FOIA Number: 2018-0758-F

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: National AIDS Policy Office

Series/Staff Member: Todd Summers

Subseries:

OA/ID Number: 21086

FolderID:

Folder Title:
Conference - 1/98 - Kaiser

Stack:	Row:	Section:	Shelf:	Position:
S	66	6	1	3

Cathy Mays

Nat'l C. T.V. Association —
Tony Clark
(202) 775-3666
→ 11,000
55.5 60 second spot
25.5 30 second spot
Liz Lazlow

THE HENRY J. KAISER FAMILY FOUNDATION

January 7, 1998

Todd Summers
Deputy Director
White House Office of AIDS Policy
808 17th St., NW, Suite 820
Washington, DC 20006

Dear Mr. Summers: Todd

Thank you for agreeing to attend the Henry J. Kaiser Family Foundation Forum on "Understanding the Impact of New Treatments on HIV Testing." The Forum will be held at the Garden Court Hotel in Palo Alto, California on January 28-30, 1998. The purpose of the forum is to bring together approximately 40 public policy experts, government representatives, providers, and HIV advocates to explore the goals of HIV testing as a public health policy. While there have been a flurry of meetings and discussions about HIV reporting policies, we are taking the opportunity to step back from political debate and reflect on the basic goals of HIV testing. That is, we plan to focus on how to get persons tested for HIVand then into treatment once they are diagnosed with HIV disease.

The meeting will include advance papers, and presentations. New data will be presented on the impact of current policies on client testing and treatment seeking behaviors, as well as current utilization of home testing and its potential impact on HIV testing policies. There will also be a series of panel discussions which will provide opportunities for the entire group to explore the hard questions raised about HIV testing in the current era of new treatments.

Enclosed are a series of materials, including the updated meeting agenda, and the series of background papers written by Drs. Morin, Coates, and Phillips. A summary of presentation materials from Dr. Bindman are also included. In order to prepare for the meeting, we ask that you read the enclosed materials prior to the meeting.

Again, we very much look forward to seeing you in Palo Alto on January 28-30th. Please feel free to contact me at (650) 854-9400, or Tim Westmoreland at (202) 662-9595 if you have any questions about the Forum. Any questions about travel or accommodation arrangements can be fielded by my assistant, Martha, who can also be reached at (650) 854-9400.

Wishing you a Happy New Year,

Sophia W. Chang, MD, MPH
Director, HIV/AIDS Programs

encl: Forum Agenda
Participant List
Manuscripts (3): Morin, Coates, Phillips
Slides: Bindman

2400 Sand Hill Road Menlo Park, California 94025 415 854-9400 Fax 415 854-4800
Washington, DC Office: 1450 G Street, NW, Suite 250 Washington, DC 20005 202 347-5270 Fax 202 347-5274

Kaiser Family Foundation Forum
UNDERSTANDING THE IMPACT OF NEW TREATMENTS ON HIV TESTING
Garden Court Hotel, Palo Alto, CA
AGENDA

Wednesday, January 28, 1998

6:00 p.m. *Dinner/Reception*
UPDATE ON HIV TREATMENTS: Dr. Paul Volberding

Thursday, January 29, 1998

8:00 a.m. *Continental Breakfast*

8:30 a.m. WELCOME AND INTRODUCTIONS: Sophia Chang
8:45 a.m. "WHY THE PROBLEM IS IMPORTANT": Todd Summers
9:00 a.m. MEETING PURPOSE/PRESENTATION OF KFF SURVEY DATA: Sophia Chang

Presentation of New Data and Papers

9:15 a.m. NEW TREATMENTS, CHALLENGES & QUESTIONS ABOUT HIV TESTING:
Steve Morin
IMPACT OF NEW TECHNOLOGIES ON HOW WE VIEW TESTING:
Tom Coates
IMPLICATIONS OF HOME TESTING UTILIZATION ON TESTING POLICIES:
Kathryn Phillips
EFFECTS OF POLICIES ON CLIENT TESTING AND CARE SEEKING BEHAVIOR:
Andy Bindman

10:15 a.m. QUESTIONS AND ANSWERS
Moderator: Steve Morin

10:45 a.m. *Break*

Rethinking Newer Models of Care

11:00 a.m. RELOOKING AT HIV TESTING GOALS FOR INDIVIDUALS
Moderator: Joe O'Neill
Responders: Jeff Levi, Steve Lew, Keith Rawlings

12:15 p.m. *Lunch*

2:00 p.m. RELOOKING AT HIV TESTING GOALS FROM A PUBLIC HEALTH PERSPECTIVE
Moderator: Art Ammann
Panelists: David Barr, Virginia Caine, Connie Cellum

3:15 p.m. *Break*

Implementation Issues: Obstacles to Newer Models of Testing

3:30 p.m. IDENTIFYING THE STRENGTHS AND GAPS IN OUR SYSTEM(S) OF TESTING & CARE
Moderator: David Harvey
Panelists: Richard Elovich, Wendy Craytor, John Auerbach, Jay Coburn

4:45 p.m. UNDERSTANDING THE LEGAL PROTECTIONS AND BARRIERS TO CARE FOR PERSONS WITH HIV
Moderator: Chai Feldblum
Panelists: Scott Burris, Larry Gostin, Katie O'Neill

5:30 p.m. WRAP-UP DISCUSSION:
Moderators: Tim Westmoreland and Sophia Chang

6:30 p.m. Reception (with Dinner at 7 p.m.)

Friday, January 30, 1998

8:30 a.m. Continental Breakfast

9:00 a.m. THE POLITICS: UNDERSTANDING THE REALITIES OF HOW WE GOT HERE AND WHERE WE NEED TO GO
Moderator: Jane Silver
Panelists: Cornelius Baker, Tim Sweeney, Julie Scofield, Jon Davidson

10:00 a.m. THINKING "OUTSIDE OF THE BOX":
SUMMARY OF THE PRESENTATIONS AND DISCUSSION
Moderator: June Osborn
Panelists: Helene Gayle, Christine Lubinski, Miguelina Maldonado

11:00 a.m. *Break*

11:15 a.m. WRAP-UP DISCUSSION: ENABLING MEANINGFUL POLICY DIALOG
Moderators: Tim Westmoreland and Sophia Chang

12:00 p.m. Lunch

UNDERSTANDING THE IMPACT OF NEW TREATMENT ON HIV TESTING

Speakers

Paul Volberding, M.D.
AIDS Program Director
San Francisco General Hospital
SFGH Ward 84, 995 Potrero Avenue
San Francisco, CA 94110
(415) 476-4082 ext 110 – phone
(415) 476-9233 – fax

Tom Coates, Ph.D.
Center for AIDS Prevention Studies
74 New Montgomery St.
Suite 600
San Francisco, CA 94105
(415)597-9157 -- phone
(415)597-9213 -- fax

Steve Morin, Ph.D.
Center for AIDS Prevention Studies
74 New Montgomer, Suite 600
San Francisco, CA 94105
(415) 597-9100 – phone
(415) 597-9213 – fax

Kathryn A. Phillips, Ph.D.
University of California, San Francisco
74 New Montgomery #502,
Box 0886
San Francisco, CA 94105
(415) 597-9190 – phone
(415) 597-9125 – fax

Andy Bindman, M.D.
Associate Professor of Medicine
Acting Chief, Division of General Internal Medicine
San Francisco General Hospital
1001 Potrero Ave., Bldg. 90, Ward 95
San Francisco, CA 94110
(415) 206-6095 – phone
(415) 206-5586 – fax

Forum Participants

Dr. Art Ammann
President
American Foundation for AIDS Research (AMFAR)
733 Third Avenue, 12th floor
NewYork, NY 10017
(212) 682-7440 – phone
(212) 682-9812 – fax

John Auerbach
AIDS Director
Department of Public Health
250 Washington Street
3rd Floor
Boston, MA 02108
(617) 624-5300 - phone
(617) 624-5399 - fax

Cornelius Baker
Executive Director
National Association of People With AIDS (NAPWA)
1413 K Street, NW
7th floor
Washington, DC 20005
(202) 898-0414 – phone
(202) 898-0435 – fax

David Barr, J.D.
Forum for Collaborative HIV Research
Center for Health Policy
2021 K Street, NW
Suite 800
Washington, D.C. 20006
(202) 530-2307 – phone
(202) 530-2372 – fax

Ron Bayer, Ph.D.
Professor
Columbia University School of Public Health
600 W. 168th Street, 7th Floor
NY, NY 10032
(212) 305-1957 – phone
(212) 305-6832 – fax

Scott Burris, J.D.
Temple University Law School
1719 N. Broad St.
Philadelphia, PA 10122
(215) 204-6576 – phone
(215) 204-1185 – fax

Virginia Caine, MD
Community Health and Hospital Corporation
of Marion County
3838 North Rural Road
Indianapolis, IN 46205-2930
(317) 541-2301 -- phone
(317) 541-2307 -- fax

Connie Cellum, MD
Harbor View Medical Center
325 9th Avenue, Box 359777
Seattle, WA 98104
(206) 521-5814 -- phone
(206) 521-5828 -- fax

Jay Coburn
2A Brown Street
Provincetown, MA 02657
(508) 487-5614 -- phone
(508) 487-0469 -- fax

Wendy S. Craytor
Coordinator, AIDS and STD Programs
Division of Public Health
Section of Epidemiology
3601 C Street, Suite 540
Anchorage, AK 99524-0249
(907) 269-8000 -- phone
(907) 561-4239 -- fax

Jon Davidson, Esq.
Lambda Legal Defense Fund
6030 Wilshire Boulevard, Suite 200
Los Angeles, CA 90036
(213) 937-2728 -- phone
(213) 937-0601 -- fax

Richard Elovich
Director , Gay Men's Health Crisis
119 W. 25th Street
New York, NY 10011
(212) 367-1380 -- phone
(212) 367-1370 -- fax

Chai Feldblum, Esq.
Director and Associate Professor of Law
Federal Legislation Clinic
111 F Street, NW Suite 340
Washington, DC 20001
(202) 662-9595 -- phone
(202) 662-9682 -- fax

Helene D. Gayle, M.D., M.P.H.
Director
National Center for HIV, STD and TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Road
Mail Stop EO7
Atlanta, GA 30333
(404) 639-8000 -- phone
(404) 639 8600 -- fax

Lawrence Gostin, Esq.
Professor of Law
Co-Director, Georgetown/Johns Hopkins
Joint Degree in Public Health & Law Program
Georgetown University Law Center
600 New Jersey Avenue, NW #470
Washington, DC 20001
(202) 662-9373 -- phone
(202) 662-9680 -- fax

David Harvey, M.D.
Executive Director
AIDS Policy Center for Children, Youth, and Families
918 16th Street, NW
Washington, DC 20006
(202) 785-3564 -- phone
(202) 785-3579 -- fax

Ernest Hopkins
Federal Affairs Director of Public Policy
San Francisco AIDS Foundation
10 United Nations Plaza
San Francisco, CA 94102-4910
(415) 487-3080 -- phone
(415) 487-3089 -- fax

Jeff Levi
Center for Health Policy Research
The George Washington University Medical Center
2021 K Street, NW
Suite 800
Washington, DC 20006
(202) 296-6922 -- phone
(202) 296-0025 -- fax

Steve Lew
Asian & Pacific Islander
Wellness Center
730 Polk Street, 4th Floor
San Francisco, CA 94109
(415) 292-3400 -- phone
(415) 292-3404 -- fax

Christine Lubinski
AIDS Action Council
1875 Connecticut Ave., NW
Suite 700
Washington, DC 20009
Tel: 202/986-1300
Fax: 202/986-1345

Miguelina Maldonado
Director of Government Affairs and Public Policy
National Minority AIDS Council
1931 13th Street, NW
Washington, DC 20009
(202) 483-6622 – phone
(202) 483-1135 – fax

Joseph O'Neill, M.D.
Associate Administrator of the HIV/AIDS Bureau
Health Resources and Services Administration (HRSA)
5600 Fishers Lane, Room 705
Rockville, MD 20857
(301) 443-1993 – phone
(301) 443-9645 – fax

Katie O'Neill
Executive Vice President and Director HIV/AIDS Program
Legal Action Center
153 Waverly Place
New York, NY 10014
(212) 243-1313 – phone
(212) 675-0286 – fax

June Osborn, M.D.
President, Macy Foundation
44 East 64th Street
New York City, NY 10021
(212) 486-2424 – phone
(212) 644-0765 – fax

Keith Rawlings, MD
Chair, National Medical Association AIDS Task Force
Southeast Medical Center
9202 Elam Road
Suite 350
Dallas, TX 75217
(214) 590-4200 – phone
(214) 590-1714 – fax

Julie Scofield
Executive Director
NASTAD
444 N. Capitol Street, NW, Suite 339
Washington, DC 20001
(202) 434-8090 – phone
(202) 434-8092 – fax

Jane Silver, M.P.H.
Director, Public Policy
American Foundation for AIDS Research (AMFAR)
1828 L Street, NW , Suite 802
Washington, DC 20036
(202) 331-8600 – phone
(202) 331-8606 -- fax

Michael A. Stoto, Ph.D.
Senior Staff Officer
Institute of Medicine
2101 Constitution Avenue, NW
Washington, DC 20418
(202) 334-2453 – phone
(202) 334-2939 – fax

Jeff Stryker
CAPS/UCSF
74 New Montgomery St.
San Francisco, CA 94114
(415) 597-9279 -- phone

Todd Summers
Deputy Director
White House Office of National AIDS Policy
808 17th Street, NW, Suite 820
Washington, DC 20006
(202) 632-1090 -- phone
(202) 632-1096 – fax

Tim Sweeney
Foundation Programs Director
Empire State Pride Agenda
230 West 17th Street
4th Floor
New York City, NY 10011-5325
(212) 627-0305 -- phone
(212) 627-4136 – fax

Tim Westmoreland, Esq.
Georgetown University
Federal Legislation Clinic
111 'F' Street, NW
Suite 340
Washington, DC 20001
(202)662-9595 -- phone
(202)662-9682 -- fax

New Technologies for Counseling and Testing:

Should We Redesign the System

or Should We Just Start Over?

Thomas J. Coates PhD, Stephen Morin PhD and Edwin Charlebois MPH

Center for AIDS Prevention Studies
UCSF AIDS Research Institute
University of California, San Francisco

Paper prepared for the Kaiser Family Foundation Forum
January, 1998

HIV testing was developed initially to insure the safety of the blood supply. HIV counseling and testing was made available to individuals was established to avoid using blood banks as the diagnostic center. Counseling and testing, once established, became one of the centerpieces of the US response to the AIDS epidemic. The diagnosis of HIV can help at risk individuals to know their serostatus and thus relieve uncertainty about whether or not they are infected. It can also strengthen their motivation for behavior change so that both infected and uninfected individuals can protect themselves and others from infection. It can also facilitate referral to clinical care, so that infected individuals can determine the stage of their illness and avail themselves of medical treatments and prophylaxis for the illnesses associated with HIV disease.

These objectives have been realized to greater or lesser degrees. The blood supply in the US is quite safe: 12 to 24 infectious donations are available annually out of a total pool of over 12 million donations (Sterner, Busch, Kleinman, & Korelitz, 1996). The CDC estimates that approximately two thirds of HIV infected individuals in the US have been diagnosed and are aware of their infection. The data on how well HIV counseling and testing improves prevention efforts to date has been equivocal. Higgins et al (1991) conducted a review of 50 studies (including, at that time, two in developing countries) reporting on the relationship between counseling and testing and behavior change. The review is summarized as follows: "All longitudinal studies of homosexual men reported reductions in risky behavior among both tested and untested men, and a few reported greater decreases among seropositive men than among seronegative men. For intravenous drug users in treatment, reductions were found in intravenous drug use and sexual risk behaviors regardless of counseling and testing experience. There was little evidence for the impact of counseling and testing on pregnancy and/or pregnancy terminations for either seropositive or seronegative high risk women. There was substantial risk reduction among heterosexual couples with one infected partner. Findings among other heterosexuals at increased risk were scanty and mixed."

Wolitski et al (1997) updated the Higgins et al (1991) review, examining 35 domestic and international studies published since that review. They found more evidence that CT could motivate risk reductions, and found that more than 50% of the studies provided evidence that counseling and testing was effective in motivating risk reductions. More definitive results have come from randomized controlled trials, of which there are only three examining the impact of counseling and testing. Wenger et al (1991; 1992) found that 27% of heterosexual subjects receiving counseling and testing avoided vaginal or anal intercourse without a condom with their most recent partner compared to 13% of those receiving counseling alone. De Zoysa (1995) reported on the outcomes of a randomized controlled study of counseling and testing vs. health information in three developing countries. Over 4500 individuals were randomized to receive counseling and testing or the comparison intervention; at the six month follow-up, there was a 50% reduction in the percentage of individuals in the counseling and testing intervention

engaging in unprotected intercourse with non-primary partners, while those in the control arm changed very little.

There is evidence, however, that HIV counseling and testing does not achieve its prevention aims as well as it might. Overall, about 25% of individuals tested for HIV do not receive their test results; individuals who are younger, African-American, those with an STD diagnosis, those receiving confidential as opposed to anonymous testing are less likely to return to receive their results ((Weber, Frey, Horsley, & Gwinn, 1997)). Many of these variables are associated with higher risk for HIV infection. Several studies have documented the same phenomenon: at least one third of infected individuals continue to engage in practices likely to transmit HIV. Lemp et al (1994) found that about one-third of young gay men aware that they were HIV-infected reported that they had unprotected anal intercourse. Kelly et al (1993) reported a rate of 29%, while Rotheram-Borus et al (in press) reported a rate of 33% among gay and bisexual men under the age of 23 years. Robins et al (1994) reported that about 35% of gay men enrolled in the Multicenter AIDS Cohort Study (MACS) and aware of their infection engaged in unprotected anal intercourse in the previous six months. Similar rates of unprotected sexual activity have been reported in groups of injection drug users (Rhodes, Donoghoe, Hunter, & Stimson, 1993; Singh, Koman, Catan, & Souuply, 1993), women (Remien et al., 1995; Rotheram-Borus et al., in press), and heterosexual men who were also IDUs (CDC, 1996a; Kelly, Murphy, Bahr, Loob, & al., 1993; Roffman, 1991).

Similarly, there is a gap between diagnosis and care; far too many HIV-infected individuals fail to seek treatment until symptoms appear. The Centers for Disease Control and Prevention estimate that between 500,000 and 600,000 of the 900,000 Americans with HIV have been diagnosed with the infection (CDC, 1996b). There is relatively little research by which to understand whether or not counseling and testing leads to care and support. Wolitski et al (1997) were able to find only four studies addressing the ability of counseling and testing to motivate individuals to seek early medical interventions, psychological counseling, or other supportive services. The studies over all suggest that individuals seek medical care and services, not so much when they are diagnosed with HIV, but rather when symptoms of HIV disease begin to appear.

The HIV counseling and testing system was established in an era of limited potential to extend the quantity and quality of life of persons with HIV. It was also established when care for persons infected with HIV and prevention for persons not infected with HIV were separated conceptually and operationally. Advances in scientific understanding and in care have altered radically our understandings of the disease process itself, our ability to extend life and improve quality of life, and our need to combine prevention and care. Advances in diagnostic, counseling, and treatment strategies need to influence how counseling and testing is justified in a comprehensive system of treatment and care. Further, counseling and testing needs to come of age and be modernized so that it can fulfill its mission while taking advantage of advances in prevention, diagnosis, and treatment.

A New Model of the Continuum
Between Exposure and Infection and
Between Prevention and Care

Concepts of HIV disease have changed radically in the past few years due to novel understandings of the process of infectivity, pathogenesis, and early natural history. These conceptual shifts have been driven by new diagnostic strategies, new treatment regimens, and also the development of novel approaches to behavioral counseling for HIV prevention and care. We will first present this new model and then discuss the advances in detail.

HIV disease is now conceptualized as a continuum extending from social and personal exposure to HIV through primary HIV infection to established infection and late stage disease (see Figure 1). The first stage represents exposure in the community, with risk of HIV infection dependent upon prevalence of infection in the community, risk behaviors, and sexual mixing. The strategies for preventing transmission are multiple and include broadly based prevention campaigns, targeted campaigns to uninfected individuals practicing high risk behaviors, and strategies for diagnosing HIV infection in individuals and for motivating them to reduce

Figure 1: A New Model of HIV Care and Prevention

Stage	Exposure	Infection	Antibodies	Strategy
Exposure in the Community	-	-	-	Community prevention
Exposure to the person	+	-	-	Intensive prevention counseling Post-exposure Supportive counseling
Primary HIV Infection	+	+	-	Intensive prevention counseling Antiretroviral therapy Supportive counseling
Established HIV Infection	+	+	+	Counseling for prevention Antiretroviral therapy OI prophylaxis Supportive counseling

transmission to others. Exposure to HIV is community-wide. In the second stage, the individual is exposed personally to HIV through sexual or parenteral contact with someone who is infected with HIV. Neither virus nor antibodies are detectable during this phase. Two prevention strategies are indicated: intensive counseling to reduce exposure to infected individuals in the future and the option of post-exposure prophylaxis with antiretroviral medications to reduce probability of infection with HIV.

The asymptomatic period of HIV infection is conceptualized as a two stage process. The primary phase is relatively short (about six weeks in duration) during which individuals are very infectious. During this period, virus is present but antibodies have not yet developed. Prevention strategies involve supportive counseling, intensive risk reduction counseling, and options of treatment with antiretroviral therapy. The second phase lasts several years and infectivity is much lower. As HIV advances, clinical AIDS begins to develop and infectivity begins to rise again. Supportive counseling, intensive behavioral counseling, antiretroviral therapy, and prophylaxis for opportunistic infections are all indicated during this phase of the disease.

The major implication of this conceptualization is that the separation between prevention and care is no longer a sharp one. In fact, the two are blended in on common theme: health preservation and promotion. Communities and individuals are encouraged to do all that they can to avoid infection and, once infected, individuals are encouraged to maintain their health and the health of their communities by managing their disease and limiting spread of HIV.

There are also financial reasons for bringing HIV counseling and testing out of isolation and for linking prevention and care in this technology. "Perhaps an even more fundamental fiscal consideration relates to the potential for HIV prevention needs and HIV treatment needs to compete for a *fixed level of resource.* In fact, one of the barriers to collaborative planning cited in the NASTAD report (NASTAD, 1995) was the fear that 'direct care could overshadow prevention because care's focus is more concrete as compared to prevention (Valdiserri, 1997).'"

Advances in Diagnostics, Therapeutics and Counseling Strategies

HIV counseling and testing was devised when diagnostic tests were few, prognostic indicators of limited utility, and behavioral counseling was in a rudimentary state of development and untested in clinical trials. That situation has now changed. Diagnostics, therapeutics, and counseling have evolved and each has advanced to a sophisticated stage of development. These advances have implications for the design of a diagnostic system that has both prevention and therapeutic missions.

Viral Diagnostics

Rapid HIV testing. Recent advances in HIV testing technology increase the probability that persons with HIV infection can learn their antibody status. Standard HIV antibody tests are currently done in central laboratories using batch-oriented enzyme immunoassays. Confirmatory Western blot or immunofluorescence assays are used to confirm the results because they are more specific. Physicians and patients typically wait for a week or more to obtain the results because of test batching and other factors related to transport and qualified personnel to conduct the tests. Rapid tests can be done in 10 to 15 minutes and have excellent sensitivity and specificity. Rapid tests have negative predictive values equivalent to traditional enzyme immunoassays, allowing individuals with negative tests to be so informed at the time of the testing (Spielberg & Kassler, 1996).

Persons who test positive on the initial rapid test can be dealt with in a number of ways. One option would be to tell them that they are potentially HIV positive, that a confirmatory test is indicated, and that they should return after a few days or weeks to receive the results of the confirmatory test. Wilkinson et al (1996) evaluated rapid testing in a rural hospital in South Africa and found complete concordance between two rapid tests (Capillus HIV-1/HIV-2 rapid test and Abbott TestPack HIV-1/HIV-2) and the rapid

test strategy was 100% sensitive and 99.6% specific compared with the ELISA strategy. The proportion of patients post-test counseled increased to 96% from 17% after the introduction of the rapid test strategy and the cost per patient post-test counseled was cut by 50%. Kassler et al (1997) evaluated the rapid test strategy in the US and found that rapid testing resulted in an increase in the number of persons learning their serostatus: a 4% increase for uninfected and a 16% increase for infected clients at an anonymous testing clinic; a 210% increase for uninfected patients and a 23% for infected patients at an STD clinic. The cost savings per client was $11.00. Thus, rapid HIV testing is feasible, preferred by clients, and results in significant improvements in the number of persons learning their serostatus without increasing the costs or decreasing the effectiveness of counseling and testing (Farnham, Gorsky, Holtgrave, Jones, & Guinan, 1996). Rapid self-testing is an option that should also be considered (Merson, Feldman, Bayer, & Stryker, 1997).

This option cannot be considered until the CDC changes its program guidelines, especially with regard to preliminary notification and until the FDA encourages manufacturers of rapid HIV tests to seek licensure in the US and agrees to move quickly on their approval.

Viral load testing. HIV RNA levels correlate with lower CD4+ counts, more rapid declines in CD4+ counts, and are a good predictor of long-term outcomes with regard to disease progression and death. The most sensitive tests today can measure down to 400 copies of virus; new tests will be available in early 1998 can measure down to 20-50 copies of virus. The importance of this test is not only its prognostic value, but also the fact that virus can be detected almost as soon as the person is infected. This speeds up the diagnosis of infection to an important earlier period of HIV infection than could be detected via assays only for antibodies. The question for prevention and care is whether or not it is prudent to provide viral load testing, in addition or in place of antibody testing, for individuals with recent exposures to HIV, high risk of exposure to HIV, or symptoms of early HIV infection.

Viral resistance testing. Several studies have shown that the degree of clinical benefit obtained from combination therapy decreases as the duration and variety of past antiviral drug exposure increases (Brun-Vezinet & Committee, 1997). Many HIV-infected individuals are unable to obtain lasting benefit from the addition of potent protease inhibitors (Feinberg, 1997). Incomplete suppression of HIV replication offers the opportunity for accumulation of mutations that result in high level drug resistance to even the most potent drugs available (Katzenstein, 1997).

Theoretically, clinical benefit could be conferred to the individual, as well as to a person infected by that individual, if it were possible to determine resistance patterns. It might be possible to tailor drug regimens for the infected individual and regimens for prophylaxis or treatment of primary HIV infection if such resistance patterns could be identified. While some reports of tests of genotypic resistance are becoming available for clinical use, Deeks and Abrams (1997) rightly point out that defining viral resistance is not

straightforward and clinically useful tests may not be on the nearest horizon. They call for ongoing studies to define the clinical value of HIV genotyping. Such studies will occur and studies of both phenotyping and genotyping will be demanded by infected and exposed individuals and there will be a rush to determine their clinical utility. HIV counseling, testing, care, and prevention studies must begin to prepare now for the day when such tests will be available.

Advances in Therapy for HIV

The emergence of new medical care regimens have extended the life and the quality of life of persons with HIV disease (Emini et al., 1996; Salgo, Mastrodonato, Schipper, & Baruch, 1996; Tumietto et al., 1996, July).

Post-Exposure Prevention. Chemoprophylaxis with zidovudine after percutaneous exposure among health care workers to HIV may be efficacious in reducing infection with HIV (Cardo et al., 1997; Gerberding, 1996). A recent case control study indicated that zivoduvine (Retrovir) decreases the odds of infection with HIV by 79% among health care workers who sustain an occupational exposure to HIV(Cardo et al., 1997; CDC, 1995). Although this observation has not been confirmed in a randomized controlled trial, antiretroviral treatment is now standard of care for parenteral occupational exposures to HIV (CDC, 1995; Gerberding, 1996). The probability of HIV infection from a contaminated needle puncture is similar to that estimated for a single episode of unprotected receptive anal or vaginal intercourse with an infected partner or a single episode of injecting drug use with contaminated equipment (De Gruttola & Fineberg, 1989; Downs & De Vincenzi, 1996; Gerberding, 1996; Kaplan & Heimer, 1992; Peterman, Stoneburner, Allen, Jaffe, & Curran, 1988; Wiley, Herschkorn, & Padian, 1989).

Combination Therapy and Treatment for Primary HIV Infection. The developments in the treatment of HIV disease in the past few years have supported the notion that the best way to treat HIV is to use drugs against multiple targets of HIV. The hypothesis is that this makes it more difficult for the virus to mutate and develop resistance. Clearly, the benefits of combination therapy have been shown and the clinical guidelines suggest that these therapies should be considered upon diagnosis (Guidelines for the Use of Antiretroviral Agents, 1997).

These same guidelines advise combination therapy for early or primary HIV infection to suppress the initial burst of viral replication, to decrease the magnitude of virus dissemination throughout the body, to decrease the severity of acute disease, to potentially alter the viral set point which ultimately may affect the rate of disease progression, and possibly to reduce infectiousness and thereby the spread of HIV.

Antiretrovirals for Reducing Vertical Transmission. Early identification of HIV infection in pregnant women is essential for preserving their health and for decreasing the probability of vertical transmission. Antiretrovirals can be offered to the mother

before, during, and after pregnancy and women can be counseled about the risks of transmission through breastfeeeding and advised about alternatives (CDC, 1994; CDC, 1997; Connor & McSherry, 1994). Similarly, once the infant is born, the baby's health can be monitored carefully and everything can be done to preserve it.

Advances in Behavioral Counseling Strategies

Counseling is neither unidimensional nor necessarily informational, but rather a complex set of interactions, derived from theory, and designed to accomplish multiple objectives. Behavioral counseling strategies have undergone important conceptual and practical advances in recent years and these developments have not necessarily been incorporated into the practice of HIV counseling and testing (Sikkema & Bissett, 1997).

Individualization of HIV Prevention Counseling. A sizable number of gay and bisexual men get tested for HIV regularly, many at six month intervals. Those at highest risk for HIV infection are those who are most likely to get tested regularly (Berrios et al., 1993; Kalichman & Hunter, 1993; McCusker et al., 1996; McFarland, Fischer-Ponce, & Katz, 1995; Valdiserri et al., 1988). Phillips et al (1995) found that repeat testers were more likely to be younger, nonwhite, sampled at bars, known to have HIV infected sexual partners, and to engage in oral sex to ejaculation. Grunseit et al(1996)found that repeat testers were more likely to have casual sex partners and engage in anal sex with or without condoms (Kalichman et al., 1997). Do these individuals get tested repeatedly to reinforce an unsafe lifestyle, or has counseling been insufficient to assist in lowering risk for HIV?

Recent reviews of behavioral interventions call for tailoring interventions to address the specific factors that contribute to sexual risk taking. There is a wide range of factors which define the varying and individual contexts in which risk behavior occurs (Donovan, Mearns, McEwan, & al, 1994; Hospers & Kok, 1995; Kelly, Kalichamn, Kauth, & al., 1991; Stall, Coates, & Hoff, 1988). Examples include being with new desired partners and assuming that they are HIV uninfected, desire to enhance intimacy in a relationship that has the potential to be long-term, being under the influence of drugs or alcohol, seeking the enjoyment of unprotected intercourse, losing control during the "heat of the moment," avoiding discussion of HIV for fear of losing a desired partner, or pressure or coercion from a partner.

A crucial understanding emanating from this perspective is that "one size does not fit all." Preventive intervention strategies require that the individualized needs and risks of individual clients need to be identified, and that risk reduction strategies need to be tailored specifically to the determinants of risk and life circumstances of that individual. The goal of individualized counseling is to increase accurate knowledge of HIV disease and develop an individualized plan for reducing susceptibility to or the probability of transmitting HIV by tailoring the intervention plan to the individual's needs, serostatus, and lifestyle.

Individual counseling permits optimal tailoring of interventions for each client, allows individualized referral procedures and follow-up to determine if the referrals were accessed, and are logistically more feasible than group delivered interventions. Men engaging in high risk behaviors are much less likely to attend group intervention sessions than men not engaging in these behaviors. Group delivered interventions are difficult to construct and usually attract the less rather than the more risky. In one community-based study conducted at CAPS, only 20% of gay men who were engaging in high risk behavior chose to attend group risk reduction sessions (Kegeles, Hays, & Coates, 1996). Similarly, in Portland where another community level intervention was delivered, only a small minority attended single and multiple group sessions (12% and 4% respectively) (Hoff et al., 1997).

A further elaboration of the individualization concept requires attention to the amount of counseling available to individuals. The Office of Technology Assessment report on behavioral interventions for gay men provided important guidance regarding the number of sessions which characterize effective interventions(Coates, Faigle, Koijane, & Stall, 1995). Greater risk reduction has been observed with behavioral interventions that have more sessions and are conducted over time to allow participants to practice behavior change skills between sessions and discuss problems and reinforce progress during sessions (Oakley, Fullerton, & Holland, 1995). Data from Project Respect suggest that few brief sessions do result in some behavior change, but that these changes are minimal in comparison to what might be needed to have epidemic impact.

Focus on HIV Infected Individuals. A major implication of this new conceptualization of HIV disease is the need to focus specifically on primary prevention strategies among HIV-infected individuals. Most HIV prevention counseling starts from the premise that the individuals are uninfected or that their infection status is unknown. Most counseling for infected persons has focused on support and care in attempt to bolster ability to cope with HIV disease. Many counseling strategies are neutral, and make no special use of the individual's serostatus to motivate and plan for behavior change. However, it has recently become obvious that specialized interventions to assist HIV infected persons in reducing transmission behaviors are not only possible but also highly desirable. HIV infection can only occur when an infected individuals passes the disease to an uninfected individual. In fact, cost-effectiveness arguments suggest that intense targeting of infected individuals to reduce transmission behaviors may be the most efficient and effective means for stopping transmission especially in high prevalence areas. Efforts to change the community norm to one of responsibility, especially among seropositives to know their serostatus and to avoid infecting others, should be a priority.

Source Contact Tracing and Partner Notification. Identifying and offering services to contacts of HIV infected persons is good prevention and medical practice. It can benefit the diagnosed individual. If that individuals has presented because of exposure, the infection status of the source contact can assist in the decision about whether or not to initiate post-exposure prophylaxis. If the source partner is infected, determining antiretroviral history and viral resistance patterns may assist in the selection of

a treatment regimen for exposed patients or those in a primary infection stage. It is also possible that source patients are unaware of their HIV infection status. They, too, may be in a primary HIV infection stage or have established but untreated HIV infection. West and Stark (1997) reviewed the literature on partner notification and summarized the data as follows: (1) most HIV-infected individuals will cooperate in identifying at least some of their sex partners of exposure to HIV; (2) sex partners are generally receptive to being notified and will seek HIV testing; (3) provider referral is probably more effective than patient referral in reaching sources; (4) sex partners quite often are unaware of or misunderstand their HIV risk; and (5) sex partners frequently are infected with HIV. Further, partner notification can lead prevention providers into high risk networks and thus lead the way to other more intensive interventions in locales and among groups where high rates of HIV transmission may be occurring. Thus, partner notification needs to be incorporated into a comprehensive program of HIV prevention and care and will benefit the patient as well as the community. Efforts may need to be targeted in order to be cost-effective, especially for purposes of targeting clusters of individuals with primary HIV infection.

Couples Counseling and Testing. Joint counseling and testing for couples is an idea emerging from work in developing countries but which should have applicability in the developed world as well. The first indications of the utility of couples counseling and testing emerged from a study of the natural history of HIV disease and risk factors for seroconversion among Rwandese women (Allen et al., 1992). HIV counseling and testing and promotion of condoms was one part of this research; only 7% of the women had used condoms at baseline, and after one year of follow-up, 16% of the seronegative and 35% of the seropositive women reported using condoms. This was compared to 3.5% among constructed concurrent control groups. Condom use rates were higher overall among the women (about 26%) whose partners volunteered to be tested (55% and 23% among seropositive and seronegative women respectively). HIV seroconversion rates decreased in seronegative women whose partners were tested, but not in women whose partners were not tested. Gonorrhea rates declined significantly (by 50%) in seropositive women whose partners compared to women whose partners were not tested. In another analysis of the study, marked increases in condom use (up to 57%) were n noted among discordant couples, and discordant couples accounted for 25% of condom users among couples with women and 30% of condom users among couples with seronegatve women (Allen et al., 1992). Marked increases in condom use were also found among discordant couples in a research project in Zaire (Kamenga et al., 1991). Such strategies have not been used in the US, but could be targeted especially to areas of the country where heterosexual transmission is the highest.

Counseling for Coping with HIV Disease. There have been significant advances as well in the development of efficacious models for helping HIV-infected individuals cope with the stresses of HIV disease. Chesney et al (1996) have developed a strategy of "coping effectiveness training" derived from stress and coping theory and designed to reduce psychological distress among HIV infected men (Chesney, Folkman, & Chambers, 1996; Folkman & Chesney, 1995). In their studies, 149 HIV infected men

were randomized to one of three conditions: a stress and coping intervention, a control condition, and a wait-list control group. Coping effectiveness training resulted in increased coping self-efficacy and reductions in perceived stress and burnout. Kelly et al (1993) found that an 8-session support group program emphasizing emotionally focused coping reduced depression and anxiety and reductions in unprotected anal intercourse.

Counseling for Adherence to Anti-HIV Medication Regimens. Data from clinical trials of coping effectiveness training and studies on adherence indicate that psychological distress interferes with adherence to clinical care and also the management of HIV disease. Specifically, higher levels of depression, anxiety, and negative morale and lower levels of optimism were all related to more missed doses of zidovudine and other antiretroviral medications. Higher levels of depression were associated with lower scores on a summary measure of health-promoting behaviors (Berkman & Breslow, 1983) found in epidemiological studies to be associated with morbidity. Chesney and her colleagues have also found that stress is associated with lower expectations of adherence to care. This research suggests that adherence among HIV+ persons may be increased by providing emotional support and problem-solving strategies to overcome barriers to adherence (Chesney, 1993; Morse, Simon, Coburn, & Hyslop, 1991). Chesney and her colleagues have also identified five strategies for increasing adherence to antiretroviral therapy including clarifying the regimen, individualized needs assessments, tailoring the regimen to one's lifestyle, removing barriers to adherence, and organizing a supportive environment are effective in improving adherence to antiretroviral regimens and improving management of HIV disease as measured by decreased viral loads (Chesney, 1997).

A Redesigned System of Counseling and Testing

Several important strategies emerge from this discussion of advances in our conceptualization of HIV disease, viral diagnostic strategies, behavioral counseling methods, and the use of antiretroviral therapies to reduce infection and progression of HIV disease.

- Individuals at risk for HIV disease should be able to have quick and easy access to the latest advances in diagnostic strategies to determine if they are infected, the stage of their infection, and the nature of the virus they harbor.

- Diagnostic strategies should be as quick as possible and require as few visits to as few places as possible to insure that individuals not be lost in the gap between visits and service locations.

- An essential part of this diagnostic strategy should include information about the possible source of HIV infection, including that person's medication history and phenotypic and genotypic characteristics of the source's virus.

- When desirable, sexual partners should have the advantage of co-counseling to deal with myriad issues of transmission, sero-discordance, and emotional consequences of HIV transmission.

- Individuals who are possible sources of HIV infection should have the advantage of learning if they are HIV-infected (if they do not already know that) and all of the benefits that accrue from that knowledge.

- Individuals who are HIV-infected and engaging in behaviors likely to infect others should have the advantage of intensive counseling to reduce the probability that they will transmit HIV to others in the future.

- Individuals exposed to HIV should be able to access the best possible counseling to support both their emotional needs and to insure that they not expose themselves to HIV in the future. and, if they are infected, that they not expose others to HIV.

- Individuals recently infected with HIV should have access to supportive counseling and to risk reduction counseling to avoid infecting others and exposing themselves to pathogens.

- Exposed or infected individuals should be offered the best combinations of antiretrovirals to prevent HIV infection if they have been exposed and to treat their infection regardless of the stage of their HIV disease.

- Infected should have access to the latest advances in prophylaxis and treatment of opportunistic infections.

- Infected individuals who are pregnant or contemplating pregnancy should have access to and be offered the best possible advice for family planning and the maximally effective antiretroviral regimens for maintaining their own health and for insuring that their infant will be born without HIV disease and remain that way.

- At risk or infected individuals should have access to other social services they might need.

The primary principle is simple: innovative approaches to the diagnosis and care of individuals with HIV that link prevention and treatment must drive the design of counseling and testing services (Osborn, 1997). At risk, exposed, and infected individuals should have quick and easy access to determine their risk of HIV infection; determine if they have been exposed to or are infected with HIV; determine the stage of their infection; receive excellent behavioral counseling for support, risk reduction, and adherence to HIV medications; and be offered antiretrovirals with state-of-the-art

adherence counseling to prevent infection, treat their disease, and prevent vertical transmission to the fetus.

Given these advances and the principles that derive from them, stand alone counseling and testing services make little sense. Indicated is "one stop shopping" in which individuals can receive, as rapidly as possible, the variety of diagnostics (including behavioral and virological assessment of themselves and their partners), and the variety of medical and behavioral counseling services they need.

References

Allen, S., Tice, J., Van de Perre, P., Serufilira, A., Hudes, E., Nsengumuremyi, F., Bogaerts, J., Lindan, C., & Hulley, S. (1992). Effect of serotesting with counseling on condom use and seroconversion among HIV discordant couples in Africa. *British Medical Journal, 304*(6842), 1605-1609.

Berkman, L.F., & Breslow, L. (1983). *Health and ways of living: The Alameda County Study*. New York: Oxford University Press.

Berrios, D., Hearst, N., Coates, T., Stall, R., Hudes, E., Turner, H., Eversley, R., & Catania, J. (1993). HIV antibody testing among those at risk for infection. The National AIDS Behavioral Surveys. *Journal of the American Medical Association, 270*(13), 1576-1580.

Brun-Vezinet, F., & Committee, D.C. (1997). HIV-1 viral load, phenotype, and resistance in a subset of drug-naive participants from the Delta trial. *Lancet, 350*(9083).

Cardo, D.M., Culver, D.H., Ciesielski, C.A., Srivastava, P.U., Marcus, R., Abiteboul, D., Heptonstall, J., Ippolito, G., Lot, F., McKibben, P.S., & Bell, D.M. (1997). A Case-Control Study of HIV Seroconversion in Health Care Workers after Percutaneous Exposure. *New England Journal of Medicine, 337*(21), 1485-1490.

CDC. (1994). Zidovudine for the Prevention of HIV Transmission from Mother to Infant. *Morbidity and Mortality Weekly Report, 43*(16).

CDC. (1995). Case-control study of HIV seroconversion in health-care workers after percutaneous exposure to HIV-infected blood - France, United Kingdom, and United States, January 1988-August 1994. *Morbidity and Mortality Weekly Report, 44*(50), 929-933.

CDC. (1996a). AIDS associated with injection drug use -- United States 1995. *Morbidity and Mortality Weekly Report, 45*(19).

CDC. (1996b). Update: Mortality Attributable to HIV Infection Among Persons Aged 25--44 Years --- United States, 1994. *Morbidity and Mortality Weekly Report, 45*(6).

CDC. (1997). Update: Perinatally Acquired HIV/AIDS --- United States, 1997. *Morbidity and Mortality Weekly Report, 46*(46).

Chesney, M.A. (1993). Health psychology in the 21st century: Acquired immunodeficiency syndrome as a harbinger of things to come. *Health Psychology, 12*(4), 259-268.

Chesney, M.A. (1997,). *Adherence To HIV Antiretroviral Therapy.* Paper presented at the Adherence to New HIV Therapies: A Research Conference, Washington, D.C.

Chesney, M.A., Folkman, S., & Chambers, D. (1996). Coping effectiveness training for men living with HIV disease: Preliminary findings. *International Journal of STD and AIDS, 7*(Suppl 2), 75-82.

Coates, T.J., Faigle, M., Koijane, J., & Stall, R.D. (1995). *Does HIV prevention work for men who have sex with men?* : Office of Technology Assessment Report, U.S. Congress.

Connor, E., & McSherry, G. (1994). Treatment of HIV infection in infancy. *Clinics in Perinatology, 1*(March 21), 163-177.

De Gruttola, V., & Fineberg, H. (1989). Estimating prevalence of HIV infection: considerations in the design and analysis of a national seroprevalence survey. *Journal of Acquired Immune Deficiency Syndromes, 2*(5), 472-480.

Donovan, C., Mearns, C., McEwan, R., & al, e. (1994). A review of the HIV-related sexual behavior of gay men and men who have sex with men. *AIDS Care, 6*(5), 605-617.

Downs, A., & De Vincenzi, I. (1996). Probability of heterosexual transmission of HIV: relationship to the number of unprotected sexual contacts. European Study Group in Heterosexual Transmission of HIV. *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology, 11*(4), 388-395.

Emini, E., Condra, J.H., Schleif, W.A., Massari, F.E., Leavitt, R.Y., Deutsch, P.J., & Choadakewitz, J.A. (1996,). *Maintenance of long-term virus suppression in patients treated with the HIV-1 protease inhibitor Crixivan (Indinavir).* Paper presented at the XI International Conference on AIDS, Vancouver, Canada.

Farnham, P.G., Gorsky, R.D., Holtgrave, D.R., Jones, W.K., & Guinan, M.E. (1996). Counseling and testing for HIV prevention: Costs, effects, and cost-effectiveness of more rapid screening tests. *Public Health Reports, 111*(1), 44-53.

Feinberg, M. (1997). Hidden dangers of incompletely suppressive antiretroviral therapy. *The Lancet, 349*(63), 1048.

Folkman, S., & Chesney, M.A. (1995). Coping with HIV infection. In M. Stein & A. Baum (Eds.), *Chronic diseases: Perspectives in Behavioral Medicine* (pp. 115-133). Mahwah, N.J.: Lawrence Erlbaum Associates, Inc.

Gerberding, J.L. (1996). Prophylaxis for occupational exposure to HIV. *Annals of Internal Medicine, 125*(6), 497-501.

Hoff, C., Kegeles, S., Acree, M., Stall, R., Paul, J., Ekstrand, M., & Coates, T. (1997). Looking for men in all the wrong places...: HIV prevention small-group programs do not reach high risk gay men. *Aids, 11*(6), 829-830.

Hospers, H.J., & Kok, G. (1995). Determinants of safe and risk-taking sexual behavior among gay men: A review. *AIDS Education and Prevention, 7*(1), 74-96.

Kalichman, S., & Hunter, T. (1993). HIV-related risk and antibody testing: an urban community survey. *Aids Education and Prevention, 5*(3), 234-243.

Kalichman, S.C., Schaper, P.E., Belcher, L., Abush-Kirsh, T., Cherry, C., Williams, E.A., Nachimson, D., & Smith, S. (1997). It's like a regular part of gay life: Repeat HIV antibody testing among gay and bisexual men. *AIDS Education and Prevention, 9*(Suppl B), 41-51.

Kamenga, M., Ryder, R., Jingu, M., Mbuyi, N., Mbu, L., Behets, F., Brown, C., & Heyward, W. (1991). Evidence of marked sexual behavior change associated with low HIV-1 seroconversion in 149 married couples with discordant HIV-1 serostatus: experience at an HIV counseling center in Zaire. *AIDS, 5*(1), 61-67.

Kaplan, E., & Heimer, R. (1992). A model-based estimate of HIV infectivity via needle sharing. *Journal of Acquired Immune Deficiency Syndromes, 5*(11), 1116-1118.

Katzenstein, D. (1997). Antiretroviral therapy for human immunodeficiency virus infection in 1997. *Western Journal of Medicine, 166*(5), 319-325.

Kegeles, S.M., Hays, R.B., & Coates, T.J. (1996). The Mpowerment Project: A community -level HIV prevention intervention for young gay men. *American Journal of Public Health, 86*(6), 1129-1136.

Kelly, J.A., Kalichamn, S.C., Kauth, M.R., & al., e. (1991). Situational factors associated with AIDS risk behavior lapses and coping strategies used by gay men who successfully avoid lapses. *American Journal of Public Health, 81*(10), 1335-1338.

Kelly, J.A., Murphy, D.A., Bahr, G.R., Loob, J., & al., e. (1993). Factors associated with severity of depression and high-risk sexual behavior among persons diagnosed with HIV infection. *Health Psychology, 12*(3), 215-219.

McCusker, J., Willis, G., McDonald, M., Sereti, S., Lewis, B., & Sullivan, J. (1996). Community-wide HIV counseling and testing in central Massachusetts: who is retested and does their behavior change? *Journal of Community Health, 21*(1), 11-22.

McFarland, W., Fischer-Ponce, L., & Katz, M. (1995). Repeat negative human immunodeficiency virus (HIV) testing in San Francisco: magnitude and characteristics. *American Journal of Epidemiology, 142*(7), 719-723.

Merson, M.H., Feldman, E.A., Bayer, R., & Stryker, J. (1997). Rapid self testing for HIV infection. *The Lancet, 349*(48), 352-353.

Morse, E.V., Simon, P.M., Coburn, M., & Hyslop, N. (1991). Determinants of subject compliance within an experimental anti-HIV drug protocol. *Social Science & Medicine, 32*(10), 1161-1167.

NASTAD. (1995). *Collaborative planning for HIV prevention and care: state and local experiences* . Washington, D.C.

Oakley, A., Fullerton, D., & Holland, J. (1995). Behavioral intervention for HIV/AIDS prevention. *AIDS, 9*(5), 479-486.

Osborn, M.O., van Praag, E., and Hackson, J.,(1997) . (1997). Models of care for patients with HIV/AIDS. *AIDS, 11*(suppl B), S135-S141.

Peterman, T., Stoneburner, R., Allen, J., Jaffe, H., & Curran, J. (1988). Risk of human immunodeficiency virus transmission from heterosexual adults with transfusion-associated infections. *Journal of the American Medical Association, 259*(1), 55-58.

Remien, R., Goetz, R., Rabkin, J., Williams, J., Bradbury, M., Ehrhardt, A., & Gorman, J. (1995). Remission of substance use disorders: gay men in the first decade of AIDS. *Journal of Studies on Alcohol, 56*(2), 226-232.

Rhodes, T.J., Donoghoe, M.C., Hunter, G.M., & Stimson, G.V. (1993). Continued risk behavior among HIV positive drug injectors in London: Implications for intervention. *Addiction, 88*(11), 1553-1560.

Roffman, R. (1991,). *AIDS prevention with gay men.* Paper presented at the Meeting of the National Institute of Mental Health, Bethesda, Md.

Rotheram-Borus, M.J., Murphy, D.A., Coleman, C.L., Kennedy, M., Reid, H.M., Cline, T., Birnbaum, J.M., Futterman, D., Levin, L., Schneir, A., Chabon, B., O'Keefe, Z., & Kipke, M. (in press). Risk acts, health care, and medical adherence among HIV+ youths in care over time. *AIDS and Behavior.*

Salgo, M., Mastrodonato, D.P., Schipper, E., & Baruch, A. (1996,). *Efficacy and safety of triple combination therapy with Invirase (Saquinavir/SOV, HIV protease inhibitor). Epivir (3TC/Lamivurdine) and Retrovir (ADV/Zidovudine) in HIV-infected*

patients. Paper presented at the XI International Conference on AIDS, Vancouver, Canada.

Sterner, G.B., Busch, M.P., Kleinman, S., & Korelitz, J.J. (1996). The risk of transfusion-transmitted viral infections. *New England Journal of Medicine, 334*(26), 1685-1690.

Sikkema, K.J., & Bissett, R.T. (1997). Concepts, goals, and techniques of counseling: Reveiw and implications for HIV counseling and testing. *AIDS Education and Prevention, 9*(Suppl B), 14-26.

Singh, B.K., Koman, J.J., Catan, V.M., & Souuply, K.L. (1993). Sexual risk behavior among injection drug-using human immunodeficiency virus positive clients. *International Journal of the Addictions, 28*(8), 735-747.

Spielberg, F., & Kassler, W.J. (1996). Rapid testing for HIV antibody: A technology whose time has come. *Annals of Internal Medicine, 125*(6), 509-511.

Stall, R., Coates, T.J., & Hoff, C. (1988). Behavioral risk reduction for HIV infection among gay and bisexual men. *American Psychologist, 43*(878-885).

Tumietto, F., Costigliola, P., Moroni, M., Colangeli, V., Borderi, M., Venturi, C., Spinosa, S., & Chiodo, F. (1996, July,). *From monotherapy to multidrug combination era: A case of sustained response to addition of Nevirapine to continued Zidovudine.* Paper presented at the XI International Conference on AIDS, Vancouver, Canada.

Valdiserri, R., Lyter, D., Leviton, L., Callahan, C., Kingsley, L., & Rinaldo, C. (1988). Variables influencing condom use in a cohort of gay and bisexual men. *American Journal of Public Health, 78*(7), 801-805.

Valdiserri, R.O. (1997). HIV counseling and testing: Its evolving role in HIV prevention. *AIDS Education and Prevention, 9*(Suppl B), 2-13.

Weber, T.J., Frey, R.L., Horsley, R., & Gwinn, M.L. (1997). Publically funded HIV counseling and testing in the United States, 1992-1995. *AIDS Education and Prevention, 9*(Suppl), 79-91.

Wiley, J., Herschkorn, S., & Padian, N. (1989). Heterogeneity in the probability of HIV transmission per sexual contact: the case of male-to-female transmission in penile-vaginal intercourse. *Statistics in Medicine, 8*(1), 93-102.

New Treatments, New Challenges, and New Questions about HIV Testing

Stephen F. Morin, Thomas J. Coates, and Edwin D. Charlebois

Policy Research Center

UCSF AIDS Research Institute
University of California, San Francisco

Paper prepared for the Kaiser Family Foundation Forum
January, 1998

Stephen F. Morin, Ph.D., Director
Policy Research Center
AIDS Research Institute
74 New Montgomery, Suite 641, Box 0882
San Francisco, CA. 94105
(415) 597-9228, fax 597-9213
email: smorin@psg.ucsf.edu

The AIDS epidemic is not over; nor is it static. Advances in science have led to new optimism about the potential to treat individuals with HIV disease. This paper explores the difficult questions raised by these new opportunities and this new optimism.

Substantial investment in AIDS research over the last fifteen years has resulted in several significant findings, particularly in the last two years. The pessimism, which for many years characterized scientific discussions on HIV disease, has given way to restrained optimism that controlling viral replication may be possible.

Most of the current optimism results from a better understanding from basic science. We now know that HIV actively replicates beginning with acute infection and continues throughout the course of the disease process (Perelson, Neumann, Markowitz, Leonard, & Ho, 1996). Billions of HIV particles are produced and cleared each day within infected individuals.

Recent findings from clinical science have established that the amount of virus in the blood, known as viral load, is a predictor of an individual's risk of developing symptoms of AIDS or dying (Mellors et al., 1997; Mellors et al., 1996; Schooley, 1995). This biological marker of disease allows clinical researchers to assess the effectiveness of new drugs and allows clinicians to monitor progress in achieving treatment goals. In fact, reducing viral load to the lowest possible level, preferably to undetectable levels, is the new goal of antiretroviral therapy.

Another major scientific accomplishment has been the development and federal approval of protease inhibitors, a new class of anitretroviral drugs that attacks HIV in a different way than the previous HIV drugs (Collier et al., 1996; NIH, 1997). Before this development, clinicians were limited to a single class of drugs and long- term treatment had proven difficult because of the ability of the virus to develop resistance to each of these drugs.

Yet another major scientific accomplishment was the finding that a combination of drugs was more effective then any single drug (Hammer et al., 1996). About three years ago, it was determined that treatment with two drugs had more clinical benefit than treatment with one drug. In the past two years, a variety of clinical studies have established that treatment with a three drug combination, including at least one protease inhibitor, can reduce the level of HIV in blood to undetectable levels in many individuals .

These advances in the scientific understanding of HIV led the National Institutes of Health (NIH) to convene a panel of medical experts to define the principles of therapy for HIV infection (NIH, 1997). Based on these principles, the Henry J. Kaiser Family Foundation and the Department of Health and Human Services (HHS) convened a panel of clinical experts to develop guidelines for the use of antiretroviral agents in treating HIV-infected individuals (DHHS, 1997).

It is in the context of these HIV treatment guidelines that policy makers must assess challenging new questions. These new questions involve all aspects of the federal and international response to the epidemic, including research priorities, financing AIDS health care, and concerns about discrimination. This paper focuses on the new questions raised about HIV testing, counseling, referral, partner notification, and surveillance.

Testing and Counseling

The emphasis on early and aggressive treatment of HIV infection in the new HIV treatment guidelines underscores the importance of testing and counseling. The Centers for Disease Control and Prevention (CDC) estimates that of 650,000 to 900,000 HIV-infected individuals in the United States, between 509,000 and 545,000 know about their infection and can seek treatment (Sweeney, 1997). Because most HIV infections are in states that do not require HIV case reporting and some individuals test anonymously, this is considered a minimum estimate of HIV-infected individuals who know their status.

Publicly supported testing and counseling programs began shortly after the licensing of HIV antibody tests in 1985 primarily to divert people from donating blood in order to find out their HIV status, a danger because of the so-called window period between infection and the development of measurable antibodies (Valdiserri, 1997). Later, testing, in combination with pre-test and post-test counseling, became a vital part of the public health effort to prevent new infections. Even in the absence of effective clinical interventions, it was believed that knowledge of serostatus could bolster resolve to practice safe behaviors, encourage HIV-positive individuals to protect their loved ones and HIV-negative individuals to stay uninfected. Eventually, when it became widely believed that early intervention with AZT had significant potential as a life-prolonging therapy, testing and counseling became the gateway to treatment programs.

About five years ago, external reviews of the CDC HIV prevention programs suggested that the heavy emphasis on clinic-based HIV testing and counseling was not the best use of limited resources (CDC, 1994a). The CDC responded by establishing an HIV community planning process that allows state and local health departments to set priorities for HIV prevention programs based on a comprehensive state or local need assessments (CDC, 1994b; CDC, 1994d; Valdiserri, 1997). Since the community planning for HIV prevention began, resources have gradually been shifted to outreach programs designed to change behaviors and away from clinic-based testing and counseling programs (CDC, 1997d).

In the last year, however, the new optimism over early intervention with combination therapies has renewed emphasis on testing as the necessary gateway to treatment. One study in the United States found that 36% of individuals diagnosed with AIDS were first tested for HIV within two months of their AIDS diagnosis, and 51% within a year of AIDS diagnosis (Wortley et al., 1995). Although these data were gathered from 1990-1992, it remains sadly true that the documented benefits of early intervention are not available to many individuals because they are tested so late in the course of their

infection. Even in 1997, people are still finding out about their HIV infection status for the first time when presenting in emergency rooms for treatment of opportunistic infections. And, even now, some HIV infections are not diagnosed until autopsy.

The new treatment options are also changing the content and importance of test-related counseling. For those who test positive, greater emphasis needs to be placed on scheduling additional testing as soon as possible. In addition to conventional HIV antibody tests, there are additional tests to determine the length of time the individual has been infected, the damage done to the immune system, and the amount of virus in the blood (Coates, Morin, & Charlebois, 1998). Thus, in addition to goal of preventing further transmission of HIV, a higher priority in counseling should be to reduce the time between HIV testing and initiating primary care for HIV disease.

Over the last several years, new HIV antibody tests have been developed. In 1996, the Food and Drug Administration (FDA) approved "home access" HIV antibody tests, allowing individuals to purchase test kits in drug stores or through the mail and receive results by phone (Phillips, Branson, & Fernyak, 1998). Oral tests were also approved for use by health care professional. Although currently available oral tests still involves laboratory analysis, they make taking an HIV test more acceptable to some people and safer for the staff conducting the tests. Oral testing is now used at many testing sites and is being marketed as a simple and easy test to take. This has removed a practical barrier for individuals who have avoided testing because they were squeamish about having blood drawn.

Rapid tests have also been developed that allow individuals to be given preliminary notification of HIV negative results within ten to fifteen minutes; positive results require a subsequent confirmatory test (Irwin et al., 1996; Kassler, 1997; Spielberg & Kassler, 1996). This allows individuals to be given their test results during an initial clinic visit or at alternative testing venues such as mobile vans. The most recent data from the CDC indicate that only 43.7% of individuals tested at STD clinics received post-test counseling and test results (CDC, 1997b). For those tested at HIV testing sites, 82.7% of individuals returned for post-test counseling and test results. The CDC has long been concerned about this low return rate (Valdiserri et al., 1993).

Rapid testing offers an opportunity to respond to the common problem of individuals not returning to receive test results. At present, the Food and Drug Administration (FDA) has approved only one available commercial rapid test for use in the United States. However, other rapid tests are in use in the developing world. With even newer advances it now seems possible that two rapid tests could be conducted at the same time that would remove the need for the individual to return for confirmatory testing of a positive result (Campbell, 1997). Clearly, advancement in HIV testing technology is moving faster than is reflected in its use in general practice throughout the United States.

It is also important to note that although publicly supported HIV testing is an important part of the overall picture, a great deal of HIV testing takes place in other settings. A

better understanding of what is happening in the private sector with regard to decisions about testing and the implementation of new technologies could inform our current debate on public policies. Clearly, the advances in science of the last several years allow us the opportunity to think in new and different ways.

- Who should be encouraged to be tested? How do we best encourage individuals to be tested? What are the most significant barriers, both psychological and practical, to getting tested? How important is the availability of anonymous testing? How can HIV testing be marketed to different target populations? What kinds of outreach and non-clinic based testing are most likely to be successful? What are innovative sites for HIV testing? Are state laws requiring face-to-face counseling still necessary? What is the best use of public funds for testing? What should be the role of non-government supported testing? What role should primary care physicians have in recommending HIV testing?

- What impact can new technologies have on increasing the number of at-risk individuals deciding to be tested? Do current CDC policies prohibiting preliminary notification of test results need to be changed to permit greater use of rapid tests in high-risk settings? What policy changes are needed to encourage companies to apply for FDA approval of rapid tests? What new tests, like rapid oral tests, need to be developed? Is there a role for an HIV test that yields results on the spot, similar to home pregnancy testing?

Psychological Issues

For any individual, the decision to be tested for HIV infection is complex (Batchelor, 1987; Coates et al., 1988b; Phillips & Coates, 1995). As a threshold matter, an individual must perceive him or herself to be at risk of having become infected. Presenting oneself for testing involves admitting this risk to strangers conducting the test. Many individuals, who are fully aware of how HIV is transmitted, avoid testing out of fear of being judged as "should have known better" than to have placed him or herself at such risk.

Individuals must also believe that there is something to be gained from discovering their HIV serostatus. Since the beginning of HIV testing, the main reasons individuals have resisted testing have been psychological (Coates, Morin, & McKusick, 1987a; Coates et al., 1988a; Coates, Morin, & McKusick, 1987b). People clearly understand that a positive test result will likely mean increased anxiety, depression and worry. It is human nature to try to avoid such devastating information. Psychological distress has been noted surrounding testing for other diseases such as mammography for breast cancer and genetic screening for Huntington's disease (Baum, Friedman, & Zakowski, 1997). Because of psychological factors, the development of HIV symptoms has often served as the motivation to first be tested. In many such cases, the individual is tested on the recommendation of a physician rather than on his or her own initiative.

While there was a period of enthusiasm around the possibility of delaying the onset of AIDS and death with the early intervention with AZT, this motivation for early testing was for the most part lost following studies indicating a lack of survival benefit for such interventions (Cohen, 1993; Cotton, 1994). When the most that was generally offered medically to individuals who were early in their HIV infection was the opportunity to be monitored closely, many individuals believed the psychological costs of testing outweighed any of the potential benefits.

Under the new treatment guidelines, decisions about beginning or changing treatments are made based on monitoring viral load, T-cell counts and physical symptoms (DHHS, 1997). While the recommendations in general are for earlier and more aggressive treatment, long-term benefit of treatment for individuals with T-cells greater than 500 has yet to be documented. Thus, decisions about early intervention for these asymptomatic individuals must balance a number of factors that influence risk and benefit. For asymptomatic individuals with T-cells below 500 or anyone with a high viral load, the guidelines do recommend that treatment be offered. Thus, in these cases waiting for symptoms to appear before HIV testing is a missed treatment opportunity.

A related psychological issue is how individuals decide to seek medical care. This may be particularly important in the case of acute HIV infection. Many physicians would recommend treatment for cases of acute HIV infection or in cases where seroconversion has been documented to have occurred within the last six months (DHHS, 1997). This treatment option would require that individuals who are at risk of infection recognize symptoms of acute infection and that physicians be aware of the new recommendations for diagnosis and potential treatment of primary HIV infection. This treatment opportunity would generally require that the individual discuss symptoms in the context of a potentially embarrassing incident that defined a potential exposure to HIV. As with seeking antibody testing, the decision to seek medical care is very personal. From a psychological perspective, as well as a medical perspective, the stakes are high.

- How do I go about assessing my risk of infection? Why would testing be more important now than two years ago? What practical things can I do to prepare myself psychologically for a positive test result? Will I be better off if I know?

- How can I identify the symptoms of acute HIV infection? If infected, what would I need to know to make an informed decision about whether or not to begin treatment?

Referral

Referral has always been a central part of counseling and testing programs. For individuals who test negative but continue to report significant risk taking behavior, referral to prevention services remains essential. CDC has developed standards and guidelines for referral in the context of HIV counseling and testing programs (CDC, 1994c). CDC has also recently released guidelines on referral for prevention case

management, a client-centered approach to providing a hybrid of HIV risk-reduction counseling and traditional case management (CDC, 1997c).

Because of the importance of early staging and clinical assessment in making decisions about treatment options, referral to medical care is now more important than ever. The treatment guidelines give particular attention to acute HIV infection and what treatment options may be considered, thus making the referral for assessment of timing of infection important. Even if treatment with drugs is not initiated, monitoring viral load and other markers is now of increased importance.

CDC and the Health Resources and Services Administration (HRSA) are currently working on ways to improve the linkage of counseling and testing programs to primary care. However, the effectiveness of referral systems will largely depend on the actions taken at a local level. A better understanding of how referral systems are working at the local level will allow more useful technical assistance to state and local health departments. Research on improving referral and linkage to primary care is now critically important.

Because a great deal of HIV testing takes place in settings not covered by CDC or HRSA guidelines, it is important to consider referrals in private health care settings. For example, state and local policies have encouraged the voluntary testing of pregnant women as part of prenatal care. Some physicians recommend HIV testing as part of routine physical examinations for patients who are sexually active with multiple partners and for patients with a history of recent needle sharing. Patients tested in primary care settings could often benefit from referral for primary prevention or support services. Access to these services depends on making information about potential resources easy to find for both consumers and service providers.

- What are current policies and practices for referral to prevention services and to primary or specialty medical care? How can referral systems be improved? Are tracking systems feasible? What are the barriers to such tracking systems at the local level? To what extent are referrals limited by lack of local resources for quality prevention or medical services? Is referral to specialty care needed due to the complexity of the new treatment guidelines? How can referral from primary care settings to prevention and support services be improved?

Partner Notification

Currently, all states receiving CDC funding for HIV prevention activities are required to establish procedures for the confidential, voluntary notification of sexual and needle-sharing partners (CDC, 1993). These partner notification services, which are perhaps better termed partner counseling services, are considered part of primary prevention efforts (West & Stark, 1997).

The new treatment opportunities have been used by some to argue for a return to a narrow "find-and-treat" STD model for responding to the HIV epidemic . Some in

Congress, who argue that AIDS should be treated like other sexually transmitted diseases, are advocating legislation which would require states to adopt name reporting policies and shift resources to contact tracing and health department mediated partner notification programs. Others in congress believe that while an important part of HIV prevention, partner notification programs need to be assessed in terms of their relative priority in the context of the local HIV community planning for the allocation of limited prevention resources.

- What is the effectiveness of contact tracing and partner notification in the control of HIV transmission? Is health department notification more effective than client referral methods? What is the cost-benefit of partner notification compared to other approaches to primary prevention? Should such programs be routine or targeted to special circumstances? Can such programs be structured to identify recently infected individuals?

Primary Prevention

Successful combination therapies can reduce the circulating level of HIV in the bloodstream, and recently such treatment has been found to lower levels of HIV found in semen (Vernazza et al., 1997). Thus, treatment may contribute to the prevention of HIV transmission by rendering individuals less infectious. However, this possibility has not been established epidemiologically. The relationship between viral load and infection is complex. It may be that on average individuals in treatment are less infectious -- but then there may be those who are not. At present, public health staff continue to counsel individuals to consider all infected people as potentially infectious, even if viral loads in blood are undetectable, and to continue to take extensive precautions.

Many service providers working on primary prevention fear that the availability of new therapies may contribute to increased risk-taking behavior (Dilley, Woods, & McFarland, 1997). This may be because individuals in treatment perceive themselves to be non-infectious or because at-risk individuals and groups perceive HIV infection as less threatening. The possibility of post-exposure prophylaxis further complicates the primary prevention message, especially if at-risk individuals came to believe inappropriately that exposure to HIV can be addressed by merely popping a few pills "the morning after" (Katz & Gerberding, 1997).

The CDC recently reported on an increase of 74% in the rate of gonorrhea in gay men between 1993 and 1996 in twenty-six selected sexually transmitted disease clinics, with the largest increases occurring on the West Coast (CDC, 1997a). Additional behavioral epidemiological data are needed to further assess the extent to which the positive message regarding treatment options may be linked to increased risk taking. Nonetheless, the need for new and clear prevention messages to individuals and groups at risk is evident.

- What should be the new messages for primary HIV prevention? What role does counseling, testing and referral play in this effort? How should the message be framed

for the uninfected, those in the early stage of infection, and those in the later stage of infection? How would these messages be best communicated through targeted media campaigns, individual and group interventions, and community-level approaches?

Surveillance

Since the first reports detailing several mysterious deaths due to unusual opportunistic diseases in 1981, the CDC has depended on reported deaths, and later reported diagnosed AIDS cases, to monitor the course of what is now understood as the HIV/AIDS epidemic. Even when HIV was identified as the cause of AIDS and an HIV antibody test was developed and approved by the federal government, AIDS cases rather than HIV infections, continued to be the official basis for surveillance.

With the recent development of more effective therapies, the number of AIDS cases and deaths are no longer reliable measures for monitoring the epidemic (Gostin, Ward, & Baker, 1997). A combination of successful prevention programs and the availability of new therapies has reduced the number of AIDS deaths by 23% between 1995 and 1996 (CDC, 1997e). Yet the number of people living with AIDS has increased by 11% in the same time frame and the number of people living with HIV infection is also believed to have increased.

The question then becomes how best to monitor the continuing HIV epidemic through counting or estimating the number of people who are infected with HIV. These surveillance data would be of assistance in determining where new infections are occurring and thus would inform community-level planning for the primary prevention of HIV infection. Such data would also be important for an equitable distribution of resources for treatment and support services under Ryan White, housing and the other similar programs.

The question also arises about the importance of monitoring the number of infections versus risk-taking behavior and sexually transmitted diseases as more directly relevant to primary prevention planning. This discussion needs to take place in the context of limited resources and perhaps needs to take place at the local, state and federal level. While the complex issues surrounding surveillance are debated elsewhere, it is important to consider the implications of such policies for encouraging individuals to seek HIV testing and access to early medical care.

- What impact does name reporting have on individual and group willingness to be tested for HIV? How important is the availability of anonymous testing or home collection tests on individual and group attitudes toward testing? How should the goals of surveillance and "getting people tested" be balanced in terms of policies? Is there a way these goals could compliment one another?

Conclusion

This paper has outlined some of the complex issues that must be addressed to make maximum use of new HIV treatment guidelines. These new treatment opportunities offer hope to those who are infected with HIV. That hope can only be realized if systems are in place that encourage individuals at risk to seek HIV testing and counseling, as well as make maximum use of health care services as early as possible in the course of the infection.

The development of effective policies will require consultation, discussion and compromise by public health officials at all levels of government and affected individuals, communities and other stakeholders. Fortunately, good models for such collaboration have already been demonstrated. Hopefully, all parties will respond to the new challenges of the epidemic posed by our better scientific understanding of the disease.

REFERENCES

Batchelor, W. (1987). Real fears, false hopes: The human costs of AIDS antibody testing. *AIDS & Public Policy Journal, 2*, 25-30.

Baum, A., Friedman, A.L., & Zakowski, S.G. (1997). Stress and genetic testing for disease risk. *Health Psychology, 16*(1), 8-19.

Campbell, C. (1997). "Uganda's Same-Day Testing Works Well for Everyone". *AIDS Alert--International, 12*, 3.

CDC. (1993,). *Announcement Number 300: Cooperative agreements for human immunodeficiency virus (HIV) prevention projects program announcement and notice of availabiltiy*, Atlanta, GA.

CDC. (1994a). *External review of CDC's HIV prevention strategies*, Atlanta, GA.

CDC. (1994b). *Handbook for HIV Prevention and Community Planning*, Atlanta, GA.

CDC. (1994c). *HIV couseling, testing and referral: Standards and guidelines*, Atlanta, GA.

CDC. (1994d). *Supplemental Guidance on HIV Prevention Community Planning for Noncompeting Continuation of Cooperative Agreements for HIV Prevention Projects*, Atlanta, GA.

CDC. (1997a). Gonorrhea among men who sex with men - selected sexually transmitted diseases clinics, 1993-1996. *Morbidity and Mortality Weekly Report, 46*(38), 889-892.

CDC. (1997b). HIV counseling and testing in publicly funded sites: 1995 summary report . Atlanta, GA.

CDC. (1997c, September 1997). *HIV prevention case management: guidence*, Atlanta, GA.

CDC. (1997d). Personal communication .

CDC. (1997e). Update: Trends in AIDS Incidence -- United States, 1996. *Morbidity and Mortality Weekly Report, 46*(37), 861-867.

Coates, T., Morin, S., & Charlebois, E. (1998, January 28). *New Technologies for Counseling and Testing: Should we redesign the system or should we just start over?* Paper presented at the Kaiser Family Foundation Forum: Understanding the Impact of New Treatments on HIV Testing, Palo Alto, CA.

Coates, T., Morin, S., & McKusick, L. (1987a. *AIDS antibody testing among gay and bisexual men.* Paper presented at the Third Annual Conference on AIDS, Washington, DC.

Coates, T., Morin, S., McKusick, L., Hoff, C., Catania, J., Kegeles, S., & Pollack, L. (1988a). *Long-term consequences of AIDS antibody testing on gay and bisexual men.* Paper presented at the International Conference on AIDS, Stockholm, Sweden.

Coates, T.J., Morin, S.F., & McKusick, L. (1987b). Behavioral consequences of AIDS antibody testing among gay men. *Journal of the American Medical Association, 258*(14), 1889.

Coates, T.J., Stall, R.D., Kegeles, S.M., Lo, B., Morin, S.F., & McKusick, L. (1988b). AIDS antibody testing. Will it stop the AIDS epidemic? Will it help people infected with HIV? *American Psychologist, 43*(11), 859-864.

Cohen, J. (1993). Early AZT takes a pounding in French-British 'Concorde' trial. *Science, 260*(5105), 157.

Collier, A.C., Coombs, R.W., Schoenfeld, D.A., Bassett, R.L., Timpone, J., Baruch, A., Jones, M., Facey, K., Whitacre, C., McAuliffe, V.J., Friedman, H.M., Merigan, T.C., Reichman, R.C., Hooper, C., & Corey, L. (1996). Treatment of human immunodeficiency virus infection with saquinavir, zidovudine, and zalcitabine. AIDS Clinical Trials Group. *New England Journal of Medicine, 334*(16), 1011-1017.

Cotton, P. (1994). Use of antiretroviral drugs in HIV disease declines following preliminary results from Concorde trial. *Journal of the American Medical Association, 271*(7), 488-489.

DHHS. (1997, November 5, 1997). *Guidelines for the use of antiretroviral agents in HIV-infect adults and adolescents*, Washington, DC.

Dilley, J.W., Woods, W.J., & McFarland, W. (1997). Are advances in treatment changing views about high-risk sex? *New England Journal of Medicine, 337*(7), 501-502.

Gostin, L.O., Ward, J.W., & Baker, A.C. (1997). National HIV case reporting for the United States. A defining moment in the history of the epidemic. *New England Journal of Medicine, 337*(16), 1162-1167.

Hammer, S.M., Katzenstein, D.A., Hughes, M.D., Gundacker, H., Schooley, R.T., Haubrich, R.H., Henry, W.K., Lederman, M.M., Phair, J.P., Niu, M., Hirsch, M.S., & Merigan, T.C. (1996). A trial comparing nucleoside monotherapy with combination therapy in HIV-infected adults with CD4 cell counts from 200 to 500 per cubic millimeter. AIDS Clinical Trials Group Study 175 Study Team. *New England Journal of Medicine, 335*(15), 1081-1090.

Irwin, K., Olivo, N., Schable, C.A., Weber, J.T., Janssen, R., & Ernst, J. (1996). Performance characteristics of a rapid HIV antibody assay in a hospital with a high prevalence of HIV infection. CDC-Bronx-Lebanon HIV Serosurvey Team. *Annals of Internal Medicine, 125*(6), 471-475.

Kassler, W.J. (1997). Advances in HIV testing technology and their potential impact on prevention. *AIDS Education and Prevention, 9*(3 Suppl), 27-40.

Katz, M.H., & Gerberding, J.L. (1997). Postexposure treatment of people exposed to the human immunodeficiency virus through sexual contact or injection-drug use. *New England Journal of Medicine, 336*(15), 1097-1100.

Mellors, J.W., Munoz, A., Giorgi, J.V., Margolick, J.B., Tassoni, C.J., Gupta, P., Kingsley, L.A., Todd, J.A., Saah, A.J., Detels, R., Phair, J.P., & Rinaldo, C.R., Jr. (1997). Plasma viral load and CD4+ lymphocytes as prognostic markers of HIV-1 infection. *Annals of Internal Medicine, 126*(12), 946-954.

Mellors, J.W., Rinaldo, C.R., Jr., Gupta, P., White, R.M., Todd, J.A., & Kingsley, L.A. (1996). Prognosis in HIV-1 infection predicted by the quantity of virus in plasma. *Science, 272*(5265), 1167-1170.

NIH. (1997). *Report of the NIH panel to define the principles of therapy of HIV infection*, Bethesda, MD.

Perelson, A.S., Neumann, A.U., Markowitz, M., Leonard, J.M., & Ho, D.D. (1996). HIV-1 dynamics in vivo: virion clearance rate, infected cell life-span, and viral generation time. *Science, 271*(5255), 1582-1586.

Phillips, K., Branson, B., & Fernyak, S. (1998, January 28). *The Home Collection HIV Test: Past, Present, and Future.* Paper presented at the Kaiser Family Foundation Forum: Understanding the Impact of New Treatments on HIV Testing, Palo Alto, CA.

Phillips, K.A., & Coates, T.J. (1995). HIV counselling and testing: research and policy issues. *AIDS Care, 7*(2), 115-124.

Schooley, R.T. (1995). Correlation between viral load measurements and outcome in clinical trials of antiviral drugs. *AIDS, 9 Suppl 2*, S15-S19.

Spielberg, F., & Kassler, W.J. (1996). Rapid testing for HIV antibody: a technology whose time has come. *Annals of Internal Medicine, 125*(6), 509-511.

Sweeney, P. (1997). *Most Americans with HIV have been tested.* Paper presented at the American Society for Microbiology, Toronto, Canada.

Valdiserri, R.O. (1997). HIV counseling and testing: its evolving role in HIV prevention. *AIDS Education and Prevention, 9*(3 Suppl), 2-13.

Valdiserri, R.O., Moore, M., Gerber, A.R., Campbell, C.H., Jr., Dillon, B.A., & West, G.R. (1993). A study of clients returning for counseling after HIV testing: implications for improving rates of return. *Public Health Report, 108*(1), 12-18.

Vernazza, P.L., Gilliam, B.L., Flepp M., et al. (1997). Effect of antiviral treatment on the shedding of HIV-1 in semen. *AIDS, 11*(10), 1249-1254

West, G.R., & Stark, K.A. (1997). Partner notification for HIV prevention: a critical reexamination. *AIDS Education and Prevention, 9*(3 Suppl), 68-78.

Wortley, P.M., Chu, S.Y., Diaz, T., Ward, J.W., Doyle, B., Davidson, A.J., Checko, P.J., Herr, M., Conti, L., Fann, S.A., & et al. (1995). HIV testing patterns: where, why, and when were persons with AIDS tested for HIV? *AIDS, 9*(5), 487-492.

THE HOME COLLECTION HIV TEST:

Past, Present, and Future

A Background Paper Prepared for the Kaiser Family Foundation Forum on Understanding the Impact of New Treatments on HIV Testing, January 28-30, 1998

Kathryn A. Phillips PhD[1]
Bernard Branson MD[2]
Susan Fernyak MD MPH[1]
Ron Bayer PhD[3]
Steve Morin PhD[1]

[1]Center for AIDS Prevention Studies, University of California-San Francisco, 74 New Montgomery #502, San Francisco, CA 94105, phillips@psg.ucsf.edu
[2]Centers for Disease Control and Prevention
[3]Columbia University

INTRODUCTION

After almost 10 years of debate, the FDA approved the first home collection HIV test in 1996. Home collection HIV tests allow the collection of dried blood spots at home using a fingerstick, with specimens then sent by mail for laboratory testing. Users remain anonymous, and results are obtained by telephone using a code number. Counselors give all positive results, whereas negative users receive their results through a recorded message unless they choose to speak to a counselor. In comparison, the standard HIV testing protocol uses venipuncture, and in-person pre- and post-test counseling is recommended.

Proponents of home collection tests had high hopes that its availability would increase access to testing (Bayer, Stryker et al., 1995). Three nationally representative surveys found that 29%- 43% of U.S adults stated that they would be likely to use home collection tests, and that these tests would be used by many individuals who had previously not been tested, who had less access to testing and who were at-risk for HIV (Phillips, Flatt et al., 1995). In testimony before the FDA, former U.S. Surgeon General C. Everett Koop called the home collection test the "single most important weapon we can employ in the fight with AIDS" (Koop, 1994). Opponents of home collection testing, however, were concerned about whether individuals could correctly use the tests, the possible negative consequences from individuals receiving their results by phone, and the impact on public health. Opponents stated that "the potential for catastrophic impact on individuals using such a home test product far outweighs the intended advantage" (National Alliance of Lesbian and Gay Health Clinics, 1994).

The home collection tests have now been available for over a year. Are home collection tests a "success" or a "failure"? What are the implications for other new HIV testing methods, HIV prevention efforts, and the larger debate over testing?

The purpose of this paper is to examine the experience of home collection tests to date, to analyze the policy issues relevant to the use of these tests, and to develop a research and policy agenda for the future. We begin with a brief history of home collection tests in order to develop a context for discussion. In the next section we present new data on the users of home collection tests during the first year after approval. We then review the evidence that supports or refutes the purported benefits and concerns that have been raised about home collection tests. Lastly, we examine the research and policy issues that must be addressed for home collection tests and other new testing technologies.

THE SAGA OF HOME COLLECTION HIV TESTS

The saga of home collection tests provides an illustration of the political and ethical controversies that have dogged efforts to stem the AIDS epidemic in the U.S. since the epidemic began. Therefore, in order to understand the debate over home collection testing, it is necessary to review the history of the tests which can be pieced together from government documents and newspaper, magazine, and journal articles over the past 10 years (see, e.g., Bayer, Stryker et al., 1995).

A test to detect HIV antibodies first became widely available in 1985, and home collection HIV tests were first proposed only one year later. Home collection tests, however, were met with almost universal opposition from groups such as the Centers for Disease Control and Prevention (CDC), American Medical Association, and the National Alliance of Lesbian and Gay Health Clinics (Leary, 1989). Because of concerns about the ability of consumers to reliably and safely perform the test and interpret the results without benefit of medical advice and professional counseling (Anonymous, 1988), the FDA determined that they would consider applications for tests kits designed for "professional use only" (Young, 1989).

Compelled by threatened legal action from University Hospital Laboratories (UHL, the forerunner to Direct Access Diagnostics), the FDA held hearings on home collection tests in 1989 (Young, 1989). However, the FDA voted in 1990 not to approve the test under review, "AIDS CHECK", citing that their submitted data was inadequate in a number of critical areas. These included:

- the operating procedures for the lab and counseling center were not well specified
- the clinical trial designed to determine the accuracy of the test was inadequate
- safe handling of potentially HIV-contaminated lancets had not been addressed
- UHL had not supported claims that AIDS CHECK would reach users who were at risk but not currently accessing testing services
- the proposed system may interfere with efforts at public health surveillance, reporting, and contact tracing (FDA, 1990).

In 1994, the FDA held hearings to reconsider home collection tests "in light of scientific and technical developments and the changing nature of the HIV epidemic" (Suydam, 1995). More importantly, opposition to the tests from key players such as the CDC had dramatically decreased. After the hearings, the FDA reported that most of the FDA Advisory Committee members believed that the potential benefits of over-the-counter home collection tests outweighed the potential risks, and therefore revised guidance was issued that allowed the consideration of such tests (Suydam, 1995).

The first home collection HIV test, "Confide", was approved in May 1996 and a second test, "Home Access", developed by Home Access Health Corporation was approved shortly thereafter. Confide was a version of the test first submitted for review in 1987 by Elliott Millenson and his company, University Hospital Laboratories. Johnson & Johnson (J&J) bought that company, later called Direct Access Diagnostics (DAD), in 1993. When J&J bought the rights to the test, the product gained an advocate with deep pockets and huge political clout (Freundlich and Hamilton, 1996). J&J poured large amounts of money into advertising and public relations, particularly with activist and community organizations. For example, former Surgeon General Koop was hired to write the educational literature to accompany the test (Freundlich and Hamilton, 1996).

The irony of the story is that, to the surprise of many, Confide was withdrawn from the market in 1997. There appear to be several reasons why the product was withdrawn. DAD stated in their announcement that the withdrawal was due to "lack of consumer demand" (Reuters, 1997) – a point that we will examine in depth later in the paper. J&J may also have decided that the

difficulties they were having with the product outweighed the potential gains. Shortly before Confide was withdrawn, the company had received two warning letters from the FDA about quality control issues (Canedy, 1997). One warning concerned how tests were sent in for processing, since some consumers were given envelopes in drugstores for a competing product ("Home Access") rather than Confide envelopes and therefore could not obtain their results. Another warning concerned the use of frozen rather than fresh blood to validate results and the allegation that some customers were given false test results (although details on these allegations are sketchy). Another factor that may have contributed to the withdrawal of Confide was the departure of Elliott Millenson, the developer of Confide and the first Chief Executive Officer of DAD. Millenson waged a long and ultimately successful fight for approval of the home collection test, but he was fired shortly before the product was approved (Freundlich and Hamilton, 1996). After the firing Millenson sued, although he and J&J successfully settled their litigation under which J&J retained all rights to Confide (PR Newswire, 1997).

Therefore, there is currently only one home collection test available in the U.S: the "Home Access" test marketed by Home Access Health Corporation (HAHC). HAHC was formed to market telemedicine and at-home diagnostic products more generally, so that the home collection HIV test is not their sole focus. They recently announced a joint venture with Abbott Laboratories, another "deep pockets" partner, to develop new home diagnostic tests (not including the HIV home collection test (Johnson, 1997)). HAHC has not stated any plans to withdraw their home collection HIV test (Frank, Wandell et al., 1997).

Another fingerstick home collection test (developed by Chemtrak) is under review by the FDA. In addition, Epitope Corporation, which previously obtained approval for professional use of their oral fluids test ("OraSure"), is now seeking approval to market the test for home collection use. However, SmithKline Beecham – another "deep pockets" partner - recently announced that they were ending their partnership with Epitope due to a "strategic decision...not to develop and market over-the-counter products" (written communication, D Sturgess et al, 9/15/97). This development – as with the withdrawal of Confide – suggests that there may barriers to the marketing or use of the tests. We turn now to examining information on who is using home collection tests and whether the tests have been a "success" or "failure".

WHO IS USING HOME COLLECTION HIV TESTS?

Data were sent to CDC on home collection test users from DAD and HAHC. Both companies agreed to collect data on users for three years as a condition of their post-marketing FDA approval, although as noted above, DAD withdrew from the market in 1997. Data were available for the first year of use (July 1996-June 1997). Data analyses were conducted by CDC staff. As with many other testing data collected by the CDC, this data represents test episodes rather than number of individual users. Because the tests are anonymous, it is impossible to ascertain how many tests are used by repeat testers. No tests of statistical significance were performed because these data represent the population of users rather than a sample.

Analyses are based on the following:

- Data from both companies included the number of users, HIV prevalence, and sample adequacy;

- Data from Home Access users included demographics, risk behaviors, and previous HIV testing. (Home Access requires users to call for a recorded pre-test counseling message, at which time it offers the opportunity to speak with a counselor and asks users to provide demographic and risk behavior information using an automated telephone response system.)
- Data from HIV-positive users from the "call log" provided by HAHC in which counselors make entries each time they speak with a user.

Data were obtained from 152,000 testing episodes, of which approximately 99,417 (65%) were performed using Confide tests (DAD) and the remaining 35% were performed using Home Access tests. Tests were submitted from all 50 states, Washington, D.C., Puerto Rico and the U.S. Virgin Islands. Response rates ranged from 64% - 82% (table 1). The higher response rates from positive users may be due to the fact that counselors asked for further demographic information when giving test results.

Table 1: Response Rates for Survey Questions by Test Result (Home Access® tests)

HIV Result (n)	Sex	Race	Age	Risk Behavior	Prior HIV Test	Zip Code	Expected Test Result
Positive (466)	82%	68%	71%	72%	72%	75%	69%
Negative (52,161)	69%	64%	66%	66%	66%	55%	65%

Table 2 provides an overview of the number of home collection tests used during their first year of availability. Ninety-seven percent of users called for their results. This compares to the approximate return rate in publicly funded clinics of 60%, ranging from 44% in STD clinics to 83% in voluntary counseling and testing clinics (CDC, 1997).

The HIV prevalence in the first year was 0.9%, which is roughly three times the general U.S. prevalence (0.3%) (Karon, Rosenberg et al., 1996), but less than the prevalence among individuals tested at publicly funded test sites (1.6%) (Table 2. Note, however, that prevalence rates are not adjusted for repeat testing) (CDC, 1997). Five percent of samples were unsuitable for testing because they were contaminated, expired, or contained an insufficient amount of blood. No data are available on whether there have been any false positive or false negative results.

Table 2: Home Collection Users (DAD and HAHC) by Test Result, July 1996-June 1997

HIV Result	Number (%) of Testing Episodes	Number (%) who Called for results
Positive	1,324 (0.9)	1,267 (95.7)
Negative	142,823 (93.9)	139,230 (97.5)
Unsuitable for testing	7,820 (5.1)	7,542 (96.4)
Total	152,044 (100)	148,039 (97.4)

The highest percentage of testing episodes occurred among those who are male, white, ages 25-34, and heterosexual (Table 3). However, HIV prevalence was highest among African-Americans and Hispanics, those 35-44 years of age, men-who-have-sex-with-men, and injection drug users. Although only 5% of users were African-American and 5% were Hispanic, they accounted for 18% and 14% of those found positive, respectively. In comparison, African-Americans and Hispanics represent a higher proportion of users of publicly funded test sites than home collection tests (33% and 15%, respectively). As with home collection tests, however, African-American and Hispanic users account for a higher percentage of positive tests at public sites (49% and 21%, respectively (CDC, 1997)).

Table 3: User Demographics (Home Access users)

Demographic category	% of Total Users (1)	Distribution of HIV-positive users (%) (1)
Sex: Female	37	17
Male	63	83
Race: African American	5	18
Caucasian	84	64
Hispanic	5	14
Other	5	4
Age: 18-24	25	7
25-34	41	46
35-44	22	33
45-54	11	10
>55	3	3
Reported risk factor:		
Heterosexual	78	24
Bisexual Male	11	37
MSM (2)	6	26
IDU (3)	3	7
MSM/IDU	2	6

(1) Reported as % of total users who responded to demographic questions (overall n=38,811 for responses to questions on sex, with slightly lower numbers for other categories).
(2) Men-who-have-sex-with-men
(3) Injection drug users

Table 4 shows that home collection tests are being used by many individuals who had not previously been tested. Overall, nearly 60% of users were being tested for the first time. In comparison, 44% of all tests at publicly funded sites were first time tests (CDC, 1997). HIV prevalence was the same among first-time testers and repeat testers who previously tested negative (0.8%). Among all HIV-positive tests, 52% were first-time testers. This large percentage suggests that persons using the test may not have been comfortable seeking testing from a standard counseling and testing site.

Table 4: Previous Testing History and HIV Result (Home Access users)

Previous Testing History	Total (%)	HIV+ (%)
No Previous Test	20,391 (59)	168 (52)
Previous Test: Negative	13,632 (40)	104 (32)
Indeterminate	170 (0.5)	6 (1.8)
Positive	58 (0.2)	43 (13)
Unknown	134 (0.3)	5 (1.5)
TOTAL	34,385	326

Evidence suggesting that individuals who may underestimate their risk are using home collection tests is provided in Table 5. Only 17% of those testing positive expected their results to be positive, while 46% expected their test to be negative.

Table 5: Actual Test Result Compared to Expected Test Result (Home Access users)

	Expected Result		
Actual Result	Positive	Negative	Don't Know
Positive	17%	46%	37%
Negative	2%	81%	17%
Unsuitable for testing	2%	79%	19%

About half of testing episodes were among heterosexuals (Figure 1). Although bisexual males comprised only 7% of testing episodes, they constituted the largest proportion of positive tests (26%) (Figure 2). The proportion of positive testing episodes who reported bisexual or MSM exposures is larger than that observed in other settings; together they constituted 44% of the HIV-positive tests, while at publicly funded sites, they account for only 28% of positive tests (CDC, 1997).

Figure 1: All users by HIV Risk Factor (Home Access users)

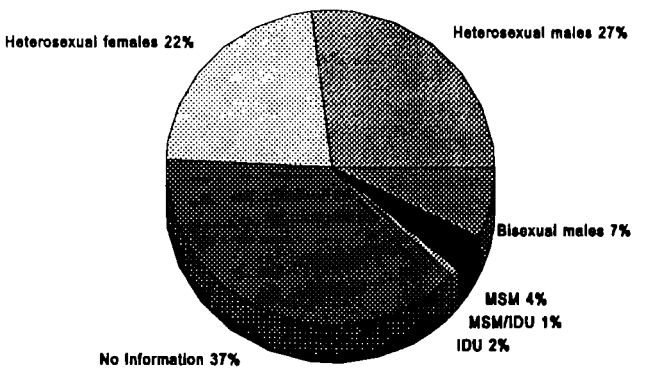


Figure 2: HIV-positive users by Risk Factor (Home Access users)

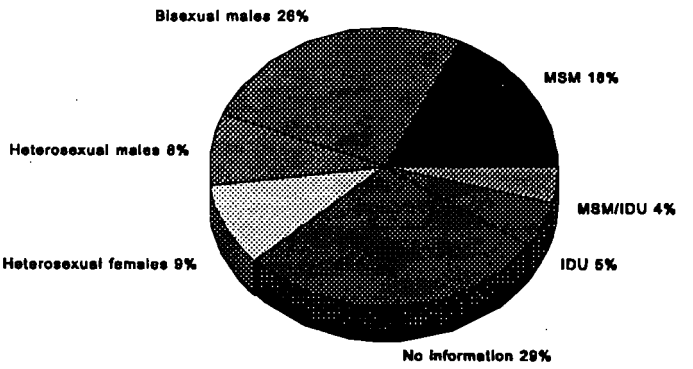


Table 7 shows the proportion of HC testers with specific risk factors who had previously been tested. The most interesting observation is that 73% of HIV-positive IDUs reported that they had not previously been tested for HIV, although this finding is based on only 16 positive IDUs.

Table 7: Previous Testing by Reported Risk Factor (Home Access users)

	All Clients		HIV Positive Clients	
	Total N	No Prior Test	N	No Prior Test
Total Tests	35,546	59%	327	52%
Heterosexuals	27,882	64%	81	65%
Bisexual males	4,002	42%	123	48%
MSM	2,366	34%	86	41%
IDU	890	56%	16	73%
MSM/IDU	406	46%	21	33%

Data were also obtained on the content of telephone counseling and referrals for Home Access users. Although 23% of those who called to receive positive test results already had an existing

source of care, 65% accepted referrals for medical and psychosocial services. Only one of the callers who received news of a positive test (0.2%) expressed suicidal ideation.

- **50,779 users called to receive negative HIV results:**
  - 14,574 (29%) called more than once to hear their results and counseling
  - 6,050 (12%) elected to speak to a counselor in person

- **449 users called to receive HIV positive results:**

Referrals for Care:
- 292 (65%) received referrals for medical care and psychosocial services
- 102 (23%) refused referrals because of an existing source of care
- 45 (10%) called back more than once for additional counseling
- 56 (12%) were receiving antiviral therapy, and had tested to see whether their HIV status had changed

Partner Notification:
- 95 (21%) discussed notifying their partners
- 36 (8%) asked the counselor to discuss their results with their partner
- 21 (5%) disclosed that their partner was HIV positive

Psychological distress:
- 24 (5%) hung up immediately upon receiving a positive result, without counseling
- 12 (3%) asked someone else to call to receive their results
- 31 (7%) expressed shock and dismay over an unexpected positive result
- 1 user expressed suicidal ideation. (The counselor documented that this client was with a friend, who agreed to facilitate mental health support.)

Data were also obtained from HAHC on comments made by users during counseling. Although the data provided only include comments that were favorable toward the testing experience, they indicate some of the reasons individuals chose home collection testing: "it's just been a lot easier with me being in control of the test process and knowing what's going to happen"..."it took a load off my mind"..."more of the public would get tested if they knew how easy and confidential this could be" (Home Access Health Corporation Website, 12/1/97).

In summary, these data suggest that:
(1) home collection tests are being used by persons who do not access other testing,
(2) home collection tests are being used by persons who are at-risk for HIV, and
(3) the majority of persons who tested positive for HIV either received referrals for medical care or already have a regular source of care.

It is important to recognize the limitations of these data. These data are only representative of persons who used home collection tests and who were willing to respond to questions and no information is available on non-responders to determine the possible extent of response bias. Although these limitations are inherent in the nature of the data, the provision of two more years of data by HAHC will allow greater confidence in the trends seen in the first year of use.

We now turn to a discussion of what the findings mean.

ARE HOME COLLECTION TESTS A "SUCCESS" OR "FAILURE"?

Although it is too early to know whether home collection tests will ultimately be a "success" or "failure", it is useful at this time to review the key arguments for and against home collection testing and the current evidence supporting or refuting those arguments.

(1) Are home collection tests expanding access to testing?

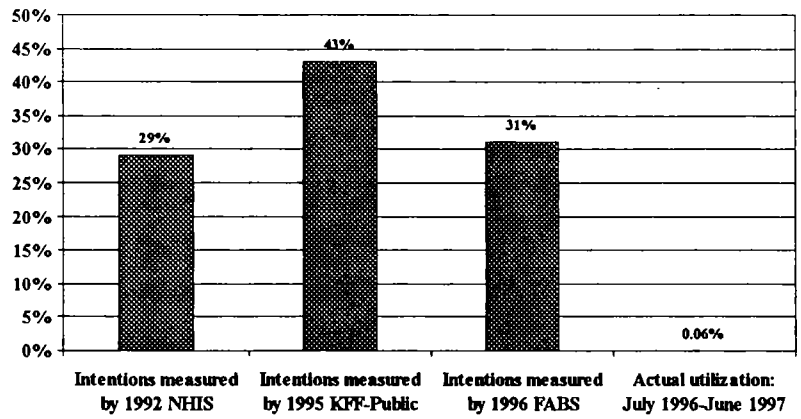
The primary argument made in support of home collection tests was that they would increase access to testing and encourage individuals to be tested who otherwise might not do so. The evidence presented above suggests that home collection tests are increasing access to testing at least for some groups. The finding that over half of users had not previously been tested suggests that the availability of home collection tests may facilitate testing for persons who would otherwise not be tested. It is particularly encouraging that HIV-infected African-Americans, Hispanics, and bisexual males are using home collection tests, since these groups may have less access to testing or be particularly concerned about confidentiality. It is disconcerting, however, that relatively few African-Americans and Hispanics are using the test, particularly since these groups were more likely to state that they would be likely to use home collection tests before they were approved (Phillips, Flatt et al., 1995).

These findings corroborate previous studies suggesting that many people, including those who had not been previously tested and who are at-risk, would use home collection tests. In a study using data from the 1992 National Health Interview Survey (NHIS) (Phillips, Flatt et al., 1995), of the 29% of respondents who stated that they would be very or somewhat likely to use home collection tests, three-quarters had never been tested. Forty-two percent of the respondents at risk said they would be very or somewhat likely to use home tests; 63% of this group said they had never been tested.

A key question that cannot yet be answered is to what extent home collection testing is increasing the numbers of persons tested overall or whether it is substituting for testing that would have been conducted at other sites. As discussed, the large numbers of users who have not previously been tested suggests that home collection testing may be increasing the numbers of persons tested, although undoubtedly it is also substituting for testing at other sites.

Although home collection tests may be increasing access to testing, its overall impact on access is marginal because of low sales. Figure 3 shows the discrepancy between surveys which found that 29%-43% of the U.S. population would be likely to use home collection tests, the percentage which planned to be tested in the next 12 months (12%), and the actual utilization of home collection tests in the first year of use, which is only a "blip" on the figure at 0.06%.

Figure 3. Intended vs. Actual Utilization of Home Collection HIV Testing



Notes: "Intentions" based on responses of "very likely" or "somewhat likely" to use home collection HIV test.

NHIS is the National Health Interview Survey; KFF-Public is the Kaiser Family Foundation Survey on HIV Public Knowledge; FABS is the Family of AIDS Behavioral Surveys.

There are four possible explanations for the wide discrepancy between estimated use (based on self-reported intentions) and actual use:

1. individuals over-estimated their likelihood of using home collection tests,
2. the currently available data on actual use are not a fair comparison to the data on intentions,
3. there are market barriers to the use of home collection tests, and/or
4. there are individual barriers to the use of home collection tests.

The evidence to date suggests that all of these explanations are true. Since the discrepancy between estimated use and actual use is a surprising finding, we discuss these issues in detail.

First, the wording of the survey questions may have encouraged individuals to over-estimate their likelihood of using home collection tests. None of the national surveys that measured intentions to use home collection tests told respondents the expected price of the test. The cost of the test ($40-$50) may be a barrier to use, particularly for many individuals who are most in need of testing. Although we do not have data on the price elasticity of HIV home collection tests, economic theory and evidence suggests that preventive services are highly price-elastic; that is, as prices go up, demand goes down (Newhouse and Group, 1993). For example, a survey which sampled respondents from gay bars, STD clinics (heterosexuals), and street outreach programs for IDUs in nine states found that 76% of individuals would use home collection tests within the next year if they were free and 40% would use them if they were $40. Among the 24% of individuals not previously tested, 65% were likely to use a free home collection test and 35% would use a $40 test (Colfax, Lehman et al., 1997).

Second, the data on intentions and actual use cannot be directly compared since the national surveys did not ask individuals *when* they intended to use a home test. Some individuals may be willing to use home collection tests in the future if they decide to be tested, but they may not

have an immediate need or plans to be tested. Therefore, use of the test within the first year may underestimate their use over time. Evidence of this is that – in comparison to the 29% of respondents who stated they were likely to use a home collection test in the 1992 NHIS - only 12% of respondents stated they planned to be tested (using *any* method) in the next 12 months.

Perhaps most importantly, we know from countless other studies that behavioral intentions often do not translate into behavior. We previously estimated that only one-third of those who said they would use a home collection test would actually do so based on a previous study of one year follow-through on plans to be tested at public or private clinics (Phillips, Flatt et al., 1995). This translates into 10% of the population, which is probably a more realistic estimate of the percentage that may eventually use home collection tests.

A third explanation is that, as with other new technologies, home collection tests probably have a long adoption curve. For example, home pregnancy tests were not widely used when they were first marketed but they now are used by at least one-third of American women (Jeng, RM Moore et al., 1991). The home collection test faces the same initial barriers as other home diagnostic tests. One article in the trade literature stated that, for any home diagnostic tests to succeed against standard, clinical testing, five factors are critical: distribution and merchandising support; a competitive price, providing exceptional customer service, developing repeat business to secure long-term consumer loyalty, and establishing credibility and endorsements from the medical professional community (Business Wire, 1996). Home collection tests face barriers in all of these five factors. First, it is our impression that the companies have had only limited marketing efforts and they have run into obstacles in placing the tests in drugstores. Second, home collection tests are competing with testing at public or private sites, which is often free to the user. The third and fourth factors – customer service and repeat business - are particular barriers because of the paradox that companies marketing HIV tests face. On the one hand, many people get repeatedly tested for HIV, so the companies have an incentive to provide exceptional service. However, unlike many other home diagnostic tests, many individuals are only tested once (either because they test negative and no longer have risk factors or because they test positive), and therefore there is less incentive to develop customer loyalty. Lastly, although the companies marketing home collection tests and other new tests (e.g., the oral fluids test) have obtained endorsements from the medical community, home collection tests are a product that are not directly linked to medical providers as many other tests are. Patients are unlikely to ask their providers about home collection tests and medical providers are unlikely to encourage their use. We found in interviews with physicians that most would prefer to do standard HIV blood testing in their office, and that they would only recommend home collection testing for patients who brought up concerns about having their testing history documented in their medical record (Morrison, Phillips et al., (working paper)).

Lastly, there may be individual barriers to the use of home collection tests. The first barrier is knowledge. Consumers must first be aware of the availability of the tests; however, it is our impression that the companies have invested only limited resources into marketing (especially after Confide was withdrawn from the market).

Several small studies or anecdotal reports shed some light on other barriers to use. A small study of an urban, low income, primarily African-American population found the population had little

interest in using home collection tests because of uncertainty about their accuracy and because respondents were more comfortable obtaining results from health professionals (Jones-Redmond, Cohen et al., 1997). This finding conflicts with the studies of intentions that found that African-Americans were more likely to use home collection tests. Other studies have found that individuals prefer to immediately obtain their results from rapid tests which are now available in some clinics or may become available if true home tests are approved (Kassler, Dillon et al., 1997), and therefore the 3-7 day wait for results is a barrier to use of home collection tests. Lastly, studies have found that some individuals are averse to blood draws and pricking their fingers to obtain blood samples and would prefer less invasive testing methods such as oral fluids or urine (MacGregor, Dunbar et al., 1994).

(2) Can consumers correctly use home collection tests?

As discussed above, five percent of samples were inadequate because they were contaminated, expired, or contained insufficient volume of blood, which is what was expected, based on the results of the clinical trials performed before approval. However, HAHC is attempting to reduce the rate of inadequate samples because it is higher than the rate in standard HIV testing (about 1.5%) (personal communication, A Frank, 11/19/97). No data are available on the percentage of false positive tests, although – given that the laboratory procedures are the same for samples obtained via home collection as they are for samples obtained via venipuncture – the rate of false positive tests should be similar to that for standard testing.

(3) Are there negative consequences from telephone counseling?

A primary concern about home collection tests was that telephone counseling would lead to increased emotional distress for those testing positive and that these individuals may commit suicide or not obtain follow-up medical care and psychological support. At this time there is no evidence that substantial numbers of positive users are having negative psychological consequences from telephone counseling or not obtaining referrals. As discussed above, in the first year of use only one caller has expressed suicidal ideation; however, five percent of callers who tested positive did hang up without counseling. There is no information on whether home collection testing actually facilities or impedes entry into medical care and whether it is effective in encouraging users to change their risk behaviors. However, as will be discussed below, these are issues that pertain to testing in general, not just home collection tests.

(4) Is there a negative impact on the public health system?

There were several concerns about the impact of home collection HIV tests on the public health system. First, there were concerns that the "worried well" – individuals with low risks of being infected with HIV – would use home collection tests rather than publicly funded clinics, and that the loss of revenue to these clinics would force their closure and reduce testing options for those who depend on them (Bayer, Stryker et al., 1995). The concern about low risk users is both true and not true: many apparently low-risk individuals *are* using home collection tests, although many individuals who are *at high risk or who are HIV-infected* are also using these tests. There is no evidence that the availability of home collection tests is reducing demand for testing at public clinics (Anonymous, 1997). At some clinics, there is support for home collection testing

because it allows them to focus their resources on high-risk individuals. As the Medical Director of the Whitman-Walker clinic in Washington, D.C. stated: "I'm glad they are mostly focusing on the less risky population. The really high risk people are the ones that really need the face-to-face counseling and the immediate access to high quality medical care." (Anonymous, 1997).

Another concern was the impact of the anonymous testing provided by home collection tests on name reporting and partner notification efforts. Several states have attempted to block the sale of home collection HIV tests, citing state laws that names of HIV-infected persons be reported or that counseling be given in-person (Anonymous, 1997). The FDA has taken the position that the federal Food, Drug, and Cosmetic Act preempts these state laws. Home collection tests are therefore currently available throughout the U.S. via a toll-free number and in outlets such as drugstores. There are no data to our knowledge on whether the availability of home collection tests is a barrier to effective and timely surveillance and partner notification.

IF HOME COLLECTION HIV TESTS ARE THE ANSWER, WHAT IS THE QUESTION?

A widely cited article on the problem of false positive HIV test results that appeared in the NEJM first asked the question: If HIV testing is the answer, what is the question? (Weiss and Thier, 1988). That question is now relevant to home collection HIV tests, since one's view of these tests will depend upon one's view about the goals of testing and the role of public policy in meeting those goals. The debate over home collection HIV tests mirrors a larger debate about testing in general that has centered on three questions:

(1) What is the primary goal of counseling and testing?
(2) How should scarce public resources for HIV testing and prevention be allocated?
(3) What are the rights of individuals to know their HIV status versus the responsibilities of government to regulate how that information is obtained?

Herein lies the debate over home collection testing and other new methods. Our goal is not to repeat these debates, since there are no "right" answers. Instead, we examine what insights the experience with home collection tests can provide about how to move beyond these debates.

(1) What is the primary goal of counseling and testing?

HIV counseling and testing has four goals (Centers for Disease Control and Prevention, 1994):

1. Provide an opportunity for persons to learn their HIV status;
2. Allow such persons to receive counseling to help initiate behavior change to prevent the transmission or acquisition of HIV;
3. Help persons obtain referrals for medical and other services; and
4. Provide prevention services and referrals for sex and needle sharing partners of HIV-infected persons.

We often hear the argument that the benefits of testing can only be fully realized if testing does not just inform individuals of their HIV status, but also facilitates behavior change, referrals, and partner notification. From this perspective, home collection tests should be judged on whether they are better or equally as good as standard methods of testing at meeting these goals. We have

little information on whether home collection testing is reducing risky behaviors or facilitating referrals, entry into care, or partner referrals. However, the evidence is mixed on whether testing using *any* method achieves these goals (e.g., (Higgins, Galavotti et al., 1991)), and therefore it will be difficult to ever demonstrate whether home collection testing is any better or worse than other methods. Furthermore, it has been argued that it is unreasonable to expect home collection tests – or any tests – to secure the receipt of appropriate care (Salbu, 1995).

Home collection tests are so controversial because they weaken the link between testing and the counseling that is believed to promote behavior change. This link has been so strong that some states requires individuals who are tested to receive in-person counseling (Bayer, Stryker et al., 1995). Although the company marketing home collection tests provides informational materials, recorded counseling messages (for those testing negative), and telephone counseling for those testing positive (with the option for those testing negative), the link between counseling and testing has now been loosened. This link would be severed if true home tests (self-tests) were to be approved, and therefore attempts to get such tests approved are likely to be met with strident debate. The irony is that many individuals who are currently tested at public or private sites obtain no or minimal counseling, regardless of recommendations or laws requiring such counseling (Phillips, Morrison et al., 1997).

Conversely, there is evidence on the ability of home collection tests to meet the first goal of testing: to provide information on HIV status. The benefits of testing for the sake of information can be assessed using two criteria: (1) the number of persons tested and receiving results, and (2) the value that individuals place on knowing their HIV status. Based on the first criteria, home collection tests are a success. Home collection tests appear to encourage individuals to be tested who have not previously done so, and the percentage of individuals tested who obtain their results is much higher than at many other sites. We do not know, however, whether home collection tests meet the second criteria. There are surprisingly few studies on the value that individuals place on knowing their HIV status and no studies to our knowledge specifically on home collection tests. One study that explored why low-risk individuals get tested found that the desire for testing arose from the desire to "do the right thing" (Lupton, McCarthy et al., 1995). Respondents reported that testing is perceived as taking responsibility for one's health, as providing peace of mind, and as demonstrating commitment to a relationship. This study would suggest that testing using any method provides valuable psychological benefits, regardless of its impact on health outcomes and risky behaviors. Further evidence on the value of information is provided by studies of screening procedures such as ultrasound for pregnant women which have been shown to be of high value to women regardless of whether the information has any bearing on decisionmaking (Berwick and Weinstein, 1985).

What insights can the experience with home collection HIV tests provide? Whether home collection testing is a success or failure will depend upon one's view of the relative importance of the multiple goals of testing. The current lack of consensus on the goals of testing will make it difficult to achieve consensus on the wisdom of home collection tests and other new testing methods. However, by explicating the goals of testing, it becomes clearer how home collection tests can be fairly evaluated.

(2) How should scarce public resources for HIV testing and prevention be allocated?

An ongoing debate is whether testing and HIV prevention efforts should be targeted to specific risk groups or universally applied to the general population (Des Jarlais, Padian et al., 1994). In the early years of the epidemic, most policies focused on targeting testing to "risk groups". For example, previous guidelines for testing of pregnant women recommended targeting women with risk factors or in high prevalence areas (CDC, 1985) (Hardy, 1991). However, because studies showed that these approaches may fail to identify as many as 70% of HIV-positive pregnant women (Centers for Disease Control and Prevention, 1995), the CDC issued recommendations in 1995 that providers should counsel and encourage *all* pregnant women and women of childbearing age to be voluntarily tested for HIV (Centers for Disease Control and Prevention, 1995).

The debate over targeted versus universal interventions is relevant to home collection testing because of the implications of these tests for *who is tested* and *who pays for testing*. As discussed previously, one concern about home collection tests is that individuals at low risk of infection will use them. The underlying assumption is that testing should be targeted to individuals at-risk rather than universally encouraged. Home collection tests will inherently be a more universal rather than a targeted approach to testing because the companies marketing home collection tests have no incentive to dissuade people from using them. Conversely, testing sites that have limited resources have an incentive to target testing to those most in need.

Regardless, the debate changes when one examines the second issue: who pays for testing. The individual user pays for home collection tests, not third parties such as the federal government or health insurers. Given that the average cost per standard HIV test in publicly funded settings is approximately $100 (ranging up to $375 per person receiving their results and counseling) (Kassler, 1997), the potential shift in costs over time is very large. This fact changes the debate over targeted versus universal testing from a debate over how to allocate tax dollars to a debate as to whether individuals can be trusted to decide for themselves whether they "need" testing and wish to spend money on it.

However, it can be argued from an ethical perspective that HIV testing should not be treated as a market good but rather a social good that should be supported by tax dollars. This would argue for continued provision of HIV testing at public clinics as well as the provision of subsidized home collection tests for persons who prefer them but cannot afford them. The question is whether government should intervene to facilitate access to home testing for low-income individuals, or whether the availability of "free" testing at publicly funded clinics already provides equitable access to testing.

What insights can the experience with home collection HIV tests provide? The experience illustrates how important it is to separate the question of who is tested from the question of who pays for testing. There may continue to be wide disagreement over the wisdom of targeted vs. universal testing since that debate is complex and involves numerous factors. However, if the goal is to get as many people tested as possible while reducing the costs of testing to the government or insurers, then the availability of home collection tests can only be helpful to achieving those goals. From the viewpoint of economic efficiency, a fundamental assumption is that individuals make rational decisions to purchase goods based on their perception of the value

or utility of those goods. Therefore, government intervention that restricts access to goods that individuals wish to purchase is inefficient. However, there remain ethical questions as to the proper role of government in ensuring equitable access to testing services.

(3) What are the rights of individuals versus the responsibilities of government?

Home collection tests were not approved for 10 years because of the FDA's interpretation of its mandate to ensure the safety and effectiveness of products. The FDA has determined that home-use products, including but not limited to HIV tests, must be evaluated in terms of the risks and benefits to both individuals and society ("public health") (FDA, 1988). In the case of home collection HIV tests, this evaluation includes the adequacy of pretest and post-test counseling, the ability of consumers to take appropriate follow-up action, the reporting of results by appropriately trained counselors, and the gathering of data on user demographics and the public health impact of the tests (Suydam, 1995).

The FDA's interpretation of its mandate has increasingly come under attack, not only for home collection tests but also for HIV treatments and other new technologies. The experience of home collection tests therefore has implications for an issue of broader significance: the role of federal regulatory bodies in protecting individuals from technically accurate devices that may produce psychologically burdensome results (Bayer, Stryker et al., 1995) and that may adversely impact public health. These issues will grow in importance as the market for home diagnostic tests continues to expand, fueled by the availability of new products, consumer interest in self-care, and the growth of managed care organizations (Business Wire, 1996). Individuals can now purchase tests to detect a variety of conditions including cancer and drug abuse, and the list continues to grow.

The proper role of the FDA in approving new products will continue to be an issue since new HIV testing technologies are continuing to be developed and submitted for approval. The approval of home collection HIV tests opens the door to new testing technologies that promise to dramatically change the nature of HIV testing. Table 7 summarizes the estimated availability of current and future testing alternatives and a short description of each test is below.

One rapid blood (EIA) test has been approved by the FDA and is currently in use in the U.S. (the Single Use Diagnostic System "SUDS", Murex Company; another test was approved but is not commercially available). Numerous other rapid tests have been developed worldwide. The rapid test can provide results in 10-15 minutes (Irwin, Olivo et al., 1996; Spielberg and Kassler, 1996). Since negative and preliminary positive results can be given out at the initial visit, rapid tests increase the number of people who obtain their test results, particularly in settings such as hospitals and STD clinics where return rates are low (Irwin, Olivo et al., 1996; Kassler, 1997). Rapid tests may also be useful when timely clinical information is needed such as in cases of occupational exposure (Kassler, 1997). Studies have found that rapid testing is feasible, preferred by clients, and may not decrease the effectiveness of counseling (Kassler, Haley et al., 1995; Kassler, 1997). The next development is expected to be the use of two rapid tests in combination, which would increase the positive predictive value of the test and allow patients to obtain more definitive results in one visit (Spielberg and Kassler, 1996).

The FDA approved one oral fluids test (OraSure, Epitope Inc.) for use by professionals in 1996 and the company is seeking approval for an over-the-counter product (Gallo, George et al., 1997). Advantages to oral fluids testing include ease of collection, portability, and increased safety for both subjects and health care workers because it does not require the use of needles or lancets (Gallo, George et al., 1997). The test is being used in private and public settings; for example, the Whitman-Walker clinic, which is the primary community-based provider of HIV and AIDS services in the D.C. area, recently replaced traditional blood testing with OraSure in order to reach those who are averse to blood-based testing with needles (Whitman-Walker, 1997).

The FDA approved a urine test developed by Calypte Biomedical Corporation in 1996. The test was approved for use only by health providers, and anyone testing positive must be retested using a blood sample; however, Calypte has preliminary approval for a confirmatory urine test. In addition, Calypte and Trinity Biotech announced in 1997 an agreement to develop the world's first one-step urine based HIV test, which would open the door to true home testing. Although the initial market would be doctor's offices, clinical laboratories, and remote testing sites, the companies plan to develop the product for the over-the-counter market (Trinity, 1997). As with oral fluids tests, advantages to urine tests include safety, ease of collection, and portability (Berrios, Hearst et al., 1993). In one study, the authors reported that 73% of IDU subjects consented to urine testing (MacGregor, Dunbar et al., 1994).

The next challenge will come with the first application for approval of true home tests which allow individuals to test themselves at-home using either a fingerstick, oral fluids, or urine sample. True home testing offers the advantages of increased convenience and anonymity beyond current home collection testing (Schopper and Vercauteren, 1996; Merson, Feldman et al., 1997). The technology for true home tests currently exists (Kassler, 1997), "bootleg" tests are available for purchase via the World Wide Web (Kassler, 1997), FDA representatives have indicated "off-the-record" that true home tests would be "potentially approvable" (Scribner, 1996), and several companies have unofficially indicated that they would eventually seek approval for such tests. Although we are not aware of any published research on individuals' preferences for true home tests versus other testing methods, our impression is that such tests (particularly if they do not require fingersticks) would be greatly preferred over the current home collection tests. These companies have also indicated, however, that they perceive the FDA approval process to be a formidable barrier to further progress. True home tests would conflict with the current Public Health Service guidance that requires the use of confirmatory testing (although this requirement could be met through the use of two different rapid tests) and the FDA requirements for reporting of results by trained counselors (Suydam, 1995).

What insights can the experience with home collection HIV tests provide? The debate is whether issues of safety and effectiveness should be limited to the device itself or include the consequences of its approved use. Some would argue that the FDA is overstepping its bounds in using a broad interpretation of safety and effectiveness as a criterion for approval. Others would argue that the FDA's obligation to protect consumers appropriately includes broader considerations, and that such protection is not unwarranted paternalism. The debate between individual rights and governmental responsibilities cannot be answered because it is a question of values. Many of the debates over home collection HIV tests and testing in general are

symbolic of the more fundamental issue of the rights of individuals to know (or not know) their HIV status versus the responsibilities of government to regulate how that information is obtained. One example is the heated debate over whether testing of pregnant women and newborns should be mandatory or voluntary. Maternal-child transmission of HIV accounts for only 0.1% of AIDS cases (CDC, 1997), so that testing of pregnant women and newborns has relatively less impact on the epidemic than other programs. The debate is often framed in terms of the responsibility of the government to protect helpless newborns. Yet, the debate has also been over whether pregnant women have the right to decide whether to know their HIV status (which is revealed through newborn testing).

In the case of home collection tests, the long FDA approval process probably improved the tests, especially by requiring the development of counseling and referral systems. In addition, the analyses presented earlier on home collection test users could not have been possible without FDA's requirement for companies to conduct post-marketing surveillance studies and disseminate the data. However, it is not clear whether the benefits gained were worth the delay in the availability of the tests. The policy question for the future will therefore be whether new HIV tests should be required to demonstrate not only the safety and effectiveness of the product itself but also their effect on other factors such as the psychological responses of users and the impact on the publicly funded testing system.

A similar issue is the extent to which the government should intervene in order to ensure that new testing technologies are developed and widely available. The withdrawal of Johnson & Johnson and SmithKline Beecham from the home collection HIV test market suggests that private industry may not have sufficient motivations to continue developing and marketing new HIV tests. The issue is similar to that of contraceptives, where progress on developing and marketing new products that may benefit individuals and public health more generally has been stymied by a lack of profits and social attitudes towards contraceptives (Samuels and Smith, 1994). The issue is therefore whether the government needs to intervene more directly by either encouraging the development of new HIV tests or ensuring their availability, for example, by subsidizing the purchase of home collection HIV tests by low-income users of public health clinics.

FUTURE RESEARCH AND POLICY AGENDA

In this section we suggest areas for future research and raise several issues for discussion. First, it will be important to continue analyses of the company-provided data on users of home collection tests. The results shown above are based on one year of use, yet two more years of data will be available. It will be important to examine the trends over time in the number of tests used and the characteristics, outcomes, and experiences of users. These results can be used to inform policy decisions on testing programs and new testing technologies.

Second, further research is needed on the characteristics of individuals who use different test sites. The data discussed above on home collection test users does not include a comparison group of individuals tested at other sites and therefore these data cannot be used to examine the factors that predict the choice of home collection tests versus testing at public or private sites. Research is also needed on the trends in testing sites over time in order to examine whether home

collection testing may be substituting for testing at other sites and whether there are differential trends in testing use among populations such as individuals with risk factors, people of color, and young adults. We currently have proposed to conduct such a study, using data from two nationally representative surveys conducted by the CDC. These surveys ask individuals whether they have been tested and where, including "at-home". These data can therefore be compared to the company-provided data and they provide more extensive information on the characteristics of users of different test sites.

Third, despite the usefulness of the above research, it is clear that new primary data collection efforts will be necessary to address many of the remaining questions about home collection tests and other new testing methods. In-depth information is needed on users' experiences with home collection tests, the factors that encourage or discourage individuals from being tested using different methods, the value placed on testing, and individuals' willingness-to-pay for testing. In particular, it is critical that data be obtained on *what* methods are preferred and *why* they are preferred. These studies should be both qualitative and quantitative. One approach to obtaining data that would be less expensive than initiating large surveys would be to "piggyback" questions onto existing surveys such as the CDC's Behavioral Risk Factor Surveillance Survey. It will also be important to conduct studies to determine if users of publicly funded test sites would use home test kits if provided to them at a reduced cost.

Research studies are needed on other new testing methods that may offer more hope in reaching high risk individuals, particularly disenfranchised individuals who often do not seek health care through traditional means, e.g., IDUs, individuals with low income, minorities, and the homeless. Methods which provide rapid results and therefore do not require return visits and which do not require venipuncture are particularly attractive to some groups and could be offered through, for example, mobile vans at needle exchange sites.

Fourth, research is needed on the cost-effectiveness of home collection tests and other new testing methods compared to testing at public or private sites using standard methods. New HIV tests may change the cost-effectiveness of testing programs and testing policies by changing the willingness of individuals to be tested and changing or shifting the costs of testing. Since testing continues to consume a large proportion of federal and state budgets allocated to HIV prevention, it is important to assess the cost-effectiveness of new testing methods as well as the shifting of costs and benefits. We have proposed to conduct such a study that would incorporate the latest data on testing utilization. We will analyze the possible impact of government interventions to encourage testing at different sites and using different methods and the possible impact of new testing alternatives on different populations such as IDUs.

Questions on the cost-effectiveness of new testing methods include:

- Are different testing alternatives more cost-effective within specific risk groups versus the general population?
- What factors will have the most impact on the cost-effectiveness of testing as the epidemic expands in certain populations?
- What interventions can increase the effectiveness of testing while decreasing costs? For example, should public clinics consider providing home collection tests on a sliding fee scale?

- What further research is necessary? For example, will home collection tests only be cost-effective if individuals who find out they are positive through home testing seek early medical treatment and avoid infecting others?
- What are the implications for individuals, providers, and policymakers of the shifting of costs and benefits as a result of the introduction of new tests?
  - Are there discrepancies between who pays for testing and who benefits from testing?
  - To what extent is government intervention necessary and appropriate to ensure that new testing technologies are developed, made available, and used appropriately?

Lastly, it will be important to examine the policy, legal, and ethical issues of not only home collection HIV tests but also other new testing methods. This is particularly critical for true home tests because they potentially offer the greatest increase in access to testing. Questions that could be addressed include:

- How can new testing methods facilitate the early identification of HIV-infected persons and their entry into care?
  - What are the advantages and disadvantages of new testing methods?
  - What practices, programs, and policies can be developed that will facilitate testing, meet the needs of individuals and testing providers, and also be cost-effective?
  - How can educational efforts be targeted to specific groups, such as individuals who intend to be tested but who do not follow-through on their intentions?

- What are the future implications of new testing technologies?
  - What are the possible advantages and disadvantages to true home tests? What mechanisms can be used to address any concerns?
  - Do current laws and regulations adequately cover the use of testing methods other than blood testing?
  - What is the role of the FDA and other governmental agencies in regulating testing?

In conclusion, home collection HIV tests - or any new testing methods - cannot overcome all of the barriers to testing. Even when testing is made readily available at no cost, some individuals with HIV risk factors will decline to be tested. For example, in the study of at-risk individuals discussed earlier (Colfax, Lehman et al., 1997), one-third of untested individuals stated they were unlikely to use even free home tests, suggesting that there are other barriers to testing. People may choose not to be tested for a variety of reasons, including denial of their risk, the potential for adverse consequences to social relationships, and concerns about coping with test results among others (Phillips and Coates, 1995). Similarly, individuals who test positive may not access health care for a myriad of reasons. The question is therefore not whether new testing methods such as home collection tests are THE answer, but whether they are a piece of the solution.

REFERENCES

Anonymous (1988). Banned at Home: An FDA Ruling on AIDS Tests. Time: 26.

Anonymous (1997). Judge Suspends Kentucky Law Banning Home Test Kits. AIDS Policy and Law: 9.

Anonymous (1997). Users mostly male, heterosexual. USA Today: 6D.

Bayer, R., J. Stryker, et al. (1995). "Testing for HIV infection at home." New Engl J Med **332**(19): 1296-1299.

Berrios, D., N. Hearst, et al. (1993). "HIV antibody testing among those at risk for HIV infection: the National AIDS Behavior Survey (NABS)." JAMA **270**(13): 1576-1580.

Berwick, D. and M. Weinstein (1985). "What do patients value? Willingness to pay for ultrsound in normal pregnancy." Medical Care **23**(7): 881-893.

Business Wire (1996). Revenues continue to grow in the home diagnostics products market.
Canedy, D. (1997). FDA Warnings Preceded Withdrawal of HIV Test. New York Times. New York, NY.

CDC (1985). "Recommendations for assisting in the prevention of the perinatal transmission of human T-lymphotropic virus type III/lymphadenopathy-associated virus and acquired immunodeficiency syndrome." MMWR **34**: 721-6,731-2.

CDC (1997). HIV counseling and testing in publicly funded sites:1995 summary report. Atlanta, GA, Centers for Disease Control and Prevention.

CDC (1997). "Update: Trends in AIDS Incidence- Unites States,1996." Morbiity and Mortality Weekly report **46**(37): 861-7.

Centers for Disease Control and Prevention (1994). National HIV serosurveillance summary: results through 1992. Atlanta, GA, US Department of Health and Human Services.

Centers for Disease Control and Prevention (1995). "U.S. Public Health Service recommendations for Human Immunodeficiency Virus counseling and voluntary testing for pregnant women." MMWR **44**(RR-7): 1-15.

Colfax, G., J. Lehman, et al. (1997). Likelihood of at-risk individuals using homes HIV test collection kits. Society of General Internal Medicine, 20th Annual Meeting, Washington, DC.

Des Jarlais, D. C., N. S. Padian, et al. (1994). "Targeted HIV-Prevention Programs." NEJM **331**(21): 1451-1453.

FDA (1988). Assessing the Safety and Effectiveness of Home-USe In Vitro Diagnostic Devices: Draft Points to consider Regarding Labeling and Premarket Submissions (Draft). Washington, DC, Food and Drug Administration.

FDA (1990). AIDS Home collection kits and home test kits. Washington DC, Food and Drug Administation.

Frank, A., M. Wandell, et al. (1997). "Anonymous HIV testing using home collection and telemedicine counseling." Archives of Internal Medicine **157**: 309-14.

Freundlich, N. and J. O. C. Hamilton (1996). The Trials of a Home HIV Test. Business Week: 56-58.

Gallo, D., J. George, et al. (1997). "Evaluation of a system using oral mucosal transudate for HIV-1 antibody screening and confirmatory testing." Journal of the American Medical Association **277**(3): 254-58.

Hardy, L., Ed. (1991). HIV Screening of Pregnant Women and Newborns. Washington, D.C, Committee on Prenatal and Newborn Screening for HIV Infection, Institute of Medicine, National Academy Press.

Higgins, D., C. Galavotti, et al. (1991). "Evidence for the effects of HIV antibody counseling and testing on risk behaviors." JAMA **266**: 2419-2429.

Irwin, K., N. Olivo, et al. (1996). "Performance characteristics of a rapid HIV antibody assay in a hospital with a high prevalence of HIV infection." Annals of Internal Medicine **125**(6): 471-475.

Jeng, L., J. RM Moore, et al. (1991). "How frequently are home pregnancy tests used? Results from the 1988 National Maternal and Infanct Health Survey." Birth **18**: 11-13.

Johnson, K. (1997). Home Access Health Announces Agreement with Abbott Laboratories to Develop Home Diagnostic Telemedicine Products.

Jones-Redmond, S., M. Cohen, et al. (1997). "HIV antibody home testing: the new craze." Abstracts of the National Conference on Women and HIV: P1.70.

Karon, J., P. Rosenberg, et al. (1996). "Prevalence of HIV infection in the United States, 1984 to 1992." Journal of the American Medical Association **276**(2): 126-31.

Kassler, W. (1997). "Advances in HIV testing technology and their potential impact on prevention." AIDS Education and Prevention **9**(Supplement B): 27-40.

Kassler, W., B. Dillon, et al. (1997). "On-site, rapid HIV testing with same-day results and counseling." AIDS **11**(8): 1045-1051.

Kassler, W., C. Haley, et al. (1995). "Performance of a rapid, on-site human immunodeficiency virus antibody assay in a public health setting." Journal of Clinical Microbiology **33**: 2899-2902.
Koop, C. (1994). Remarks by C.Everett Koop, MD, ScD, FDA Blood Products Advisory Committee Meeting.

Leary, W. E. (1989). Home Tests for AIDS: Concept is Attractive But Experts Are Wary. New York Times. New York: Y19.

Lupton, D., S. McCarthy, et al. (1995). ""Doing the right thing": The symbolic meanings and experiences of having an HIV antibody test." Social Science and Medicine **41**(2): 173-180.

MacGregor, R., D. Dunbar, et al. (1994). "Tuberculin reactions among attendees at a methadone clinic: Relation to infection with the human immunodeficiency virus." Clinical Infectious Diseases **19**(December): 1100-1104.

Merson, M., E. Feldman, et al. (1997). "Rapid self testing for HIV infection." Lancet **349**(February 1): 352-353.

Morrison, K., K. Phillips, et al. (working paper). "The quality and provision of HIV counseling & testing in the private sector." .

National Alliance of Lesbian and Gay Health Clinics (1994). Letter from Michael Savage, Chair, to David Kessler, Commissioner, FDA.

Newhouse, J. and t. I. E. Group (1993). Free for All? Lessons from the RAND Health Insurance Experiment. Cambridge, Havard University.

Phillips, K. and T. Coates (1995). "HIV counseling and testing: research and policy issues." AIDS Care 7(2): 115-24.

Phillips, K., K. Morrison, et al. (1997). "HIV counseling and testing of pregnant women and women of childbearing age by primary care providers: self-reported beliefs and practices." Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology **14**(2): 174-78.

Phillips, K. A., S. J. Flatt, et al. (1995). "Potential use of home HIV testing [comment]." N Engl J Med **332**(19): 1308-10.

PR Newswire (1997). Direct Access Diagnostics and Elliott Millenson Settle Litigation.
Reuters (1997). Firm to withdraw home HIV test; low demand cited. Los Angeles Times. Los Angeles, CA: A14.

Salbu, S. R. (1995). "HIV Home Testing and the FDA: The Case for Regulatory Restraint." Hastings Law Journal **46**(September): 403-57.

Samuels, S. and M. Smith, Eds. (1994). The Pill: From Presecription to Over the Counter. Menlo Park, CA, The KaiserForums.

Schopper, D. and G. Vercauteren (1996). "Testing for HIV at home: What are the issues?" AIDS **10**(13): 1455-1465.

Scribner, C. (1996). HIV Home Sample Collection Kits: Maximizing the Public Health Benefits. ASHTO, Arlington, VA.

Spielberg, F. and W. Kassler (1996). "Rapid testing for HIV antibody: A technology whose time has come." Annals of Internal Medicine **125**: 509-511.

Suydam, L. (1995). "Home Specimen Collection Kit Systems Intended for Human Immunodeficiency Virus (HIV-1 and/or HIV-2) Antibody Testing: Revisions to Previous Guidance." Federal Registrar **60**(36): 10087-1008.

Trinity, B. (1997). Trinity Biotech Announces Collaboration with Calphyte.
Weiss, R. and S. O. Thier (1988). "HIV Testing is the Answer -- What's the Question?" NEJM **319**(15): 1010-1012.

Whitman-Walker, C. (1997). Whitman-Walker Clinic Adopts OraSure Oral HIV-1 Antibody Testing System: Conversion from Blood to OraSure System Offers Broad Opportunities to Expand HIV Testing in Metropolitan Washington. Washington, DC.

Young, F. (1989). "Blood Collection Kits Labeled for Human Immunodeficiency Virus Type 1 (HIV-1) Antibody Testing: Home Test Kits Designed to Detect HIV-1 Antibody: Open Meeting." Federal Register.

Young, F., Commissioner, Food and Drug Administration (1989). Statement before the Subcommittee on Regulation and Business Opportunities, Committee on Small Businesses, U.S. House of Representatives. Washington, DC.

HIV Testing Survey (HITS) and AIDS Patient Survey (APS)

UCSF/UC Berkeley	CDC	State Health Departments
Frederick Hecht	J. Stan Lehman	AZ: Denis Boyd, Vjolica Bertsha
Andrew Bindman	Patricia Fleming	CO: Ken Gershman, Cornelius Reitmeijer
Dennis Osmond	John Ward	MD: Jan Markowitz, Rebecca Cohen
Karen Vranizan		MO: Kristen Wendt, Linda Bell
Dennis Keane		MS: John Newman, Craig Thompson
Shoshana Colman		NC: Dell Williams, William Graham
Margaret Chesney		NM: Michael Samuel, Jill Gatwood
Arthur Reingold		OR: Steve Modesitt, Roger Wirt
		TX: Ann Robbins, Sharon King
		And many other interviewers and Project Staff

HITS Research Questions

- Do at-risk persons know their state HIV reporting policies?
- How important is reporting as a perceived deterrent to testing?
- Perceived intent to test in the future under different test reporting conditions?

HITS Design

- Cross-sectional anonymous survey
- Survey performed 12/95 to 11/96
- 9 states
  - Named reporting: AZ, CO, MO, MS, NC
  - Anonymous or no reporting: OR, NM
  - Unique identifier reporting: MA, TX
- Goals for study recruitment
  - Persons at-risk of HIV exposure
  - Consistent recruitment venues across states

HITS Study Populations

- MSM
  - Recruited from $\geq$ 4 gay bars per state
  - Bars selected to achieve range of age, race, ethnicity
  - Sexually active in past 12 months
- Heterosexuals
  - Recruited from STD clinics
  - Client with suspected new STD
- IDU
  - Recruited through street outreach
  - Injected within past 12 months
- Target enrollment: 100 per venue per state

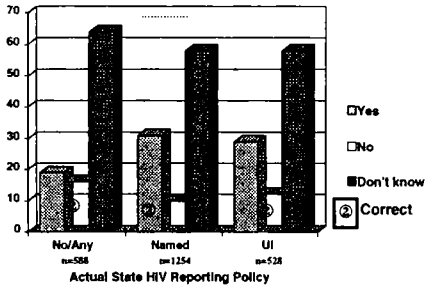
Participant Characteristics

	HIV Reporting Policy		
Characteristic	*Named*	*Non-Named*	*Unique ID*
Total (n)	1254	588	528
Risk behavior (%)			
MSM	33	32	28
Hetero	38	32	36
IDU	29	36	36
Male (%)	77	73	72
Race (%)			
African-American	43	14	63
Latino	15	34	9
White	38	45	26
Other	4	7	2

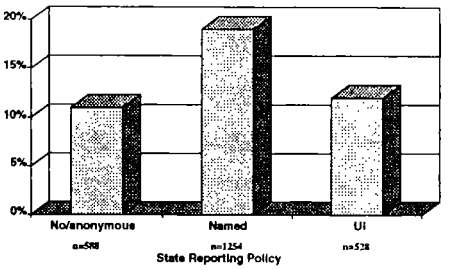
Participant Characteristics

	HIV Reporting Policy		
Characteristic	*Named*	*Non-Named*	*Unique ID*
Education > 12th Grade (%)	42	47	39
Monthly Income (%)			
< 1,000	40	44	38
$1,000 - 1,999	29	30	29
> $2,000	31	26	34
Age (median)	32	33	36
Previously HIV tested (%)	74	84	83

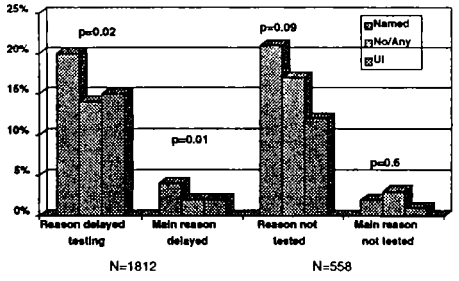
If you test HIV positive in your state, is your name reported to the Health Department?



Proportion of Participants Who Could Correctly Identify State Reporting Policy



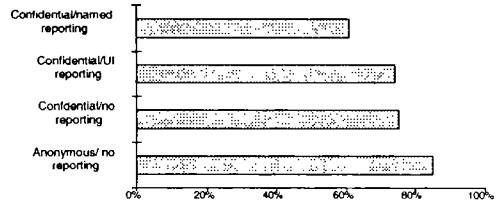
Worry About Named Reporting As a Reason for Delaying or Not Testing by State Reporting Policy



Reasons for not HIV testing among those not tested

Reason	*% Gave As Reason*	*% Gave As Main Reason*
1. Afraid to find out	48	28
2. Unlikely to have been exposed	43	20
3.Thought HIV negative	48	15
4. Didn't want to think about it	48	9
5. Little could do if positive	32	6
6. Didn't have time	18	5
7. Unsure where to go	22	4
8. Worried name would be reported to gov't	**19**	**2**
9. People might think you have AIDS	17	2
10. Test costs too much	8	2

Likelihood of HIV Testing in the Next Year Under Different Reporting Scenarios



Limitations

- **Many recruitment venues have had outreach**
  - **May overestimate knowledge**
  - **May underestimate concern about reporting**
- **Response bias**
- **Generalizability uncertain**
  - **e.g. MSM at bars may be different from MSM who don't go to bars**
- **Stated intent to test may not match actual behavior**

Conclusions

- Knowledge of HIV reporting policies is low
- Concern about named reporting sometimes delays testing, but is rarely the main reason for not testing
- Eliminating anonymous testing might decrease testing rates
-

APS Research Questions

- Do persons with AIDS perceive named reporting as a reason they delayed HIV testing or entry into medical care?
- Do persons in named reporting states get HIV testing later in the course of disease?
  - Lower CD4 cells
  - Less time before AIDS diagnosis
- Found contact with the health department helpful in getting medical care?
-

APS Study Design

- Cross-sectional study in 8 states
  - Named reporting: AZ, CO, MO, MS, NC
  - Without named reporting: OR, NM, TX
- New AIDS cases reported 5/95 to 12/96
- Population based with oversampling of non-MSM risk groups
- ≥18 years old, healthy enough to interview, living in state, English or Spanish speaking
- Structured interview by HIV/AIDS surveillance staff

APS Enrollment

- 3,321 cases sampled
- 2801 met eligibility criteria
- 1913 patients interviewed
- 68% response rate

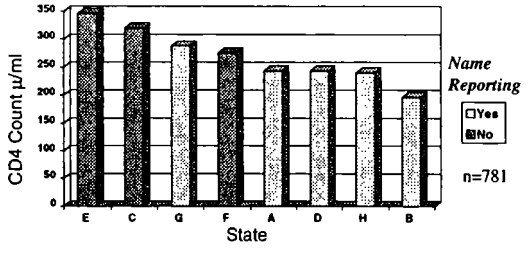
APS Patient Characteristics

Age (mean years)	37.4
Male (%)	83
Race/Ethnicity (%)	
A.A.	34
Asian	0
Hispanic	10
White	53
Other	3
Education (mean years)	12.7
Income (median $/mos)	1,880
Insurance (%)	
Private	42
Medicaid	10
Other	48
Regular source of care (%) at time of HIV (+) test	44

Reporting as Reason for Delay in Testing and Care

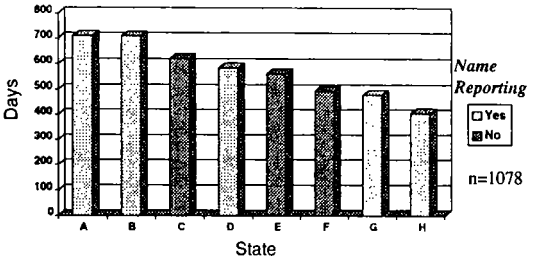
- 28% of all participants waited > 1 month after + HIV test to enter care
- 10% of these (3% of the total) reported fear of being reported to the health department as a reasons for delay
- 0.5% (0.1% of total) said it was the main reason for delay

Adjusted* Mean Self-Reported First CD4 Count by State (1990-97)



* adjusted for age, sex, race/ethnicity, education, income, health insurance, risk behavior, confidential/anonymoue testing, regular medical care prior to testing

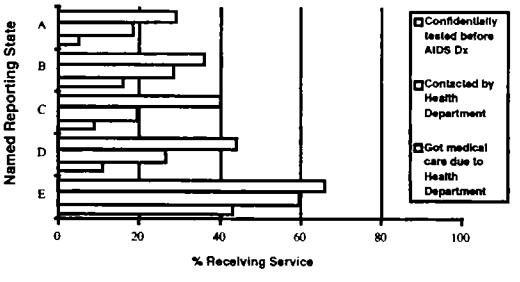
Adjusted Intervals in Time from HIV + Test to AIDS by State (1990-97)



Comparisons of First CD4 Count and Days between HIV Dx and AIDS Dx based on Reporting Policies

- **Mean adjusted self-reported first CD4 count**
  - **Named reporting states: 225 cells /µl**
  - **Non-named reporting states: 304cells/ µl**
  - **p <0.001**
- **Adjusted mean days between HIV diagnosis and AIDS diagnosis**
  - **15 days shorter in reporting states**
  - **p=0.7**

Medical Care Encouraged by Health Department



Differences in Time From HIV Test to Entering Care

- **Among 399 participants testing HIV+ > 1 month prior to AIDS in HIV reporting states**
  - **Compared time from HIV test to care based on whether contacted by HD**
  - **Multivariate linear regression model**
  - **Adjusted for age, race, exposure group, education, income, insurance, regular medical care prior to testing, symptoms, tested in MD office**
  - **Persons contacted by the health department entered care 21 days earlier (95% CI: -15 to 27 days)**
- **No difference between reporting vs. non-reporting states**

Limitations

- **Type of testing and state reporting policy not randomized**
- **Inaccuracy of self-reports**
- **State differences not captured by measured variables**
- **Comparisons of state-level variables have only 8 data points**

Conclusions

- Reporting concerns rarely the main reason for delaying entry into care
- Mean CD4 count lower in named reporting states
  - May reflect differences in outreach and accessibility of care as well as effect of reporting
- No difference in time from HIV diagnosis to AIDS diagnosis based on reporting policies
- Health department contact to about medical care
  - Variable proportions contacted, some found it useful
  - Not associated with more rapid access to care