COMMUNITY HIV/AIDS CHAMP MOBILIZATION PROJECT
HHS WATCH

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SPECIAL EDITION ON HIV TESTING:
Commentary on upcoming CDC testing guidelines by David Gilden, Walt Senterfitt; Update on House bills on prison-based testing

A Test of our Commitment: what it would really take to fix HIV testing

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Among the problems with the CDC's new HIV testing guidelines is that they're being oversold. The CDC has a dispiriting habit of regularly announcing some new ostensible panacea for the failures in HIV prevention, from endless reorganizations to the "Strategic Plan to Cut HIV Incidence in Half By 2005" to SAFE to DEBI to AHP to PEMS. Now we can add a new presumed magic bullet to the list: routine HIV testing in healthcare settings. We at CHAMP think we need to step back and try to put this and other proposed testing initiatives into a bigger picture. Here are some of our premises.

1. Damn right, our current systems to promote early detection of HIV infection and linkage to effective treatment, care, support and prevention are failing us, and especially people of color, gay men and other MSM, and youth.

More than 25% of people with HIV don't know it and disparities by race and ethnicity are glaring. More than 40% of HIV-positive people of color don't discover they are positive until, or just before, they have AIDS symptoms. Up to 90% of HIV infected African American MSM in a recent multi-site CDC study were unaware of their status until tested during the study.

The key questions are, why is this so and what strategy(ies) would work best to turn around this failure?

2. HIV/AIDS is a cluster of interrelated epidemics, not a single one. From differences in and between communities, populations, exposure groups, ages, or the degree to which one intersects with violence, poverty, the legal system, and more, it is highly unlikely there is a single magic bullet or one-size-fits-all solution.

3. For some populations -- women of child-bearing age for instance -- routinely offering HIV testing to every client or patient coming into care has worked very well, and has played a critical role in drastically reducing mother-to-child transmission in this country.

It has also allowed tens of thousands of women to benefit from earlier, more effective treatment themselves. Most pregnant women enter pre-natal care of some type and thus can be offered testing and appropriate counseling.

4. Less universally but still significantly, some other populations not previously provided HIV testing will at some point, use the acute or emergency healthcare system.

Uninsured people without regular healthcare, but vulnerable to the violence, injury risk and illness-inducing living conditions in many urban cores show up in emergency rooms or acute care hospitals when urgently ill. Removing the current barriers to universally offering HIV testing can be a critical way of reaching those in these populations who have HIV but are unaware of it.

If done right, it can also be a way to spread accurate HIV transmission and prevention information more deeply into vulnerable populations, and to identify those still HIV negative but at high risk of later contracting HIV without specific prevention intervention.

5. However, some other populations where there is a high prevalence of undetected HIV infection are *not* particularly likely to encounter the healthcare system, such as younger black and Latino MSM.

They are generally healthy and are often uninsured, and thus on average have little contact with the formal healthcare system. In fact, late teenagers and young adults in general, where as many as 50% of new infections occur, fit this category.

Proposals to routinely screen or test for HIV in healthcare settings will have minimal impact on HIV detection and prevention in these large and critical populations.

6. The specialized HIV testing system developed over the past 20 years in CBOs, outreach vans, and community clinics has shown the ability to reach special populations at high risk, if given sufficient resources *and* if they are innovative, persistent and results-based in refining their approaches to changing local epidemics.

Starved for funding and thus always hamstrung from reaching their potential, these programs harbor a veritable army of in-the-trenches experts and innovative approaches the CDC has barely tapped.

7. The promise of this system, which couples voluntary HIV testing with risk assessment and risk-based counseling, is that it theoretically offers a chance to help *stop* new infections by intervening with those who test negative but practice high risk behaviors.

Routine screening, on the other hand, offers nothing to the HIV negative part of the high-risk population, and may indeed have the unintended adverse consequence of confirming current risky behaviors since "well I haven't gotten it this far, what I am doing must be okay."

However, research shows that the most common current models and programs of pre/post test counseling are not especially effective for people who test negative.

We speculate that this failure may be attributable to a combination of poor implementation, inadequate focus on triaging those at highest risk of becoming infected and a lack of adequate referral services to meet the risk-associated needs of the most vulnerable negatives.

Figuring this out and widely disseminating explanations it would be very helpful to the people doing the work. The literature shows that there are models that work to reduce risk, particularly *if* there are appropriately intensive prevention and risk reduction services available in the community. We need to permit and encourage (even require!) people to shift from the ineffective models to more flexible ones.

8. There are other promising strategies of finding HIV positive persons unaware of their infection and linking them to care and support, such as those based on social networks among those at high risk. But these approaches have never been ramped up to nearly their research-indicated potential, and to do so should be a top priority.

9. The way in which any of these strategies are implemented, or priorities for funding are shifted, matters immensely to not only their likelihood of success but also their ability to minimize unintended adverse consequences and ethical breaches that ultimately undermine the health of us all.

For example, there is no justification to remove or undermine informed consent to any test or medical procedure absent an immediate, clear and present danger to life or limb. Elimination of informed consent jeopardizes individual autonomy and minimizes the obligation of the practitioner to explain procedures and lay out their benefits and risks.

For another, the new CDC guidelines' injunction to "deliver positive HIV test results in the same way as those of other screening tests" is highly suspect. While this may be a sufficient injunction to privately insured patients receiving individualized attention in private practices, it belies common sense to think this will be adequate, effective and humane in most "steerage class" healthcare settings. *Research has shown that the way in which HIV positive test results are delivered* *has considerable impact on the likelihood of successfully accessing and remaining in care and treatment.*

If funding for widespread screening comes out of the current limited prevention budgets and thus requires reduction of targeted outreach, risk assessment, testing and follow-up, then we are likely to lose at least as much ground against this epidemic as we gain.

Finally, if we implement healthcare screening without seeking every possible way to integrate some basic risk and harm reduction education and counseling into the flow of the process, we unnecessarily lose a tremendous opportunity to combat widespread incorrect information and also stigma extant in the general population.

10. Given that the devil is in the details, it is critical that the CDC and/or its federal partners such as NIH undertake a comprehensive operational research program simultaneously with the promotion and implementation of these guidelines.

At what rate and with what fidelity are the guidelines adopted and implemented? How many previously unidentified cases are detected through this system and at what cost, and compared to what similar resources could achieve through alternate strategies? How many of the cases identified are successfully linked to care and treatment and support and how many remain in care after a year? What additional burden did these new cases place on overstretched or absent healthcare systems and with what consequences? In what populations and demographic strata does this strategy yield relatively better and worse results? Are there unintended adverse and/or positive consequences?

The Bottom Line: The Fix is Not In

These new guidelines will be promulgated this week, having undergone only minor modifications after a very limited process of consultation and input from stakeholders. That event by itself changes nothing. For any of the suggested change to happen will require changes of law and/or regulation in most states, determination of standards of delivery in practice and training of personnel, persuasion of large and in most cases already overburdened urban healthcare systems to add new tests and procedures without at the outset any new funds, decisions as to who should pay for the testing and counseling/referral costs and getting whoever it is to pony up, and so on.

The last set of CDC guidelines on this subject, issued in 1993, were, according to a recent talk by Dr. Rob Janssen "perhaps the least observed guidelines in the history of the Public Health Service."

Wouldn't it be great it we could turn this next period of predictable resistance and confusion over implementation into a real dialogue among the feds, the docs, the healthcare execs, the community-based organizations serving high-risk communities and the people living with HIV to come up with a comprehensive plan to offer real treatment and real prevention for everyone in at country with, or at risk for, HIV

HIV Testing: A new era that looks a lot like the past

David Gilden

On September 21, the CDC is set to release the final version of its new HIV guidelines for streamlined mass HIV screening. The guidelines will apply to HIV testing conducted by healthcare facilities, not community organizations. Still, the recommendations' broad reach supports a shift in testing from service provider to medical provider. Whatever the setting, their impact is to undermine the emphasis that the current model places on counseling and education at the time of testing.

Supporters have welcomed the move to generalized HIV testing as a "new paradigm" (see, for example the editorial by Ronal Bayer and Amy Fairchild in the *New England Journal of Medicine,* August 16, 2004). But the

CDC guidelines draft issued last spring admitted that “these recommendations advocate routine voluntary HIV screening as a normal part of medical practice similar to screening for other treatable conditions.” In another words, the testing recommendations represent a return to traditional medical practice.

The new guidelines now advocate “routine” HIV testing as part of regular health care for virtually all Americans, not just those in communities with HIV prevalence of 1.0% or greater. Persons judged to be at high risk for HIV should be tested annually. It is not clear how often HIV testing should occur in the rest of the public. Medical facilities have in the past been reluctant to test for HIV. To facilitate testing at healthcare sites, the guidelines advocate doing away with pre-test consent and HIV counseling requirements.

Instead, doctors are supposed to tell patients that they will be tested for HIV and give them an opportunity to decline (an “opt-out” process). The HIV test will indeed become a test like any other: test results should be delivered “in the same manner as results of other diagnostic or screening tests,” the CDC says. People who are found positive are supposed to be counseled and referred for further medical care.

The Arguments for Change

There is a strong concern that many people do not know that they have HIV. They are therefore unable to obtain the healthcare they need or take measures to prevent spreading the infection. The CDC estimates that there are over 1,000,000 Americans with HIV, of which about a quarter do not know their HIV status.

CDC officials recently estimated that the rate of transmission in this unaware group is 3.5-5 times that of the aware group (see Gary Marks et al. *AIDS,* June 2006). This estimate includes assumptions about reductions in unsafe sex among those aware of their HIV status. Also, many infected people (33% according to the CDC estimate) are receiving successful anti-HIV treatment. Their viral levels are extremely low, and the CDC assumes they are a negligible source of HIV transmission.

Medical facilities have tested for HIV only rarely. The CDC says that this is because “HIV testing is often not reimbursed; providers in busy health care settings often lack the time necessary to conduct risk assessments and perceived counseling requirements as a barrier; and explicit information on HIprevalence is usually not available to guide selection of specific settings for screening.”

New cost-effective models take include reductions in HIV transmission by those aware of their HIV infection as well as the extend life that treatment advances have made possible. They estimate that generalized screening is now cost-effective at HIV prevalences of 0.1% or more, i.e. throughout almost the entire country.

The CDC’s Citation Shell Game

The main arguments for dramatic changes in the way healthcare facilities practice HIV testing is buttressed by only a handful of studies cited in the CDC draft – and it misrepresents most of those. For example, the CDC lists six articles to support the statement quoted above about the barriers to testing in medical settings, but only one of these articles includes a survey of healthcare personnel’s reluctance to order HIV tests.

Elucidating the barriers to testing are not the primary concern of three of the six articles: One is an editorial and two are mathematical models to test the cost-effectiveness of routine testing. A fourth article is a review that concludes that combining counseling and testing is indeed practical in hospital emergency departments (EDs): “Despite the limitation of time in EDs, many studies have shown that routine HIV counseling, testing, and referral in the ED is a feasible and effective strategy” (see Richard Rothman, *Annals of Emergency Medicine*, July 2004).

A final reference is an enlightening account of a Midwestern hospital ED's HIV testing experience. It shows how targeted testing of high-risk patients in a low HIV prevalence area could be successfully carried out with a full range of counseling and referral services (see Michael Lyons, *Annals of Emergency Medicine*, July 2005). About two-thirds of the 8,500 patients approached accepted testing. The most common reason given for refusal was a recent negative test. This program was dependent on public funding from the Ryan White CARE Act. Unfortunately, the program needed more funds to extend full counseling to the evening and night shifts.

The CDC mentions only one 1999 medical journal report to bolster its major contention that test-related prevention counseling is of dubious value in altering the behavior of HIV-negative testees (see Lance Weinhardt et al. *American Journal of Public Health,* September 1999). The agency says in its guidelines draft that "a meta-analysis of 27 studies concluded that HIV counseling and testing was an effective intervention for HIV-positive participants, who increased their safer behaviors and decreased their risk behaviors, but little effect was noted for HIV-negative participants from HIV counseling and testing as it was implemented in the studies." Actually, the Weinhardt article reaches the conclusion that "because inadequate attention has been paid to the psychological and social contexts of testing, the theoretical grounding of counseling, and the type and amount of counseling provided, a closer examination of these factors may reveal that HIV [counseling and testing] is effective with HIV-negative individuals under some circumstances."

Indeed, Project RESPECT, a randomized controlled trial published the year before Weinhardt and colleagues' paper, did observe positive results. Short counseling sessions provided at the time of testing as well as the time of receiving results resulted in lasting, albeit modest, benefits for those testing negative (see Mary Kamb et al. *JAMA*, October 1998). Twelve months later, study participants who had received the two brief sessions had an STD rate equal to that of participants who had received much more extensive counseling and 20% less than those who had heard short informational messages only. Participants were 5,700 patients at STD clinics who agreed to HIV testing. (The CDC guidelines draft did mention the Project RESPECT results but left out the equivalent value of the brief and more extensive counseling programs. This was the CDC's own study, by the way.)

It's Not That Simple

The most extraordinary aspect to the guidelines draft is the curious appendix in which the CDC concedes most of the basic objections to its approach. In the last few pages of the draft, we learn that test-associated counseling is important after all. HIV is incurable, life-threatening, and transmitted by intimate behavior. Testing for it has different implications than testing for other conditions.

On three specific points, the CDC comments as follows:

• *Testing as an as an "ideal opportunity" for counseling for making connection with high-risk, HIV-negative individuals:*
"Some patients may be more likely to think about HIV and consider their risks when undergoing an HIV test. This may present an ideal opportunity to provide or arrange for prevention counseling to assist with behavior changes that can reduce risks for acquiring HIV infection. Prevention counseling should be offered or available through referral in all health care facilities serving high risk patients and in those, such as STD clinics, where information on HIV risk behaviors is routinely elicited."

• *The immediate need to counsel those who test positive:*
"HIV-positive test results should be communicated through personal contact. This may be done by a clinician, nurse, or counselor. Active efforts are essential to ensure that infected patients receive their

positive test results and linkage to clinical care, counseling, support and prevention services."

- *The essential role for community-based programs in filling the large gaps left by the medical system:*

"Often, the population most at risk for HIV includes many persons who are least likely to interact with the conventional health care system. The need to maintain primary prevention activities and provide HIV testing for high-risk persons in non-clinical venues remains undiminished. New approaches such as enlisting HIV-positive persons and HIV-negative persons at high risk to recruit persons from their social, sexual, and drug-use networks for counseling, testing, and referral have shown considerable efficacy for identifying persons who were previously unaware of their HIV infection."

The Shotgun versus the Therapist

There is no doubt that identifying the unaware HIV-positive can have benefits for both individual and public health. As the CDC guidelines draft finally admits, broader testing necessitates new counseling and treatment initiatives, not the reverse. There is no sign of support for such efforts. We have a simplistic shot-gun approach when the situation calls for individualized therapy. Lance Weinhardt and colleagues contended back in 1999, "Research should examine the effects of theory-based counseling with different contents, modes of delivery, and levels of intensity." Little progress has occurred since then. It may well be true that existing test-related counseling is costly, tedious and only marginally effective. But the Project RESPECT trial indicates that short, test-associated counseling sessions can have significant impact.

With the newly available rapid HIV testing, HIV test-takers have to wait for 20-30 minutes to obtain their results. It seems an "ideal opportunity" (to again borrow the CDC's words) for a brief counseling and referral intervention. While waiting for the test results, there could be a discussion about behavioral concerns and then further discussion with appropriate referrals when the test results are known. Testing could be an occasion for initiating a discussion, not necessarily for providing the answers.
To cite one example, the Adolescent AIDS Program at Montefiore Hospital (Bronx, NY) has devised a brief test-associated intervention called ACTS (Assess, Counsel, Test, Support, http://www.adolescentaids.org/healthcare/acts.php). It grew out of a 2001 survey of Bronx physicians, who infrequently offered HIV testing to their patients despite the relatively high HIV prevalence in the borough. The ten-minute ACTS is applicable to both adolescent and adult populations. It depends heavily on sex-positive handouts and referrals to further prevention and medical services. In a year-long randomized trial in the Bronx, ACTS training helped physicians gain confidence that HIV testing and counseling was something they could supervise in a practical manner. Rates of testing doubled at ACTS sites. Clinics implementing ACTS tested 20% of patients for HIV compared with 10% at the control sites. Another trial, funded by the CDC, is now ongoing in Cape Town, South Africa.

A second recently reported program had HIV counselors approach as many patients as possible in the acute care ward of a Boston hospital (see Jeffrey Greenwald et al. *AIDS Patient Care and STDs*, May 2006). The program (HITS, for HIV Inpatient Testing Service) was hobbled by limited funding, like the program described by Lyons and colleagues. Still, it managed to quintuple the amount of HIV testing. The testing rate rose from an average 1.2 tests per day to 6.2. Rates of positive results remained high – from 2.5% pre HITS to 2.0% in its first two years – a good reminder that it isn't enough to boast of increased testing if the point is to discover more people with HIV.

Additional funding and the introduction of rapid HIV testing have greatly increased HITS' scope. Voluntary counseling and testing is now available to all inpatient admissions and to other surgery and gynecology patients as well.

Always Better to Convince than to Command

With momentum for mass HIV screening building in Atlanta, Washington and the 50 states, it is important to press for improving counseling and treatment programs – and their link to testing. Public health officials and others have dismissed such linkage as bothersome "HIV exceptionalism" (see New York City health commissioner Thomas Frieden and coworkers in the *New England Journal of Medicine*, December 1, 2005 as well as Boyer and Fairchild this August).

These assertions distort history. The current system for counseling, testing and referral grew out of 1980s AIDS activism and had its roots in the feminist healthcare movement of the 1970s. The idea was to create a new healthcare model that recognized the integrity of people's bodies and their ability to make educated decisions about the care they received. The new model was not supposed to be an exception to traditional healthcare methods. Rather, it represented an overall challenge to medical practice. If there is exceptionalism here, it arose in the absence of alliances with other patient populations. AIDS activists were left with only the argument that HIV presented unique issues.

New protective measures, such as pre-exposure prophylaxis (PrEP) and microbicides, are coming soon. They will make HIV prevention both easier and more complicated. Each individual will have to find the prevention strategy that best suits his or her individual situation. That will require better counseling and education. In the meantime, HIV is infecting 40,000 Americans year in and year out, and the CDC is promoting a return to passive HIV testing. It is indeed a different direction, but it's not new, and could fumble the chance to enhance the public's power to reduce the epidemic.

Note: David Gilden contributed to the revision of the manual for ACTS, but he was not involved in formulating the ACTS counseling and referral process.

House Bills Try to Tackle HIV Testing in Fed Prisons

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CDC's new guidelines for HIV testing in clinical settings are expected to apply to jails and prisons, for which the agency will develop a separate implementation guidance.

Two bills introduced within a week of each other in the House represent an attempt by members of the Congressional Black Caucus (CBC) to address the alarming rates of HIV in the African-American community through expanding HIV prevention-related services in federal prisons. Although staff for both Members of Congress report that they are supporting each others' bills, they offer distinct HIV testing strategies and related approaches to improving prison-based prevention services.

Congresswoman Maxine Waters (D-CA), chair of the CBC's Domestic AIDS Task Force, first indicated during a press conference organized by the Black AIDS Institute at the International AIDS Conference that she was considering a bill that would require universal mandatory HIV testing in federal prisons. As reported in *The Hill* on September 12th, she attempted to respond to concerns from the community by including a routine, opt-out testing policy in the final version of her bill, although her press statements continued to describe the bill as an effort to promote mandatory testing even after it had been introduced.

The legislation, titled the *Stop AIDS in Prison Act of 2006* (H.R. 6038) and introduced on September 6, would require routine HIV screening for all inmates both when they enter and are released from federal prisons. It includes an "opt-out" provision that would allow an inmate to decline a test and, although it would be noted in their medical record, would "not be considered a violation of prison rules or result in disciplinary action," according to the bill.

Despite this clause, advocates remain concerned about whether there is a practical distinction between opt-out screening and mandatory testing in prison settings where there is an inherent power imbalance between inmates and staff. The bill does not current require documentation that an inmate has been informed of her/his right to refuse a test.

The standing federal law that would be amended by the Waters bill allows mandatory testing without consent in federal prisons in some instances, but does not require universal testing for every inmate. For example, if an individual incarcerated in federal prison is determined to be at risk for HIV, or if there is a "well-founded" belief they may have transmitted HIV to prison official, they can currently be tested without consent.

Rep. Waters has said that the bill would improve the care available to inmates who test positive, although there are scant details about how that would be achieved and the only change to the current law focuses on universal HIV screening.

Congresswoman Barbara Lee (D-CA) introduced a separate bill on September 14th titled the *Justice for the Unprotected Against Sexually Transmitted Infections for the Confined and Exposed, (JUSTICE) Act of 2006 (H.R. 6083)*. Most notably, the bill would allow community-based organizations to make condoms available to inmates as part of a strategy to prevent transmission of STIs (including HIV as well as hepatitis C) in federal prisons. In this respect, it is similar to a bill, passed by the California legislature and currently awaiting Governor Schwarzenegger's approval, that would allow CBOs to make condoms available in California state prisons.

In addition to citing support for CDC guidelines, the testing section of the *JUSTICE Act* would also require pre-testing counseling and notification of the option to decline a test, along with stronger language around linking people who test positive into services. Rep. Lee's bill would also require an annual survey monitoring STI prevention efforts in federal and state correctional facilities and the development of five-year strategies to reduce the transmission of STIs in those settings.

Both pieces of legislation are available at http://www.champnetwork.org/index.php?name=Testing or via links at www.champnetwork.org

HHSWatch, a watchdog newsletter from CHAMP, monitors and reports on activities related to HIV prevention at Health and Human Services agencies, including CDC, NIH, HRSA and SAMHSA.

HHSWatch is a resource for community members, policy advocates, researchers and anyone interested in more fully understanding and tracking the committees, panels and administrators whose recommendations and decisions affect our work.

HHSWatch is committed to providing an outlet for those concerned about infringements upon science-based HIV prevention and treatment, and will respect your wishes for confidentiality. If you are interested in contributing information or suggesting a story, please contact champ@champnetwork.org.

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