# Revised Recommendations for HIV Testing in Healthcare Settings in the U.S.

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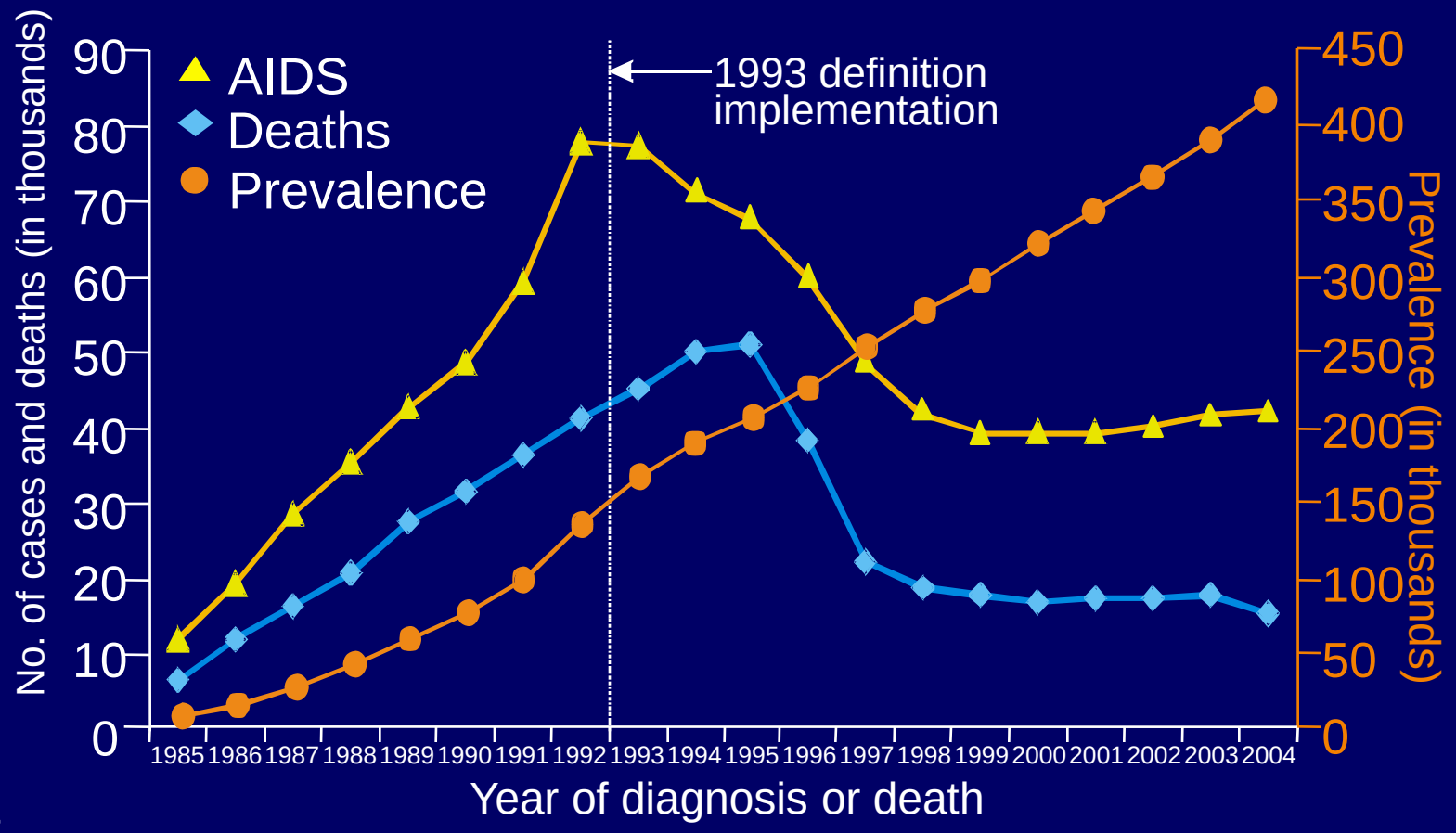
# Presentation Outline

- Where we are now –
  - HIV epidemic
  - Current testing
  - Previous recommendations and their effects
- The case for increased HIV testing
- Rationale for revised recommendations
- CDC's New Recommendations

# Estimated Number of AIDS Cases, Deaths, and Persons Living with AIDS,1985-2004, United States



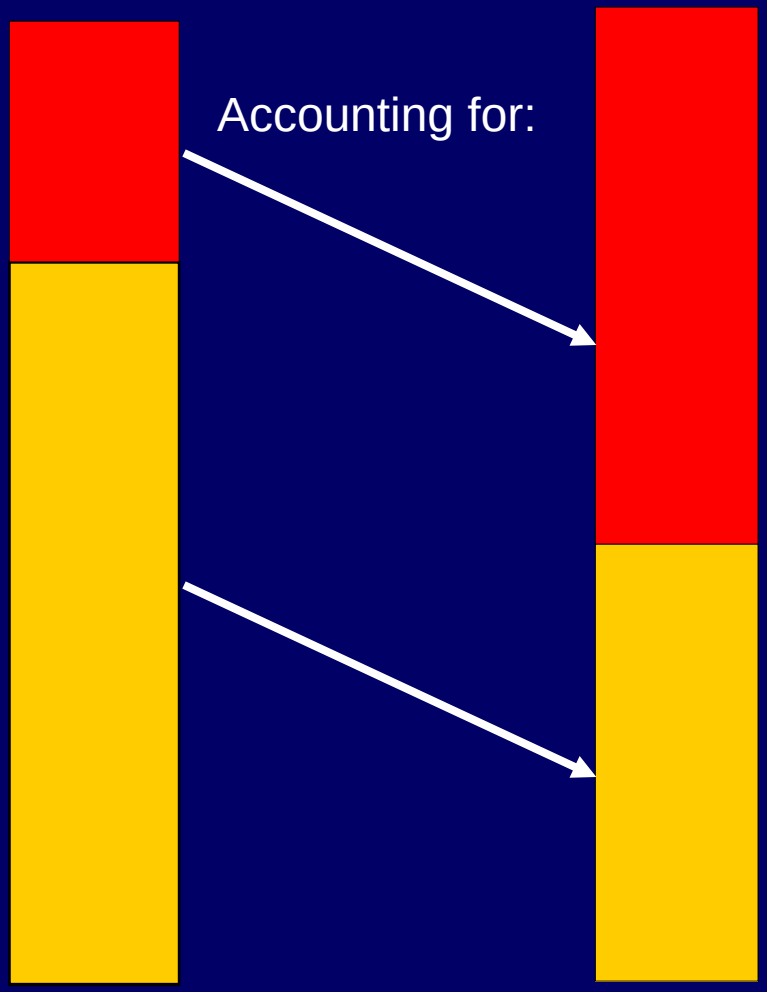

Note. Data adjusted for reporting delays.

# 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*

# Awareness of Serostatus Among People with HIV and Estimates of Transmission

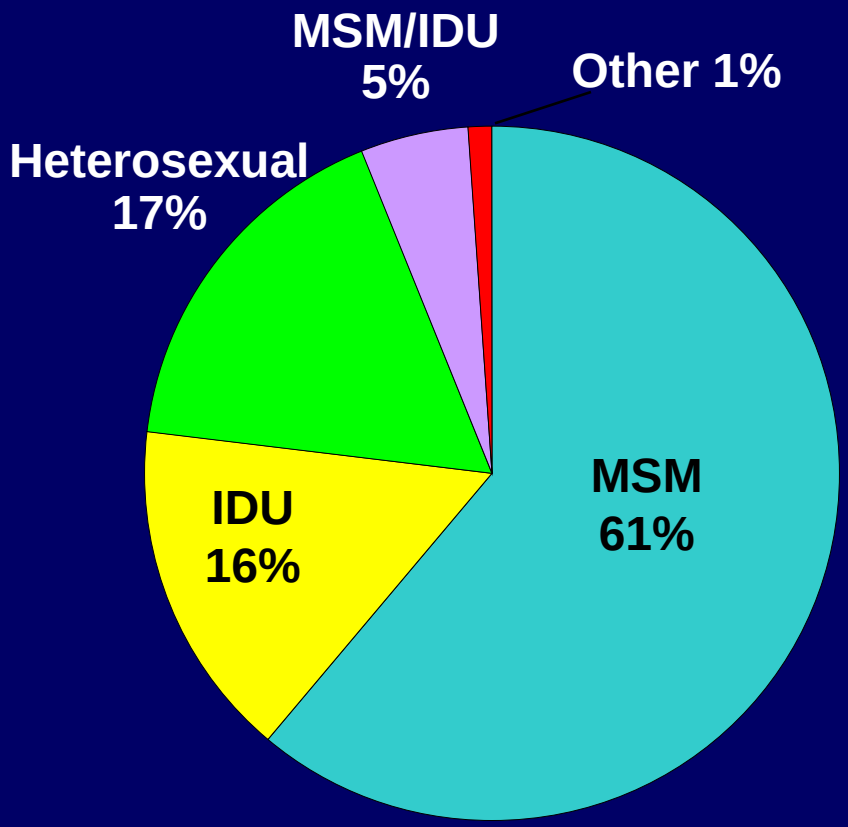



**Marks, et al**
**AIDS 2006;20:1447-50**

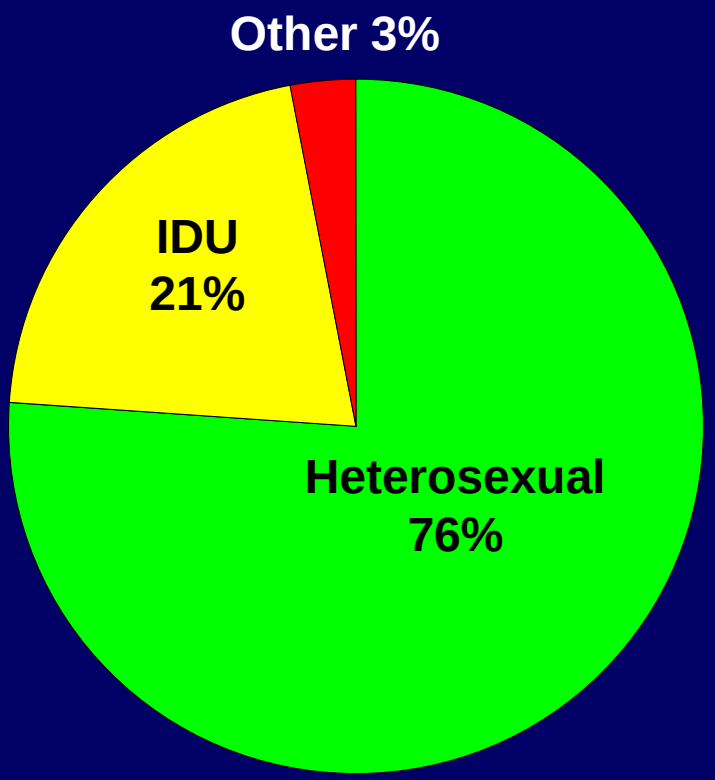
People Living with HIV/AIDS: 1,039,000-1,185,000

New Sexual Infections Each Year: ~32,000

# HIV/AIDS Diagnoses among Adults and Adolescents, by Transmission Category — 33 States, 2001–2004



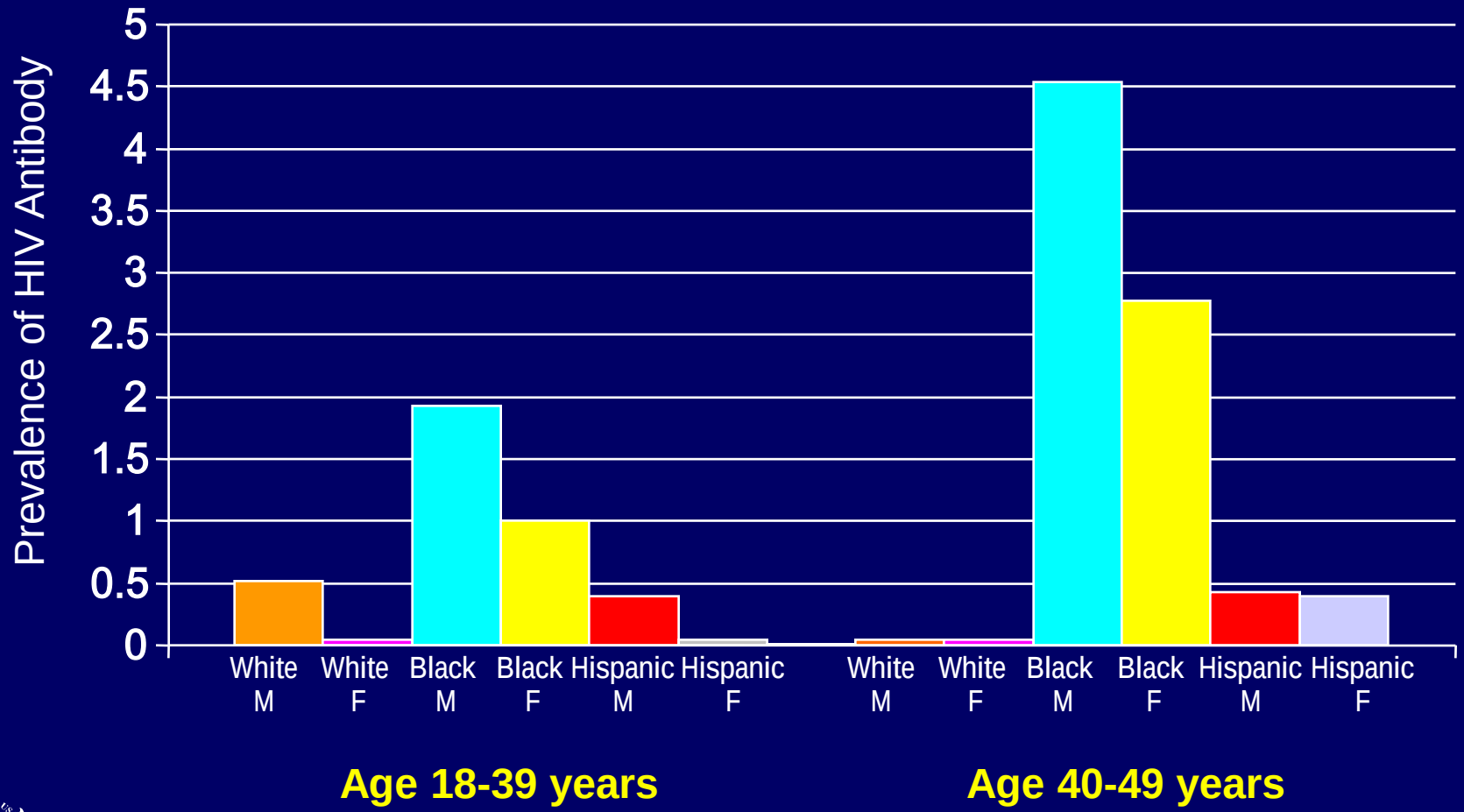

Males
(n ≈ 112,000)




Females
(n ≈ 45,000)

*MMWR, Nov 18, 2005*

# HIV Prevalence, NHANES 1999-2002




*- McQuillan et al, NCHS: JAIDS April 2006*

CDC

MMWR

Morbidity and Mortality Weekly Report

Weekly April 18, 2003 / Vol. 52 / No. 15

# Advancing HIV Prevention: New Strategies for a Changing Epidemic — United States, 2003

In several U.S. cities, recent outbreaks of primary and secondary syphilis among men who have sex with men (MSM) (*1*) and increases in newly diagnosed human immunodeficiency virus (HIV) infections among MSM and among heterosexuals have created concern that HIV incidence might be increased rapidly during the 1980s. During 1981–2001, an estimated 1.3–1.4 million persons in the United States were infected with HIV (*3*), and 816,149 cases of AIDS and 467,910 deaths were reported to CDC (*4*). During the late 1990s, after the introduction of combination antiretroviral

# AHP Strategies

- **Four priorities:**
  1. **Make voluntary HIV testing a routine part of medical care**
  2. **Implement new models for diagnosing HIV infections outside medical settings**
  3. **Prevent new infections by working with persons diagnosed with HIV and their partners**
  4. **Further decrease perinatal HIV transmission**

# Current Testing

# Terminology - I

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

# Terminology - II

- *Informed consent:* process of communication between patient and provider through which the patient can participate in choosing whether or not to undergo HIV testing
- *HIV prevention counseling:* interactive process to assess risk, recognize risky behaviors, and develop a plan to take steps that will reduce risks

# 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

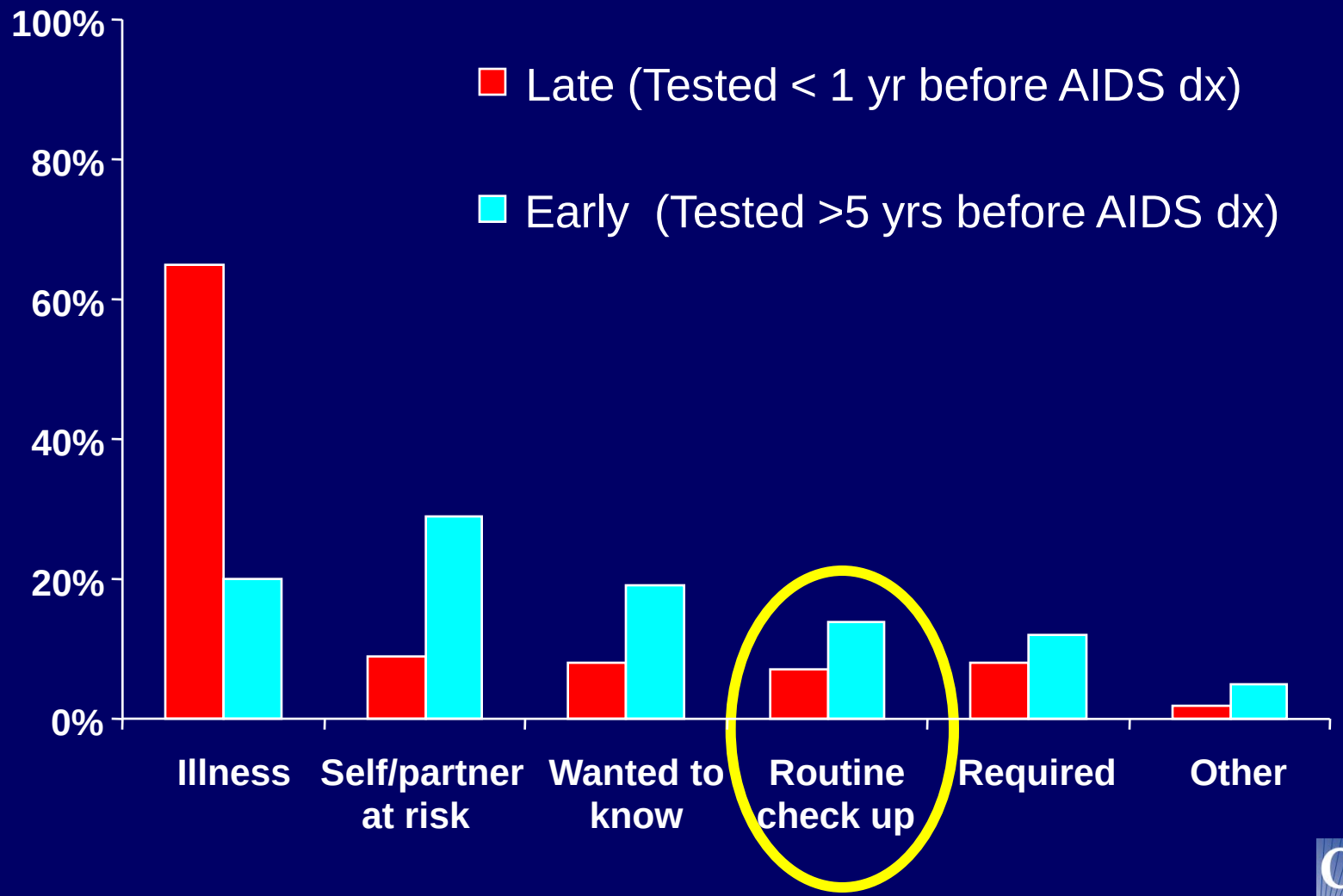
- Among 4,127 persons with AIDS*, 45% were first diagnosed HIV-positive within 12 months of AIDS diagnosis (“late testers”)
- Late testers, compared to those tested early (>5 yrs before AIDS diagnosis) were more likely to be:
  - Younger (18-29 yrs)
  - Heterosexual
  - Less educated
  - African American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

*MMWR June 27, 2003*

*16 states

# Reasons for testing: late versus early testers

## Supplement to HIV/AIDS Surveillance, 2000-2003

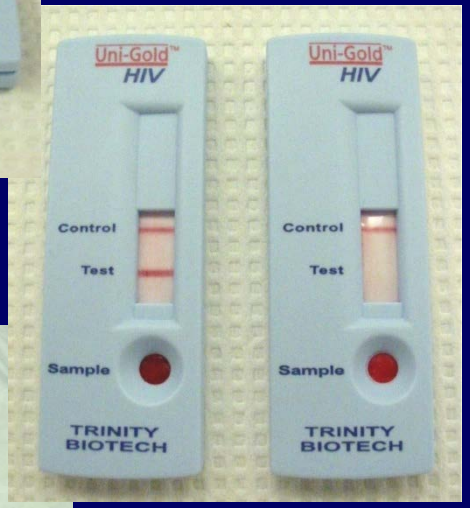


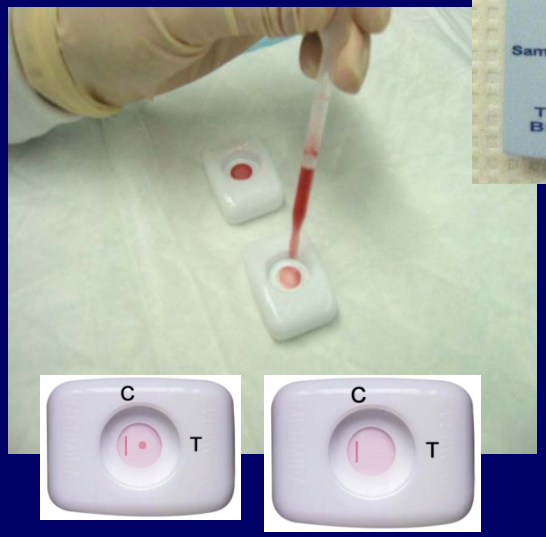
# HIV Rapid Tests

# Public Health Need for Rapid HIV Tests

- High rates of non-return for test results
  - *In 2000, 31% did not return for results of HIV-positive conventional tests at publicly funded sites*
- Need for immediate information or referral for treatment choices
  - Perinatal settings
  - Post-exposure treatment settings
- Screening in high-volume, high-prevalence settings


Uni-Gold
Recombigen



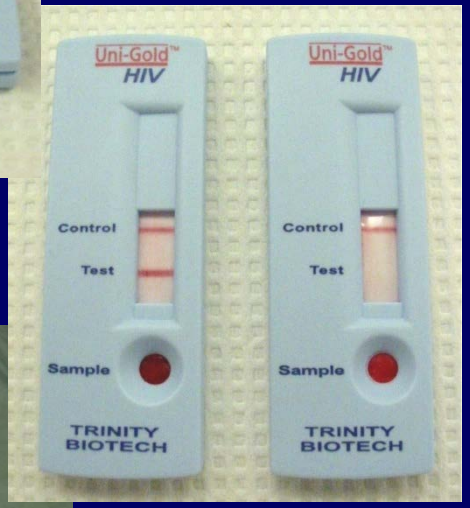

Reveal
G2

Multispot
HIV-1/HIV-2


OraQuick
Advance

CDC


Uni-Gold
Recombigen





Reveal
G2

Multispot
HIV-1/HIV-2


OraQuick
Advance

CDC

# Four FDA-approved Rapid HIV Tests

| | Sensitivity *(95% C.I.)* | Specificity *(95% C.I.)* |
|---|---|---|
| **OraQuick Advance** | | |
| **- whole blood** | **99.6** *(98.5 - 99.9)* | **100** *(99.7-100)* |
| **- oral fluid** | **99.3** *(98.4 - 99.7)* | **99.8** *(99.6 – 99.9)* |
| **- plasma** | **99.6** *(98.5 - 99.9)* | **99.9** *(99.6 – 99.9)* |
| **Uni-Gold Recombigen** | | |
| **- whole blood** | **100** *(99.5 – 100)* | **99.7** *(99.0 – 100)* |
| **- serum/plasma** | **100** *(99.5 – 100)* | **99.8** *(99.3 – 100)* |

# Four FDA-approved Rapid HIV Tests

| | Sensitivity *(95% C.I.)* | Specificity *(95% C.I.)* |
|---|---|---|
| **Reveal *G2*** | | |
| **serum** | **99.8***(99.2 – 100)* | **99.1** *(98.8 – 99.4)* |
| **plasma** | **99.8***(99.0 – 100)* | **98.6** *(98.4 – 98.8)* |
| **Multispot** | | |
| **serum/plasma** | **100** (99.9 – 100) | **99.9** (99.8 – 100) |
| **HIV-2** | **100** (99.7 – 100) | |

# Additional Rapid Tests

- FDA approved – May 2006

Sure Check


Stat Pak

# Confirmatory Testing

- Confirmatory test is essential (not just EIA)
- For Western blot:
  - Venipuncture for whole blood
  - Oral fluid specimen
- Follow-up testing of persons with negative or indeterminate Western blot results after 4 weeks

# Postmarketing Surveillance: 2004-2005

Project-specific median (range) for confirmed HIV seropositivity, specificity and positive predictive value of OraQuick
(347 testing sites, 14 project areas)

| | No. of Tests | **HIV Seropositive** Median %(range) | **Estimated Specificity** Median % (range) | **PPV** Median % (range) |
|---|---|---|---|---|
| **RT whole blood** | 135,724 | **0.8** (0.1-2.6) | **99.98**(99.7-100) | **99.2** (66.7-100) |
| **RT oral fluid** | 26,066 | **1.0** (0-4.0) | **99.89**(99.4-100) | **90.0** (50.0-100) |
| **Conventional** | 31,811 | **1.5** (0.5-5.1) | --- | --- |

*Wesolowski et al, AIDS 2006*

# HIV Screening with OraQuick in MIRIAD
# Mother Infant Rapid Intervention At Delivery

**Testing of pregnant women in labor for whom no HIV test results are available; 12 hospitals in 5 cities**

**7680 women screened**

- **54 (0.7%) new HIV infections identified**
- **6 false positive OraQuick tests, no false negatives**
- **15 false-positive EIAs**

**Specificity: OraQuick 99.92%; EIA 99.80%**

**Positive predictive value: OraQuick 90%; EIA 76%**

*Bulterys et al, JAMA July 2004*

# Post-marketing Surveillance: 2004-2005

Project-area specific median (range) of clients who received test results

(368 testing sites in 17 project areas)

| | Received Negative Results<br>Median % (range) | Received Preliminary Positive Results<br>Median % (range) | Received Confirmed Positive Results<br>Median % (range) |
|---|---|---|---|
| **Rapid** | **99.5**(93.7-100) | **100** (89.8-100) | **89.7** (49.4-100) |
| **EIA*** | **77.3**(30.4-98.5) | --- | **81.0** (33.3-100) |

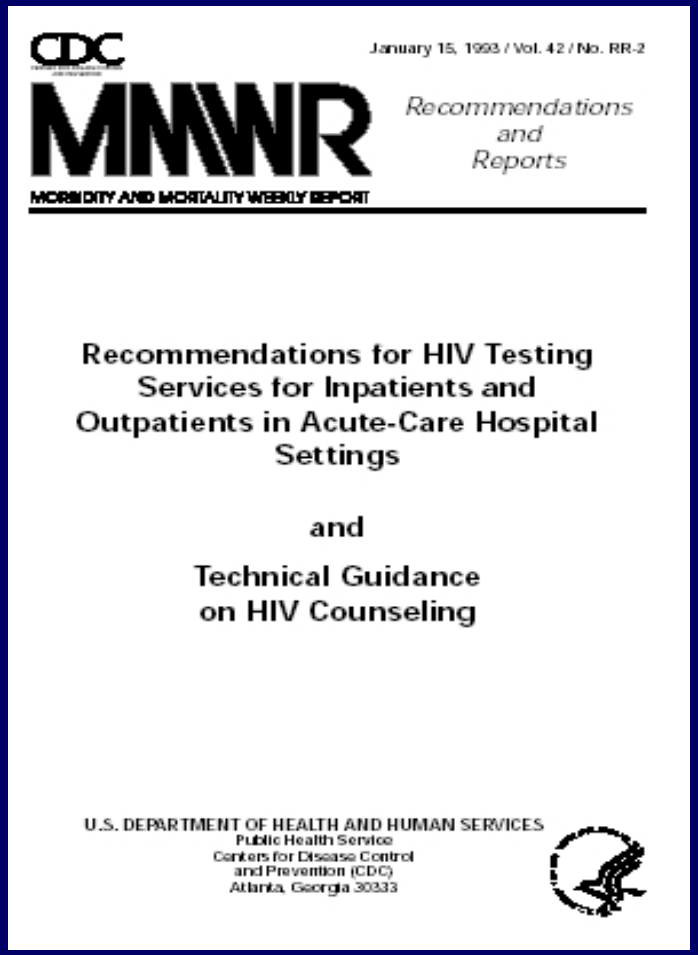
*16 project areas

# Role for Rapid HIV Tests

- Increase receipt of test results
- Increase identification of HIV-infected pregnant women so they can receive effective prophylaxis
- Increase feasibility of testing in acute-care settings with same-day results
- Increase number of venues where testing can be offered to high-risk persons

# Previous Guidelines and their Effects

# Previous Recommendations



CDC

January 15, 1993 / Vol. 42 / No. RR-2

MMWR

Recommendations and Reports

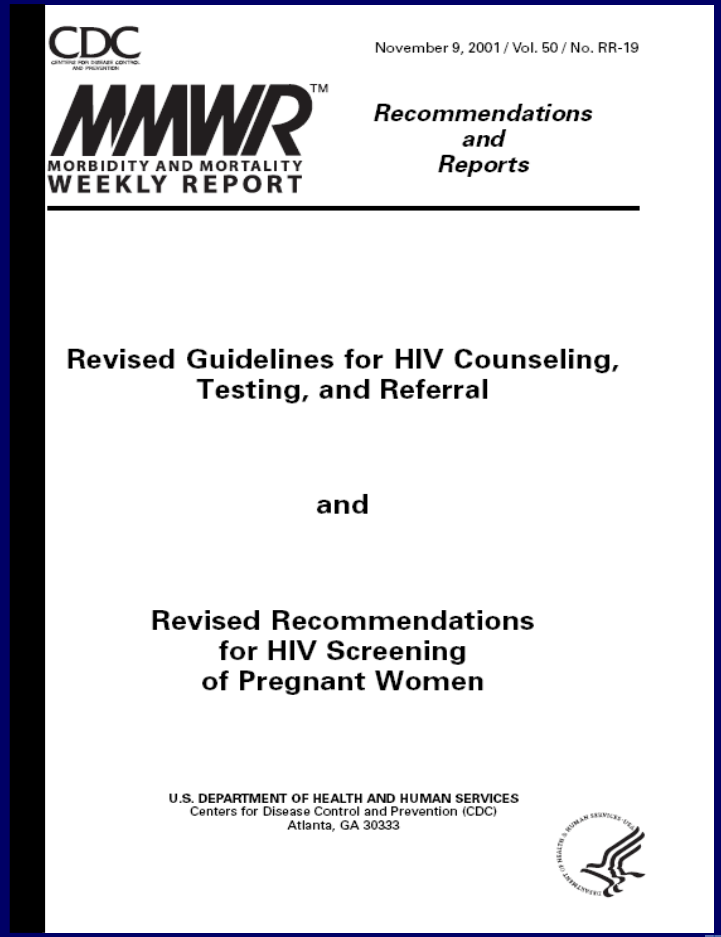
MORBIDITY AND MORTALITY WEEKLY REPORT

**Recommendations for HIV Testing Services for Inpatients and Outpatients in Acute-Care Hospital Settings**

**and**

**Technical Guidance on HIV Counseling**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention (CDC)
Atlanta, Georgia 30333



CDC

November 9, 2001 / Vol. 50 / No. RR-19

MMWR™

MORBIDITY AND MORTALITY WEEKLY REPORT

*Recommendations and Reports*

**Revised Guidelines for HIV Counseling, Testing, and Referral**

**and**

**Revised Recommendations for HIV Screening of Pregnant Women**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention (CDC)
Atlanta, GA 30333

# Previous CDC **Recommendations** Adults and Adolescents

- Routinely recommend HIV screening in settings with high HIV prevalence (≥1%)
- Targeted testing based on risk assessment
- Routinely recommend HIV Testing seeking treatment for STDs
- Annual testing for sexually active MSM

# 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

# Recommendations Are Not Having Their Intended Effect in Acute Care Settings

- EDs account for 10% of all ambulatory care visits

| | 2000 | 2001 | 2002 |
|---|---|---|---|
| ED visits | 108 million | 107 million | 110 million |
| Age 15-64 | 68.3 million | 69.4 million | 69.6 million |
| HIV serology | 215,000 | 201,000 | 163,000 |

# Characteristics, Rapid Test Positive Patients Identified in ED Screening

| | N= 83 |
|---|---|
| No previous test | 47 (57%) |
| Risk factors | |
| MSM | 30 (34%) |
| IDU | 8 (10%) |
| High risk hetero partner | 3 ( 4%) |
| No identified risk | 42 (51%) |

*- Cook County Bureau of Health Services, 2003*

# HIV Testing Practices in EDs

- Survey of 95 Academic EDs

- For patients with suspected STDs:
  - 93% screen for gonorrhea
  - 88% screen for chlamydia
  - 58% screen for syphilis
  - 3% screen for HIV

*- Wilson et al, 1999: Am J Emerg Med*

# 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*

# HIV Prevalence and Proportion of Unrecognized HIV Infection Among 1,767 MSM, by Age Group and Race/Ethnicity NHBS, Baltimore, LA, Miami, NYC, San Francisco

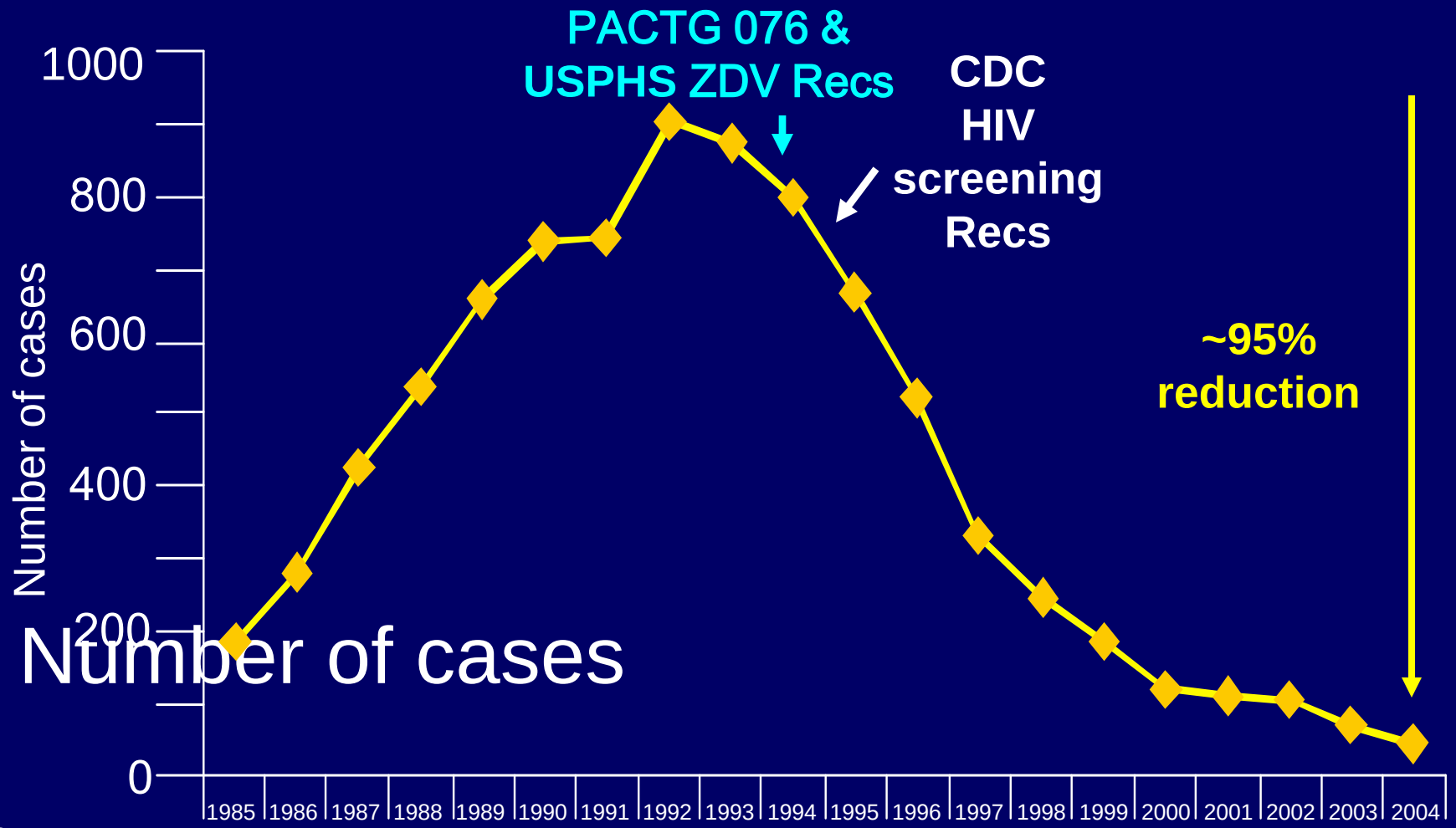
| | Total Tested | HIV Prevalence | | Unrecognized HIV Infection | |
|---|---|---|---|---|---|
| **Age Group (yrs)** | | **No.** | **%** | **No.** | **%** |
| 18-24 | 410 | 57 | (14) | 45 | (79) |
| 25-29 | 303 | 53 | (17) | 37 | (70) |
| 30-39 | 585 | 171 | (29) | 83 | (49) |
| 40-49 | 367 | 137 | (37) | 41 | (30) |
| ≥ 50 | 102 | 32 | (31) | 11 | (34) |
| **Race/Ethnicity** | | | | | |
| White | 616 | 127 | (21) | 23 | (18) |
| Black | 444 | 206 | (46) | 139 | (67) |
| Hispanic | 466 | 80 | (17) | 38 | (48) |
| Multiracial | 86 | 16 | (19) | 8 | (50) |
| Other | 139 | 18 | (13) | 9 | (50) |
| **Total** | **1,767** | **450** | **(25)** | **217** | **(48)** |

*MMWR June 24, 2005*

# 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



# The Case for HIV Screening

# 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

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

# Example: Newborn Screening

Newborn screening results, 1994

- 3.7 million infants screened, twice

| | Cases | Incidence | PPV |
|---|---|---|---|
| PKU | 289 | 1:13,050 | 2.65% |
| Galactosemia | 54 | 1:62,800 | 0.57% |
| Hypothyroidism | 1203 | 1:3,300 | 1.77% |
| Adrenal Hyperplasia | 51 | 1:25,100 | 0.53% |

*-Arch Pediatr Adolesc Med, 2000*

# Example: Chlamydia Screening

- First recognized as major cause of STDs in 1970s (Schachter, 1975)
- Screening tests (other than culture) became available in the 1980's – 1990's
- Screening criteria developed based upon results of pilot screening programs
- Like HIV: Primary, community (eg, school) and health care provider prevention strategies

# Recommendations for Prevention and Management of *Chlamydia Trachomatis* Infections, 1993

Health care provider strategies:

- Recognize and manage associated conditions
  - *MPC, PID, urethral syndrome, urethritis*
- Implement screening
  - *Sexually active women < 20 years of age*
  - *Women 20-24 who meet either criteria or women >24 years who meet both:*
    - *Inconsistent use of barrier contraception*
    - *New or more than one sex partner in the past 3 months*

# Rapid HIV Screening in Acute Care Settings

| *Study site* | *New HIV+* |
|---|---|
| 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% |

# Rapid HIV Screening in Medical Settings

| Demonstration Project | No. tested | No. (%) HIV+ |
|---|---|---|
| New York City<br>Bronx- Lebanon: 2 clinics, 1 ED | 3,039 | 61 (2%) |
| Los Angeles<br>2 clinics, 1 ED | 6,909 | 75 (1.1%) |
| Alameda County (Oakland)<br>1 ED | 6,283 | 84 (1.3%) |
| Massachusetts<br>1 outpatient, 1 inpatient, 1 clinic | 5,994 | 45 (0.75%) |
| Wisconsin<br>3 clinics | 1,763 | 6 (0.34%) |

*CDC, preliminary data - Dec 2005*

# Lessons Learned

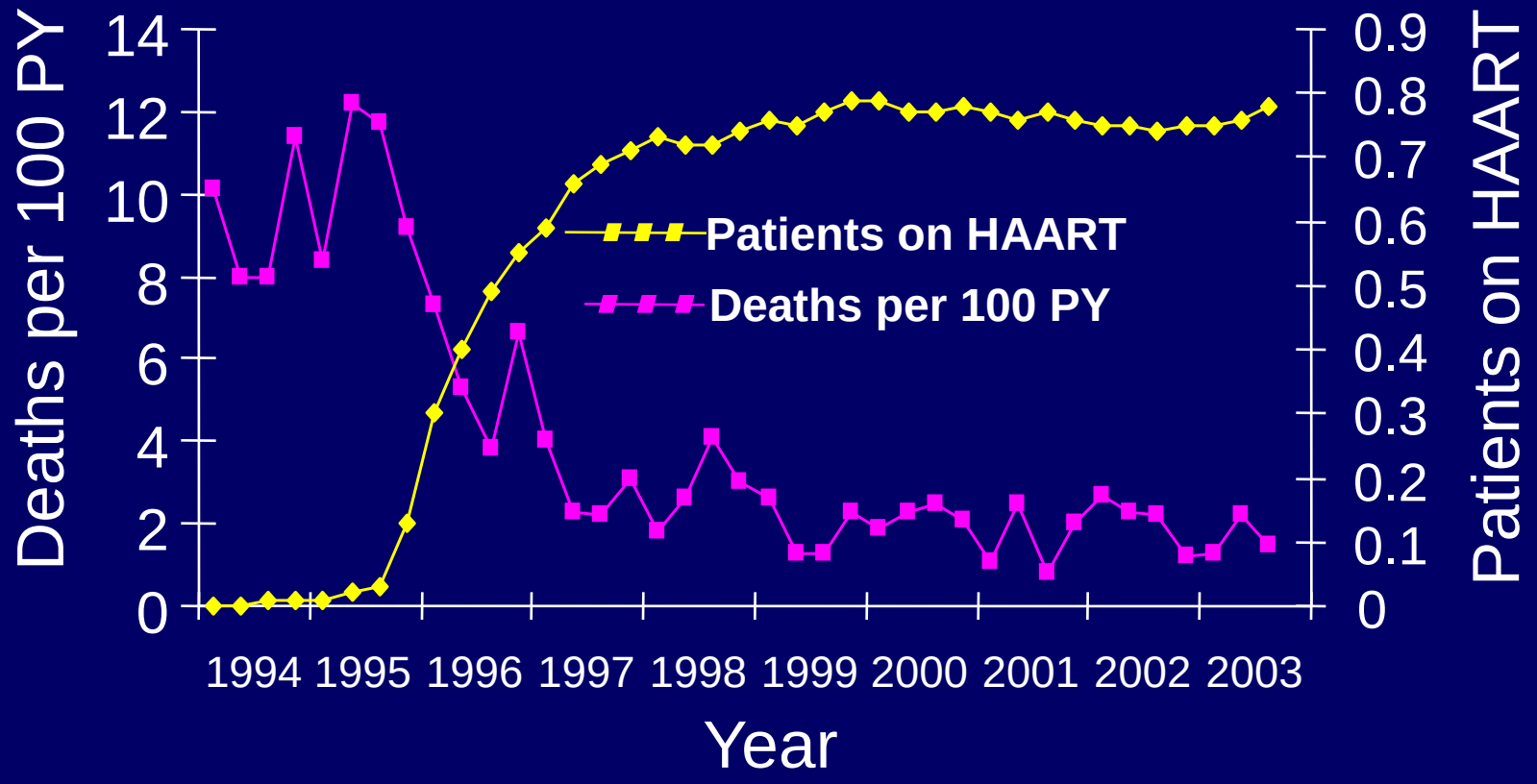
- Difficult to obtain written consent and provide counseling, yet still screen the large numbers of patients in acute care settings.

- Sustainability will depend on streamlined systems, additional staff, or both.

# 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

# Mortality and HAART Use Over Time
# HIV Outpatient Study, CDC, 1994-2003



# 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**

# 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."**

# 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*

# 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***

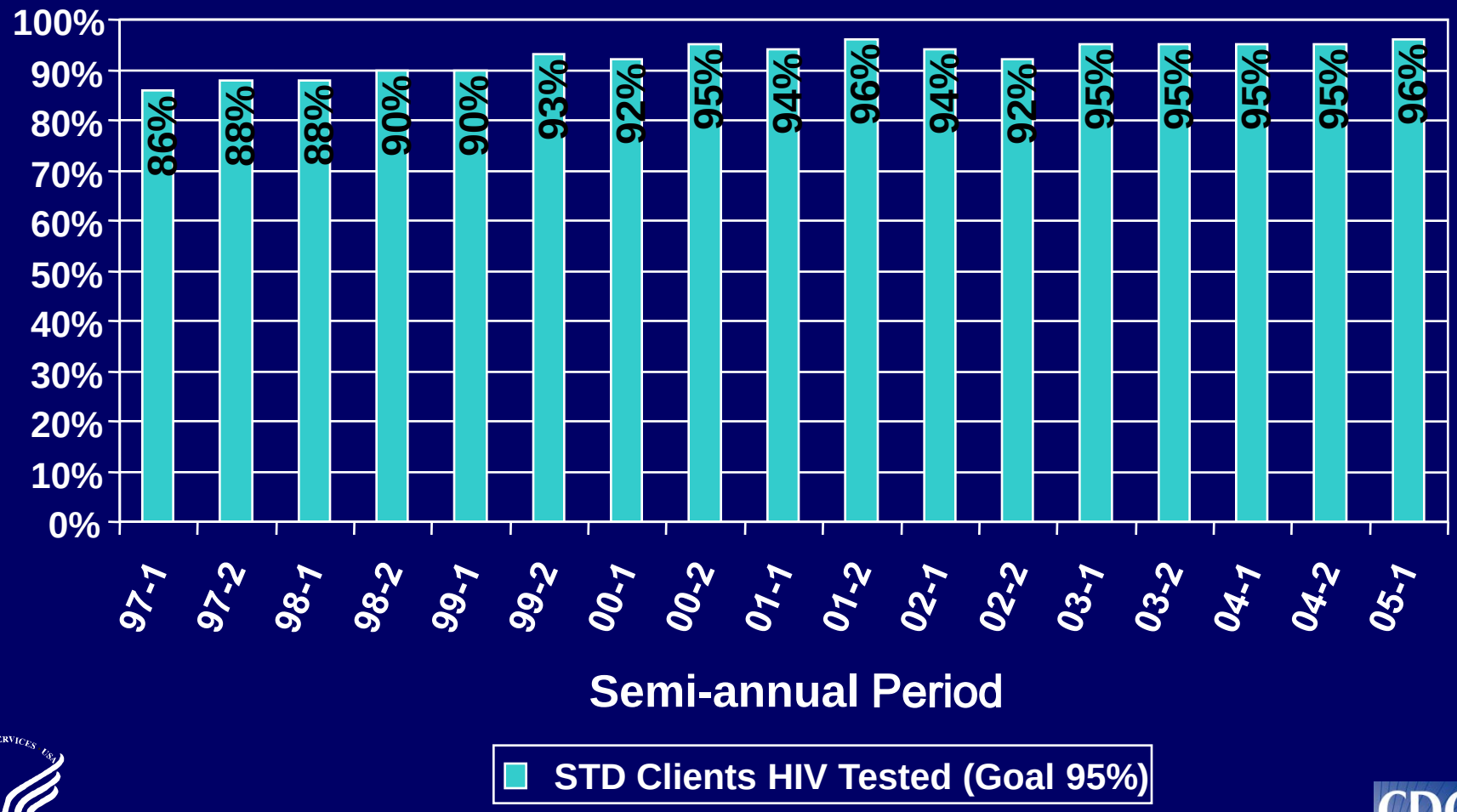
*Simpson W, et al, BMJ June,1999*

# Routine Opt-Out HIV Testing Texas STD Clinics, 1996-97

| | Opt-In N (%) | Opt-Out N (%) | % change |
|---|---|---|---|
| STD Visits | 31,558 | 34,533 | +9 |
| Eligible Clients | 19,184 (61) | 23,686 (69) | +23 |
| Pre-test counsel | 15,038 (78) | 11,466 (48) | -24 |
| Tested | 14,927 (78) | 23,020 (97) | +54 |
| Post-test counsel | 6,014 (40) | 4,406 (19) | -27 |
| HIV-positive | 168 (1.1) | 268 (1.2) | +59 |

*Texas Department of State Health Services, 2005*

# Eligible STD Clients
# Percent Tested for HIV, 1997 - 2005



# Summary of Review of Evidence

- HIV meets the criteria for screening, and effective treatment is available
- Many patients with HIV visit healthcare providers but their infection goes undetected
- People decrease their risk behaviors when they find out they are infected with HIV
- HIV screening in healthcare settings is cost-effective
- Opt-out screening increases testing rates

# Process for Revising Recommendations

- Consultation with providers, March 2004
- HIV Prevention Leadership Summit, San Francisco, August 2005
- Community consultation, Atlanta, September 2005
- Professional consultation, Atlanta, November 2005
- Peer review by recognized experts
- Public comment on revised draft, March 2006
- Final recommendations, September 2006

# Revised Recommendations Adults and Adolescents - I

- Routine, voluntary HIV screening for all persons 13-64 in health care settings, not based on risk
- Repeat HIV screening of persons with known risk at least annually
- Opt-out HIV screening with the opportunity to ask questions and the option to decline
- Include HIV consent with general consent for care; separate signed informed consent not recommended
- Prevention counseling in conjunctions with HIV screening in health care settings is not required

# Revised Recommendations Adults and Adolescents - II

- **Intended for all health care settings, including inpatient services, EDs, urgent care clinics, STD clinics, TB clinics, public health clinics, community clinics, substance abuse treatment centers, correctional health facilities, primary care settings**
- **Communicate test results in same manner as other diagnostic/screening tests**
- **Provide clinical HIV care or establish reliable referral to qualified providers**

# Revised Recommendations Adults and Adolescents - III

- Low prevalence settings:
  - Initiate screening
  - If yield from screening is less than 1 per 1000, continued screening is not warranted

- Steps should be considered to resolve conflicts between the recommendations and state or local regulations

# Revised Recommendations Pregnant Women - I

- Universal opt-out HIV screening
  - Include HIV in routine panel of prenatal screening tests
  - 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

# 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

# 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
- Recommendations Revised: September 2006
- Several jurisdictions have already begun