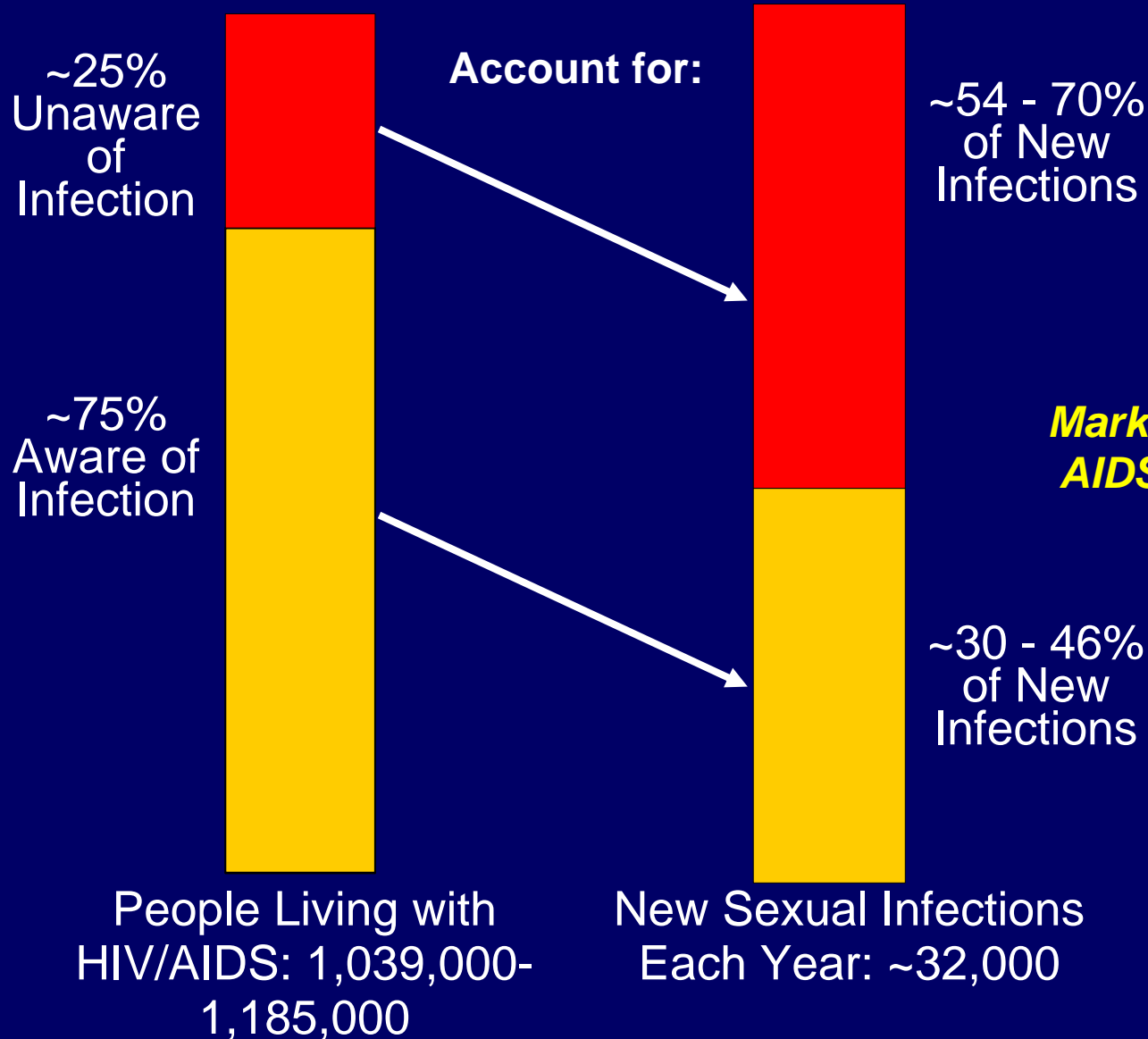
Reduction in Unprotected Anal or Vaginal Intercourse with HIV-neg partners: **68%**
HIV-pos Aware vs. HIV-pos Unaware

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



Awareness of Serostatus Among People with HIV and Estimates of Transmission



Effect of Counseling in Conjunction with HIV testing

- Meta-analysis of 27 studies of HIV-CT:
 - **HIV-positive** participants reduced unprotected intercourse and increased condom use.
 - **HIV-negative** participants did not modify their behavior more than untested participants.



- Weinhardt et al, 1999: *Am J Public Health*



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



Cost Effectiveness

- Expanded screening for HIV in the U.S. – an analysis of cost effectiveness. *Paltiel AD, et al. NEJM 2005;352:586.*

“In all but the lowest-risk populations, routine, voluntary screening for HIV once every 3 to 5 years is justified on both clinical and cost-effectiveness grounds. One-time screening in the general population may also be cost-effective.”



Cost Effectiveness

- Cost-effectiveness of screening for HIV in the era of HAART. *Sanders G, et al. NEJM 2005;352:570.*

“The cost-effectiveness of routine HIV screening in health care settings, even in relatively low-prevalence populations, is similar to that of commonly accepted interventions, and such programs should be expanded.”

1% HIV prevalence: \$15,078 per QALY

>0.05% prevalence: <\$50,000 per QALY



Perinatal: Cost Savings

- Universal prenatal screening is cost savings in the U.S.
- Repeat testing in 3rd trimester is cost-effective in areas of elevated HIV incidence among women of child-bearing age.
- The discounted lifetime treatment cost for perinatally-infected children
 - \$113,476 for 9 years of survival
 - \$228,155 for 25 years of survival
- As years of survival increase for HIV-infected children, the lifetime costs are also likely to increase.



Sansom, et al. JAIDS 41: 4, April 2006



The Status Quo

- Has brought us a long way, but we are currently stalled
- Late diagnosis is frequent, especially of socio-economically disadvantaged persons
- Numerous missed opportunities for earlier diagnosis, treatment, and prevention



Summary

- There is an urgent need to increase the proportion of persons who are aware of their HIV-infection status
- Expanded, routine, voluntary, opt-out screening in health care settings is needed
- Such screening is cost-effective
- Revised recommendations: September 2006
- Several jurisdictions have already begun



Resources

<http://www.cdc.gov/hiv/topics/testing/healthcare/>

- Recommendations
- Slide Sets
- Podcasts
- Fact Sheets
- Journal Articles
- Questions and Answers
 - For professionals and public



Discussion

- Repeat testing in 3rd trimester – what is your state/jurisdiction doing?
- What are the overall implications for:
 - women & children?
 - perinatal programs?
- Opportunities?
- Threats?



MIRIAD Eligibility & Acceptance 2001-2005

- **153,014** visits evaluated at 17 hospital L&D units
- **12,481** women were eligible to participate
 - **38%** had no prenatal care
- **9,233 (74%)** offered MIRIAD (rapid HIV testing)
- **7,898 (86%)** consented for participation/testing

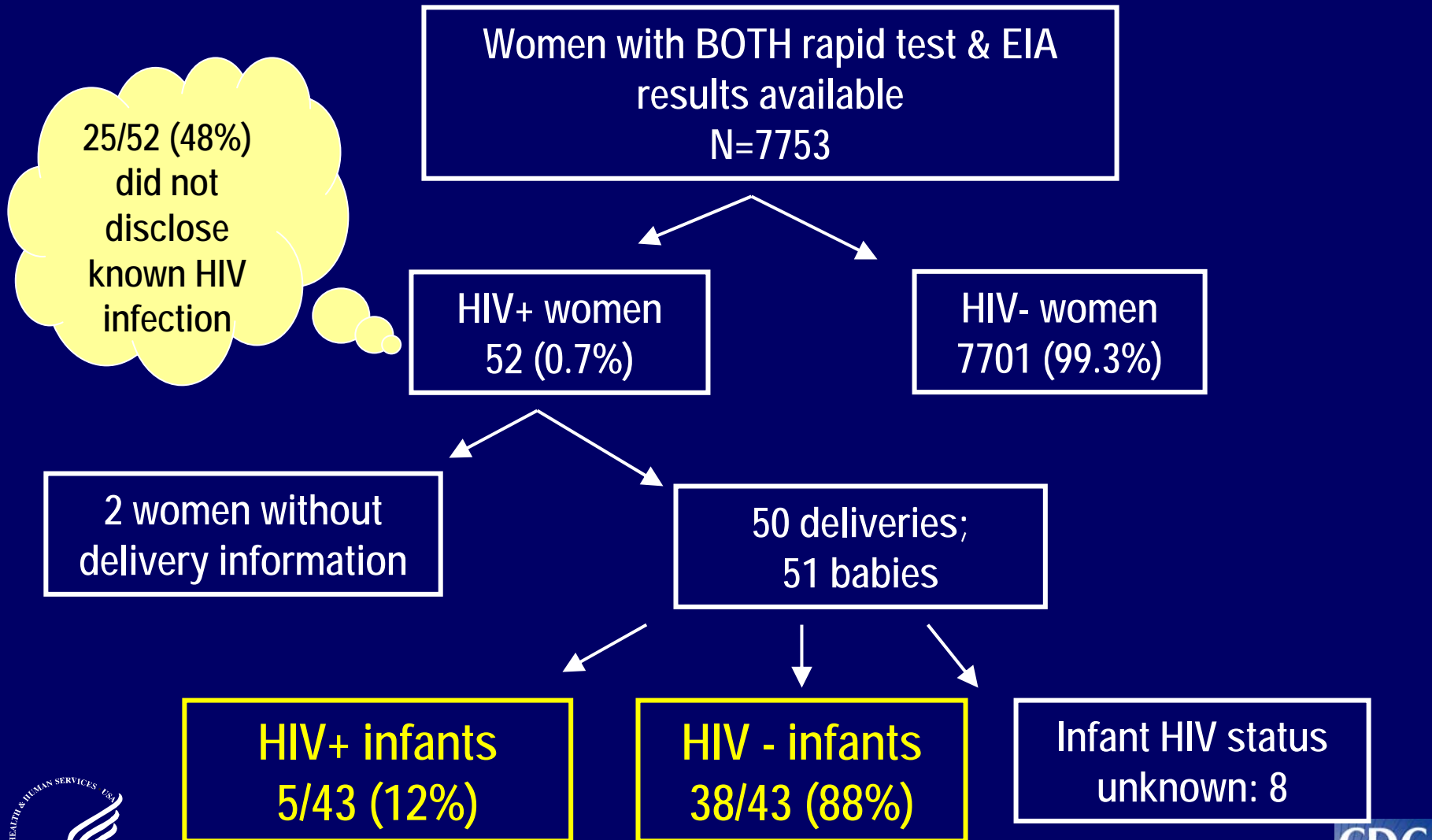
Acceptance rates varied:

- **87.2%** using residual from other labs vs.
- **73.9%** when additional finger stick required.
($p < 0.0001$)



Jamieson, et al. AJOG, In press.

MIRIAD Participants, 2001-2005



Turnaround Times for Rapid Test Results, Point-of-Care vs. Lab Testing: MIRIAD 2001-2005

	Point-of-Care	Laboratory
Arrival on L&D to result to woman	242 min (4hrs, 2min)	295 min (4hrs, 45min)
		p<0.0001
Blood drawn to result to provider	30 min	68 min
		p<0.0001



Jamieson, et al. AJOG, In press.



Odds of < 60 minute turn-around time (blood draw to provider receiving results) MIRIAD, 2001-2005; N=6719

		<u>AOR*</u>	<u>95% CI</u>
Testing Location	Laboratory	1.0	Ref
	Point-of-Care	14.3	(12.3, 16.6)
Hours arrived prior to delivery	0-2	1.0	Ref
	3-6	1.19	(1.02-1.38)
	7-12	1.21	(1.04-1.42)
	>12	1.26	(1.09-1.46)

Adjusted by study site

