

**HIV Testing
in Massachusetts:
Considerations for Increasing
Consensual and Routine Testing**

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Revised CDC Estimates of HIV Infection Rates

- No reduction in the number of new HIV cases each year between 2001-2007
- 56,000 new infections each year (41% increase) based on more accurate model
- Greatest increase among MSM
- Disproportionate rates continue among Black and Latino men and women

Examples of Bush Administration HIV Prevention Education Agenda

- Abstinence only education and faith-based initiatives
- Ban on federal funding of needle exchange programs
- “Conscience Rule” for health care providers

A Few Key Components of an HIV Prevention Agenda for 2009

- Implement (and evaluate) science-based prevention efforts
 - Research PRep and microbicides
 - Targeted sex and drug education initiatives
 - Needle exchange and other behavioral interventions
- Implement early HIV testing (diagnosis) and early access to care (treatment)

Part 1

- **Overview of the problem of late diagnosis and lateness to care on individual and public health**

Problem: Lateness to Testing

- 28% of newly diagnosed with HIV in MA have AIDS diagnosis within two months
- 34.5% of newly diagnosed with HIV in MA have an AIDS diagnosis within one year
- While MA performs better than national average in early testing (nationally, 39% have AIDS diagnosis within one year) the problem is real, large, and untenable

MMWR June 27, 2003

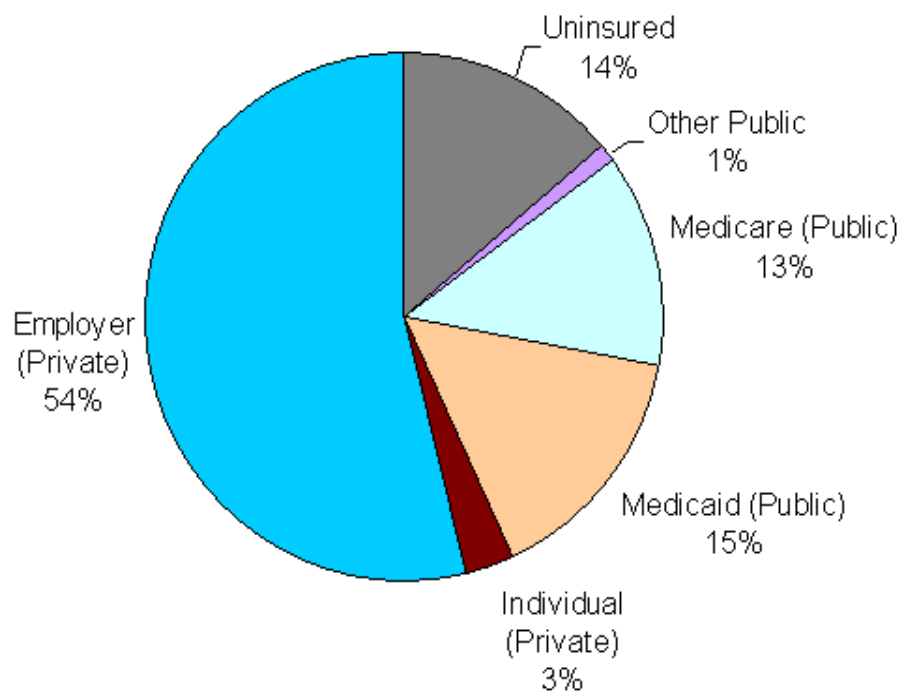
Problem:

Lack of Access to Early HIV Care

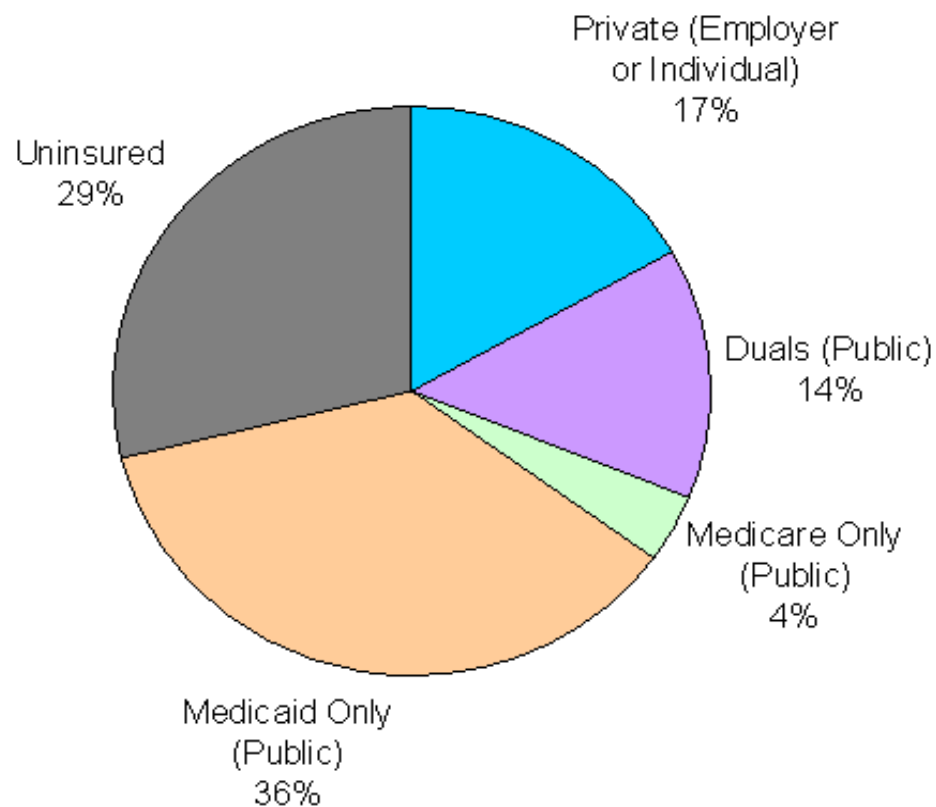
- 50% living with HIV are NOT in regular care
 - 21% don't know they are infected and 29% are uninsured
- The private employer-based system fails PWHIVs
 - 62% of PWHIV are unemployed
- The public disability care system fails PWHIVs
 - Both Medicaid and Medicare generally require an AIDS diagnosis for access
 - Thankfully, not in MA as MassHealth (Medicaid) allows for early access through a federal waiver

People with HIV/AIDS: Health Care Coverage of Those in Care

General Population



PWHIV/AIDS

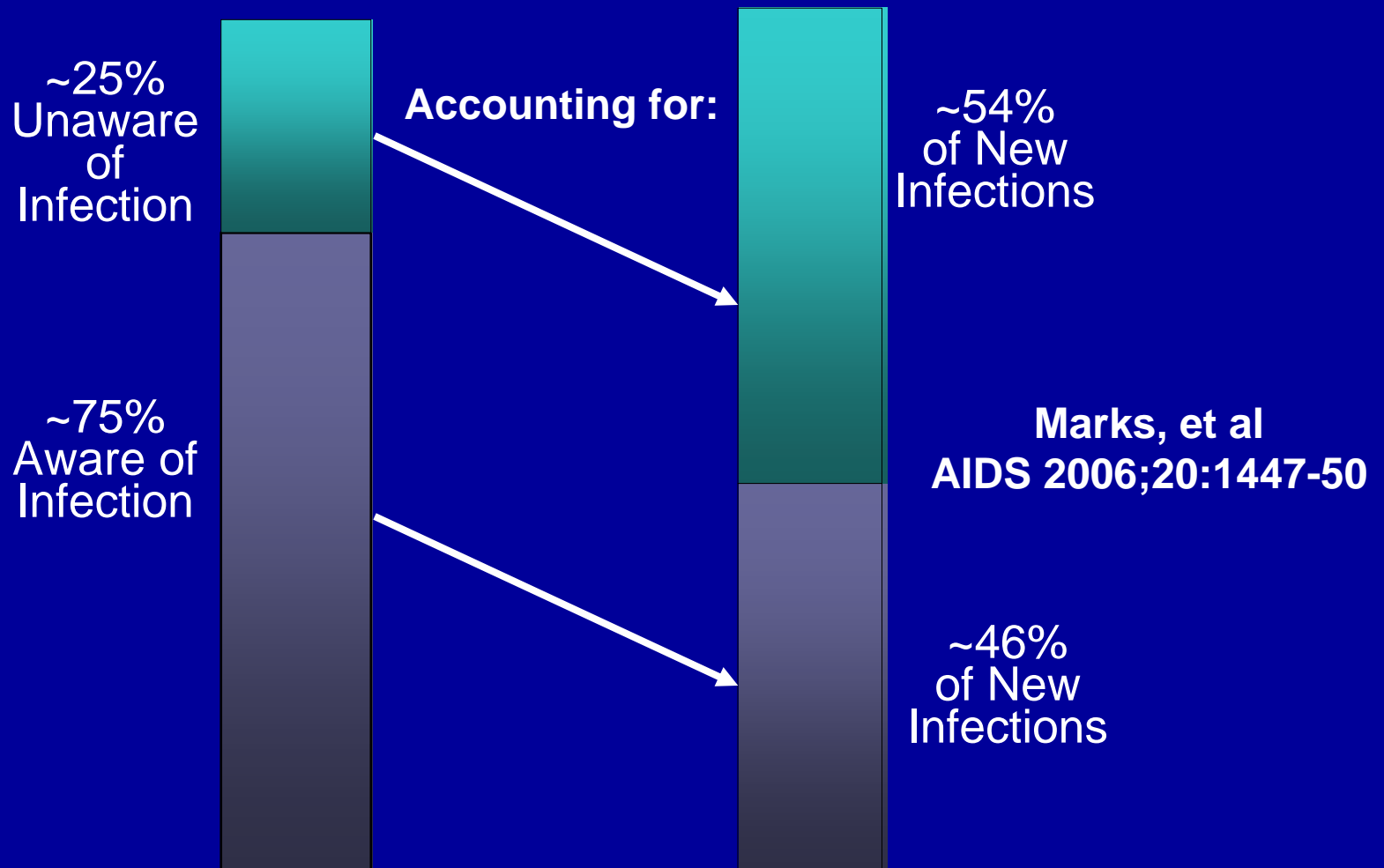


SOURCE: Kaiser based on Fleishman JA et al., "Hospital and Outpatient Health Services ...", Medical Care, Vol 43 No 9, Supplement, September 2005.; Fleishman JA, Personal Communication, July 2006

Importance of Early Diagnosis & Care on Individual Health

- Dramatically reduces AIDS mortality
 - 50-60%
- Improves health and quality of life
 - Diagnosis/treatment transforms HIV from life-threatening to chronic manageable medical condition
- Decreases unnecessary high-cost medical interventions and lowers annual base-line healthcare costs
 - Treating HIV = \$12k per person/year rather than AIDS = \$36k

Awareness of Serostatus Among People with HIV and Estimates of Transmission



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

Importance of Early Diagnosis and Treatment on Public Health:

Knowledge of HIV Infection and Behavior

- **People who are aware of their HIV+ status engage in 68% less unprotected intercourse compared to people unaware of their HIV+ status.**



68%

- **Those in regular care even more likely to reduce high-risk activities**

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*

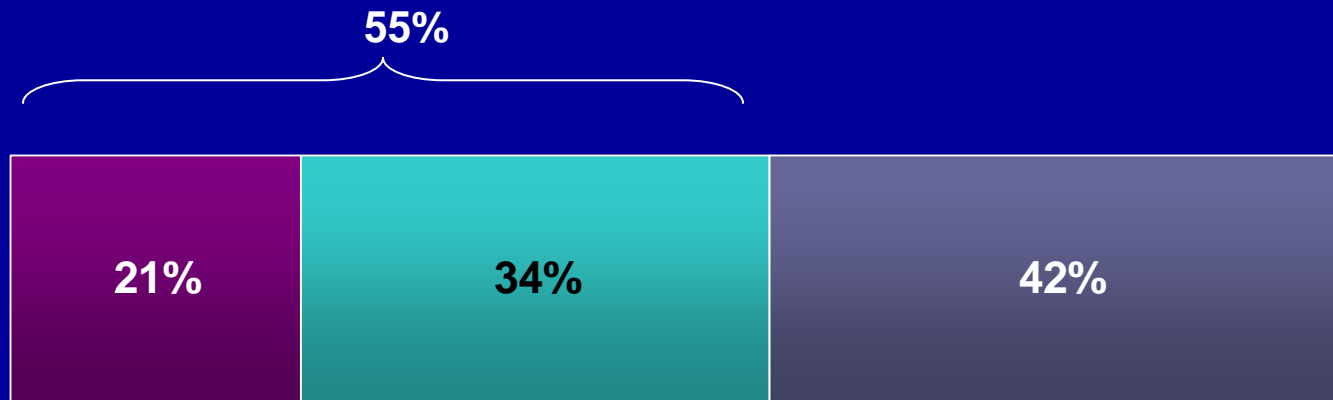
Testing & Health Care as Prevention

- Two recent studies concluded that HIV therapy can reduce HIV viral load to a level where it can't be transmitted through sexual contact.
- Many remain skeptical of these conclusions, but the relationship between effectively treating HIV and reducing the risk of transmitting the virus cannot be overlooked.

So How Many Americans Have Been Tested?

Non-Elderly

■ Yes, in last 12 months ■ Yes, but not in last 12 months ■ No, never tested



Note: Don't know responses not shown; Numbers may not add up due to rounding.

Source: Kaiser Family Foundation Survey of Americans on HIV/AIDS (conducted March 24 – April 18, 2006).

Part 2

- **Overview of the revised CDC HIV testing recommendations**
- **Overview of current HIV testing law, regulation and policy in MA**
- **Overview of the key elements of the HIV testing debate in MA**

Revised CDC Recommendations for Adults and Adolescents

- Routine, voluntary HIV screening for all persons 13-64 in health care settings, not based on risk
- Opt-out HIV screening with option to decline
- HIV consent with general consent for care; separate signed informed consent not recommended
- Prevention counseling with testing should not be required
- Communicate test results in same manner as other diagnostic/screening tests
- Resolve conflicts between the recommendations and state or local laws and regulations

Revised CDC Recommendations for Pregnant Women

- **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 3rdtrimester for pregnant women:**
 - ~Known to be at risk for HIV
 - ~In jurisdictions with elevated HIV incidence
 - ~In high HIV prevalence health care facilities
- **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

Current Law: MGL c. 111, §70F

The MA HIV Testing and Confidentiality Law

- Requires written informed consent to conduct HIV antibody or antigen test
- Requires written informed consent to release the results of an HIV test to a 3rd party
- Requires consent to be separate and distinct from all other consent
- Applies specifically to health care providers and facilities

Current MA Regulation and Policy

- Laboratory regulation (105 CMR 180.300) requires pre-test HIV counseling to include:
 - voluntary nature of the test
 - meaning/limitations of the test results
 - availability of additional counseling
 - data maintenance requirements of laboratory/hospital
 - rapid testing may bypass these regulation
- Contractual requirements of MDPH funded counseling and testing programs have more rigorous counseling requirements:
 - pre-/post-test counseling -- disclosure of results
 - specimen transport -- data management

Current Testing Practice On the Ground

- Obtaining separate, informed, written consent for HIV testing has been pattern and practice
- Most testing programs have 1-3 priority populations who must form the majority of their testing clients (targeted based on risk hierarchy)
- Move toward integrated testing (linking HIV/STD/ viral hepatitis screening) forms the groundwork of more routine screening; still dependent on client/patient presentation

The key question:

**Are current MA HIV testing requirements inconsistent with more routine testing?
And if so, why?**

Summary of The Debate:

Arguments in favor of **eliminating** separate written informed consent/counseling/in-person notification requirements

- High rates of late to care; evidence of missed opportunities
- Besides genetic testing, no other biologic testing requires this level of counseling/consent
- Artifact of an earlier era where stigma/discrimination common
- Reinforces the stigma related to HIV and HIV testing
- Procedural burdens create barriers to higher volume of tests
- Physicians should be free to order any test that is medically indicated (with or without consent)
- Consent and privacy rights are more of a concern of lawyers/advocates than patients

Summary of The Debate

Arguments in favor of retaining separate written informed consent/counseling/in-person notification requirements

- HIV is still a highly stigmatized disease
- HIV continues to affect the most vulnerable
- Prevents testing without knowledge
- Creates an educational moment
- Necessary to effectively link to care & morally reprehensible without link to care
- Consent debate is “red herring” -- real issue is providers’ lack of comfort about sex and drugs
- Administrative burdens can be reduced

Part 3

- **Overview of other state responses to CDC guidelines**
- **Overview of efforts to improve access to testing and care in MA**
- **Next steps in the debate**

State Responses to CDC Recommendations

Many states are following the CDC recommendations

- 18 states have changed law or rule to accommodate some aspect of the recommendations
- 21 states have indicated some future change in law or rule is possible
- California has eliminated written consent requirement and instead now requires advice to patient of right to decline HIV test. Also enacted law to mandate insurance coverage of HIV screening

State Responses to CDC Recommendations

Several states have reduced barriers while retaining enhanced informed consent requirements

- Illinois has replaced “written informed consent” requirement with “informed consent” with provider obligation to document pre-test information and consent in medical record
- Illinois has adopted enhanced penalties for providers’ failure to contemporaneously document and for breaches of confidentiality

State Responses to CDC Recommendations

As in MA, several states are consciously retaining historic testing laws.

- New York State has retained law which mandates opt-in consent, but is working to interpret existing statute to support reduced counseling requirements in clinical settings

MA DPH Response to Date

- New revised protocol addresses “over-interpretation” of written informed consent requirements
- Modified risk hierarchy developed
- Move toward integrated testing (linking HIV/STD/viral hepatitis screening) forms the groundwork of more routine screening; still dependent on client/patient presentation

MA Medical Society Bill -- H. 2209 (2008 Legislation)

- Bill would have repealed all provisions of MGL c.111 § 70F except for prohibition to use HIV testing for employment
- Would have enabled opt-out testing in MA
- Committee referred the bill to study, effectively killing the bill, March 18, 2008

“Gilead Bill” - Senate 821

- Allows for opt-out HIV testing with informed consent
- Retains HIV disclosure law prohibiting disclosure to anyone 3rd party without written informed consent.

Next Steps:

The CDC and Federal Government

- President Obama should lead efforts to develop a national AIDS strategy that recognizes the interconnection of care and prevention
- CDC/Medicaid/Medicare/Private Insurance should mandate coverage of voluntary, routine testing – CDC recommendations are disingenuous without \$\$\$
- Enact meaningful health care reform to ensure early access to care to promote individual and public health – ineffective and cruel to test w/out providing access to care

Next Steps in Massachusetts

- Continue to examine legal, regulatory and policy factors
 - Including adjustment of contractual obligations
- Develop a modified risk hierarchy for clinical screening
- Develop tools to support more routine testing
 - Revised testing protocols, testing brochures and sample consent forms
- Ensure that Mass Health creates an HIV screening CPT code and a separate rate for rapid tests
- Consider new state funding and/or allocation of limited state \$\$ to support increased HIV testing

Summary of Where There is Common Ground for Building Support of Increased Testing

- Too many HIV+ patients in the U.S. do not know HIV status
- Too many newly diagnosed are late tested
- Awareness of status reduces transmission
- Mortality and health care costs are higher with late diagnosis
- Policy and \$\$\$ barriers prevent routine testing
- Providers, advocates and consumers must work together in support of policy changes and \$\$\$ to support increased voluntary, routine screening