

Controversies in HIV Testing, 2007

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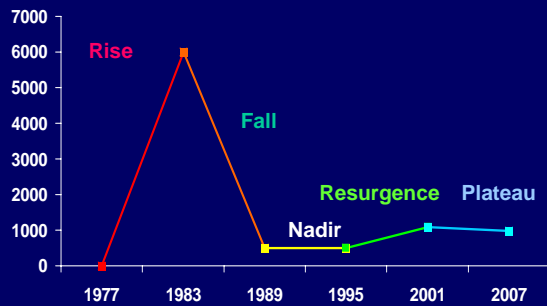


Select Controversies

- Routine testing
 - Consent, opt-out, counseling
 - AB 682
- RNA testing
- Rapid testing

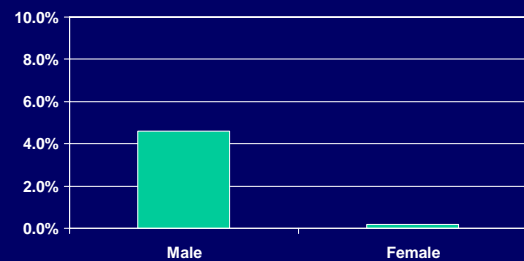
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New HIV infections San Francisco 1977-Present



Willi McFarland, SF Seroepidemiology Section

HIV Prevalence by Sex San Francisco, 2006



SF Population 2000 Census: 394828 male, 381905 female
2005 Annual Report HIV/AIDS Epidemiology, SFPDPH, www.SFPDPH.org

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TABLE 1. HIV prevalence and proportion of unrecognized HIV infection among men who have sex with men, by city, age group, and race/ethnicity—five NHBS* cities, June 2004–April 2005

Characteristic	Total tested	HIV prevalence No. (%)	Unrecognized HIV infection No. (%)
City			
Baltimore	462	186 (40)	115 (62)
Los Angeles	382	73 (19)	31 (42)
Miami	222	41 (18)	19 (46)
New York City	336	62 (18)	32 (52)
San Francisco	365	88 (24)	20 (23)
Age group (yrs)			
18–24	410	57 (14)	45 (79)
25–29	303	53 (17)	37 (70)
30–39	585	171 (29)	93 (49)
40–49	367	137 (37)	41 (30)
≥50	102	32 (31)	11 (34)
Race/Ethnicity†			
White, non-Hispanic	616	127 (21)	23 (18)
Black, non-Hispanic	444	206 (46)	139 (67)
Hispanic	466	80 (17)	38 (48)
Multiracial	86	16 (19)	8 (50)
Other‡	139	16 (13)	9 (50)
Total	1,767	450 (25)	217 (48)

* National HIV Behavioral Surveillance.
 † Numbers for HIV prevalence do not add to 450 because of missing data in three records.
 ‡ Because of small sample sizes, category includes Asian/Pacific Islander, Native American/Alaska Native, and other.

Routine testing

- In September 2006 CDC recommends routine opt-out testing for 13-64 year old patients in healthcare settings
 - No written consent; general consent OK
 - Prevention counseling not required
 - Those as high-risk annually

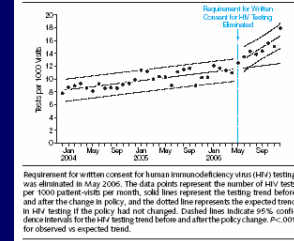
Routine HIV testing at SFGH

- May 2006 SFDPH updated policy to allow for non-written patient consent for HIV testing at SFGH/COPC
 - Informing patients, counseling and disclosure standard medical practice
- Physician documentation of consent in chart
- Evaluated impact of that administrative change on HIV testing and HIV case identification with time-series analysis

RESEARCH LETTER

Association Between Rates of HIV Testing and Elimination of Written Consents in San Francisco

Figure. Mean Rate of HIV Tests per 1000 Patient-Visits in Persons Aged 15 Years or Older (December 2003–December 2006), San Francisco Department of Public Health/Medical Care System



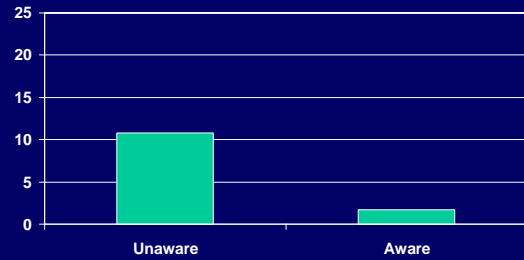
Requirement for written consent for human immunodeficiency virus (HIV) testing was eliminated in May 2006. The data points represent the number of HIV tests per 1000 patient-visits per month; solid lines represent the testing trend before and after the change in policy, and the dotted line represents the expected trend in HIV testing if the policy had not changed. Dashed lines indicate 95% confidence intervals for the HIV testing trend before and after the policy change. $P < .001$ for observed vs expected trend.

Routine testing

- Benefits
 - Identifies more persons with HIV infection
 - May reduce HIV spread
 - Streamlines and may 'normalize' HIV testing process
- Costs/ risks
 - Requires more provider time and laboratory resources
 - Increased burden of care
 - May result in stigma, discrimination, psychological stress

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Percent transmission by awareness of HIV status



Holtgrave et al., Int J STD AIDS 2004;15:789; Marks G et al., JAIDS 2005; 39:446. In: Bartlett JG. Routine Opt-Out Testing for HIV: Rationale and Obstacles, MedScape Today, 2007.

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Consent

- Legal informed consent is a legal not a medical issue
- General consent covers procedures where risks and benefits are well known
- Informed consent is a communication between a clinician and patient resulting in authorization to perform a specific medical intervention

Mayer KH. Routine Opt-Out Testing for HIV: Key Concerns Regarding Implementation, MedScape Today, 2007.

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California law and HIV testing in medical settings

- California law allows for *treating physicians and surgeons* to test patients for HIV after obtaining informed consent (120990)
 - How that consent is obtained is not specified
- General consent for care is insufficient
- California has unique requirements for minors and pregnant women (written acceptance)

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Proposed changes to California law
AB 682 Berg, Garcia, and Huffman
(Coauthors: Beall and Laird)

120990. (a) Prior to ordering a test that identifies infection with HIV, a medical care provider *shall*:

- inform the patient that the test is planned,
- provide information about the test, and
- advise the patient that he or she has the right to decline the test.

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Counseling

- Informational counseling
- Prevention or risk reduction counseling
 - Little evidence of benefit in HIV-negative
 - Beneficial in newly identified HIV-positive
 - Project Respect
 - Reduction in new STDs in those counseled
 - Model of select counseling vs. routine counseling

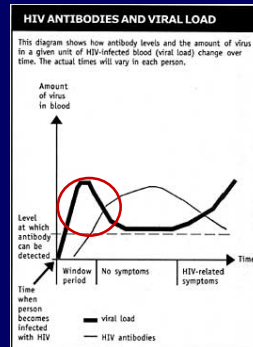
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HIV RNA Screening

- HIV RNA detected 10 days earlier than HIV antibody, 10-12 days after exposure
- HIV RNA+/HIV Ab- specimens identify those with acute infection
- Staging of HIV infection allows for targeted medical care and public health activities

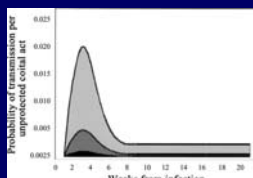
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Period of HIV RNA+/HIV Ab-

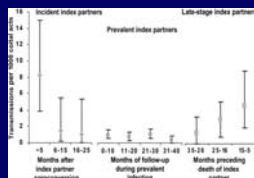


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HIV infectivity by stage of infection



Pilcher et al, JID, 2004



Wawer et al, JID, 2005

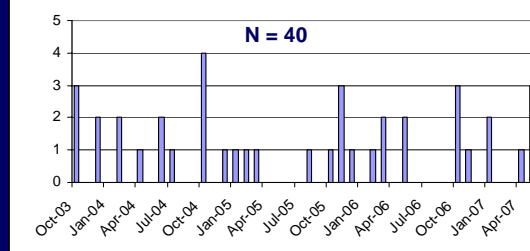
HIV Testing Protocol SF City Clinic

- All persons informed HIV RNA testing part of HIV test
 - Pooled testing at SFDPH (Bayer VERSANT bDNA 3.0) or from Sept—Feb 2007 (NGI/LabCorp (PCR))
- Qualitative RNA results
 - No RNA detected
 - $\leq 10,000$ RNA copies detected
 - $> 10,000$ RNA copies detected
- RNA positives assigned to investigator for disclosure, confirmatory testing and case management

RNA Screening SF City Clinic, 2003-2006

- 10,200 persons tested
 - 317 (3.1%) HIV Ab positive
 - 9883 HIV Ab negative
 - 34 (.34%) RNA positive
 - 11% increase in HIV case detection
 - All who had repeat testing confirmed

Acute HIV cases by month, 2003-2007



HIV RNA Screening Demographics/Sexual Networks

- All gay men/ men who have sex with men
 - 47% white, 30% Hispanic, 17% black
 - 54% age > 30 years
 - 23% had an STD
 - 39% methamphetamine use
 - 40% Internet sex partners
 - 1 new sex venue
 - 27% HIV test in past 6 months; 73% past yr

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Expanded HIV RNA screening

- Extended HIV RNA screening to MAGNET and AIDS Health Project
- 22 AHP and 40 MAGNET patients screened Fall 2006 through May 2007
- All (0/62) HIV RNA negative

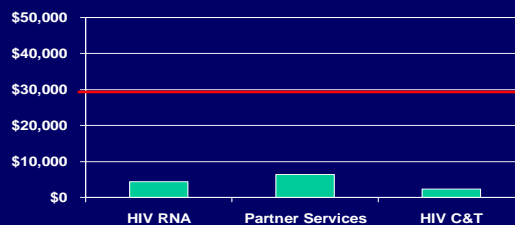
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RNA testing

- Benefits
 - Identifies those that standard HIV Ab testing misses
 - Finds highly infectious cases
 - Enables tracking and interventions at the leading edge of epidemic
- Costs/risks
 - Added expense
 - Complicated
 - Delays “definitive” test result
 - Requires universal application

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Cost per new HIV case identified



\$30,000 estimated cost-effective amount to identify new HIV case, Coco Am Fam Med 2005

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RNA screening

- Every HIV test should include HIV RNA testing in those HIV Ab negative
 - Reflex testing
 - Routine
 - Pooled, more cost-effective

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Rapid HIV Testing

- City Clinic: Rapid tests offered to select patients at very high risk of HIV infection
 - Gay men and other men who have sex with men
 - Patient who report injection drug use
 - Patients with known HIV-infected partners



Philip et al, CROI 2007

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Rapid HIV Testing SF City Clinic, 2005-2006

- 1148 tested by rapid testing
 - 88 (7.7%) rapid HIV Ab positive
 - 1048 HIV Ab negative and RNA tested
 - 13 (1.2%) RNA positive
 - Rapid HIV Ab testing identified 88 (87%) of 101 HIV-infected patients
- Sensitivity = 87% (95% CI 80-94%)

Philip et al, CROI 2007

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San Francisco Chronicle S.F. clinics getting high false-positive rate on oral HIV test

Sabin Russell, Chronicle Medical Writer, December 9th, 2005

OPEN ACCESS freely available online

PLoS ONE

Investigation of False Positive Results with an Oral Fluid Rapid HIV-1/2 Antibody Test

Krishna Jafa^{1,2*}, Pragna Patel¹, Duncan A. Mackellar¹, Patrick S. Sullivan¹, Kevin P. Delaney¹, Tracy L. Sileo¹, Alexander P. Neenan^{1,3}, Shady M. Fawzi¹, Evan M. Cabib¹, Eugene S. Marouf¹, Patrick A. Keenan¹, Bernard M. Branson¹, for the OralQuick Study Group

Performance of an oral fluid rapid HIV-1/2 test: experience from four CDC studies

Kevin P. Delaney^a, Bernard M. Branson^a, Apurva Uniyal^b, Peter R. Kerndt^c, Patrick A. Keenan^a, Krishna Jafa^{a,c}, Ann D. Gardner^d, Denise J. Jamieson^e and Marc Bulterys^b

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Rapid testing

- Benefits
 - Results in 20-40 minutes
 - Increases disclosure rate
 - Expands availability of testing
- Costs/ risks
 - Regulated testing procedures
 - Missed cases and false positives
 - Fails to identify those with acute infection

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