

IMPLEMENTING A NATIONAL STRATEGY OF TESTING AND LINKAGE TO CARE PLUS WOULD IMPROVE THE HEALTH OUTCOMES OF MANY MORE HIV-POSITIVE AMERICANS, AND SUPPORT A REDUCTION IN NEW CASES OF HIV INFECTION

The Report of a U.S. Think Tank on HIV Treatment as Prevention - February, 2010

1. Background on Testing & Linkage to Care, Plus – TLC+

A significant question that has perplexed and even divided HIV/AIDS experts in recent years is whether and how efforts to assure that a greater percentage of HIV-positive people learn their serostatus and take antiretroviral medications might serve to reduce HIV incidence. It has generally been true that control of the spread of communicable diseases, including tuberculosis, hepatitis and sexually transmitted infections, has been achieved in part by assuring that infected individuals are diagnosed and treated in order to cure their illness and prevent transmission to others. With regard to HIV, it has long been known that one benefit of testing is that people who know they are HIV-positive are less likely to engage in behaviors that might transmit the virus to others. Antiretroviral treatment of HIV-positive pregnant women has been credited for a significant reduction in transmission of HIV to infants. With this one exception, however, treatment of HIV has generally been focused on the important benefits of antiretroviral treatment for the individual, and has not been pursued as a means of reducing transmission.

Several lines of evidence suggest that viral suppression resulting from effective antiretroviral therapy makes it less likely that an HIV-positive person can transmit HIV to an HIV-negative partner, even in the absence of condom use during sex. Statistical models have come to differing conclusions about the extent to which programs to increase the diagnosis and treatment of HIV-positive people might reduce HIV transmission on a population-wide basis, but various models have concluded that they could achieve reductions.

At the community level, however, concerns have been expressed that, as a public health strategy, “Test & Treat” programs might be coercive; that they are overly medical in nature and devalue the role of social services and support in addressing the needs of HIV-positive people; that HIV treatment is not the most urgent or achievable goal for every HIV-positive person; and that both HIV-negative and positive people might engage in behaviors that transmit HIV if they believe that antiretroviral treatment might reduce or even eliminate their chances of becoming infected or infecting others (behavioral disinhibition). Additionally, many community-based HIV agencies are concerned that a significant scale-up of Test & Treat programs might displace existing prevention programs.

The U.S. Centers for Disease Control & Prevention (CDC) is engaged in a much needed and significant expansion of HIV testing nationally, which has the potential to result in a great

improvement in the individual health outcomes of HIV-positive people and a reduction in HIV incidence. Additionally, the National Institutes of Health (NIH) is conducting research in Washington, D.C. and the Bronx, New York to determine whether Test & Treat programs are feasible in those, and perhaps other, highly impacted jurisdictions.

In December 2009 a multi-disciplinary group of fifty-four HIV/AIDS experts (listed at the end of this document) met to consider whether implementing a Test & Treat strategy could help the United States accomplish three important goals: 1) to increase the percentage of HIV-positive Americans who know their serostatus, 2) to improve the health outcomes of individuals who are HIV-positive, and 3) to reduce HIV incidence.

Based upon a review of available data and existing programs from multiple jurisdictions, the Think Tank resulted in a recommendation that establishing a program called “Testing & Linkage to Care Plus,” or “TLC+” (the Plus referring to Treatment) as part of the National HIV/AIDS Strategy has significant potential to help the United States to meet the three goals described in the preceding paragraph. (A review of scientific literature on this subject is available at <http://www.projectinform.org/testandtreat/index.shtml>) Think Tank participants also concluded that TLC+ should become a key element of the National HIV/AIDS Strategy because of its potential to support the three stated goals of that pending document. Those goals include increasing the percentage of HIV-positive Americans who are engaged in care and treatment and optimizing their health outcomes, reducing disparities in the health outcomes of populations impacted by HIV disease, and reducing HIV incidence.

2. Defining TLC+

While it is predicated on the need for strengthened efforts to assure that nearly all HIV-positive Americans know their serostatus, TLC+ would establish a national standard of care in which all public and private testing providers work intensively with HIV-positive people as soon after diagnosis as possible to link them voluntarily to a spectrum of care and support services including, but not limited to, primary medical care, social services that support readiness to engage and maintenance of participation in HIV treatment, if appropriate, and prevention with positives counseling. Its component parts are designed to benefit people newly diagnosed with HIV, those who have not previously been ready or able to engage in care and treatment owing largely to a lack of needed social services to support their readiness, and those who have been lost to systems of care and treatment. Credit is due to the Washington, D.C. Department of Health for defining the elements of TLC+ as part of its participation in the NIH study of the feasibility of such an approach.

The elements of TLC + include:

Assuring that HIV-positive individuals know their HIV status as soon after infection as possible - both through efforts to make testing a routine part of medical care for all Americans aged 13 to 64 and innovative programs targeting testing to high-risk individuals. Increasingly

effective efforts are needed to promote the benefits of knowing one's HIV status, and knowledge of the availability of affordable or no-cost testing, care and treatment services. The CDC has begun important work in this regard, but further efforts are needed, particularly through increased cooperation by private medical providers.

While TLC+ is focused on HIV-positive individuals, it is critical that people who test HIV-negative and report engaging in behaviors that are likely to result in infection are quickly offered linkage to prevention and social services, including housing, violence prevention, mental health and substance abuse services that can support them to remain HIV-negative.

Effective and timely linkage of newly diagnosed HIV-positive people to primary medical care and social services that will prepare them to consider initiation of treatment, as well as efforts to re-engage individuals who have been lost to systems of care - Intensive efforts by public and private HIV testers to deliver a newly diagnosed person into the hands of a medical professional who can discuss care and treatment benefits and options immediately, if feasible, or as soon after an HIV diagnosis as possible, are critical to HIV health outcomes. Additionally, newly diagnosed HIV-positive people need to be quickly engaged in a conversation about the availability of support services that can prepare them to engage in care and treatment. These include housing, mental health, substance use, legal services, language interpretation, transportation, violence prevention, childcare and others. HIV test sites and clinics should identify staff whose job is to help HIV-positive individuals move through the various steps they may want to take to initiate care and treatment.

All people testing positive for HIV should be counseled about their medical rights, including confidentiality of their medical information, avoiding disclosure to others who do not need to know their HIV status, the existence of non-discrimination legislation and legal services.

Health departments, hospitals, clinics and community-based organizations should conduct innovative outreach efforts, including peer-based approaches, to engage and retain previously diagnosed but out-of-care individuals. The use of HIV case registries by local health departments to contact HIV-positive people in a highly sensitive and confidential manner could bolster efforts to engage additional HIV-positive people in voluntary care, treatment, social support and prevention with positives services.

Prompt evaluation of eligibility for antiretroviral therapy (ART), and support for ART initiation – Patients should receive standard diagnostics to establish viral load and CD4 counts as quickly as possible after diagnosis and be encouraged to consider options for when to initiate therapy, consistent with federal guidelines. Again, patients should be evaluated for their readiness to initiate treatment and linked to needed services that will support them to take medications, if they choose. HIV-positive people should also be counseled that, in addition to improving their HIV health outcomes, treatment combined with safe behaviors can support them in their efforts to avoid transmitting HIV to others.

Effective efforts to support retention in care and adherence to ART for maintenance of viral suppression – Providers must talk with their patients about the importance of remaining in care and treatment and adherence in order to determine whether linkage to social services, including housing, mental health, substance use, legal services, language interpretation, transportation, childcare and others, will assist them with these goals.

Prevention for positives counseling – It is essential that HIV-positive patients are told upon initiating treatment and periodically reminded that treatment alone does not provide assurance that they cannot still transmit HIV. Instead, the combination of safe behaviors and treatment will most effectively prevent transmission. Regardless of whether an HIV-positive person receives care and treatment, counseling about their role in HIV prevention and linkage to effective prevention with positives programs, if indicated, are critical.

STI screening and treatment – A thorough medical evaluation, including evaluation for sexually transmitted infections (STIs), should be conducted on all newly diagnosed and returning patients. All HIV patients should also be regularly vaccinated or screened for viral hepatitis.

Monitoring and Evaluation – An extremely important component of TLC+ is the early integration of metrics for evaluating the impact of this strategy both on the health outcomes of HIV-positive individuals and on the community as a whole. These metrics might include changes in participation in testing, care and treatment; access to a clearly defined standard of HIV care; patient quality of life; changes in surveillance data indicating whether CD4 and viral load counts community-wide are rising or falling and their correlation with incidence; as well as changes in social determinants impacting health outcomes, such as stigma and discrimination.

3. Important Points in Considering TLC+

To be sure, TLC+ is not a new concept, as many localities and HIV/AIDS agencies across the United States are already taking important steps to implement programs that include some or all of its various elements. However, the approach is far from being consistently or thoroughly applied across the country. The added value of TLC+ is that it provides a framework for assembling into one visible and cohesive national initiative a set of best practices that can be measured and evaluated for their ability to help HIV-positive individuals engage in and adhere to care, treatment and prevention in order to improve their health outcomes and reduce incidence. Its inclusion as an element of the National HIV/AIDS Strategy, and meaningful coordination of federal agencies to fully support its implementation, would recognize the linkage programs now being conducted in many jurisdictions as an essential and universal standard of care.

TLC+ would promote much-needed coordination of existing testing, care and treatment, support services and prevention programs at all levels of government, and it would clarify the potential benefits of those combined activities for treatment and prevention outcomes. TLC+ should be implemented throughout the country and adapted to local conditions using intensive

collaborations of state and county health departments, medical providers, social services agencies, and AIDS service organizations, including advocacy, social justice and prevention-focused agencies.

The further design and implementation of TLC+ necessitate an unprecedented level of planning and coordination among the Health Resources Services Administration, Centers for Medicare & Medicaid Services, Substance Abuse & Mental Health Administration, Centers for Disease Control & Prevention, National Institutes of Health, Department of Housing & Urban Development, Veterans Administration and other federal agencies responding to HIV/AIDS, as well as intensive efforts to assure that these agencies' funding streams are combined to enable such a strategy at the local level.

Initially, TLC+ might be targeted to a carefully selected set of jurisdictions with especially high prevalence and incidence rates. Currently available mapping techniques derived from effective use of HIV surveillance data also make it possible to target TLC+ to specific neighborhoods that suffer from a particularly high disease burden.

NIH studies of the potential benefit of HIV treatment for prevention (HPTN052) and of the feasibility of Test & Treat programs as a possible tool for prevention (HPTN065) are ongoing. Nevertheless, TLC+ can and should become a part of the National HIV/AIDS Strategy and be implemented nationally in the near future. It would not be ethical or prudent to delay improved efforts to increase the percentage of HIV-positive Americans who know their serostatus and are engaged in care and treatment that may protect their health, in addition to the possible benefits for prevention accruing from this strategy.

The name TLC+ was chosen to describe this strategy for several reasons. It differentiates this approach from "Test & Treat," which is considered intimidating for many HIV-positive individuals, directive in nature and lacking in the provision of social services and counseling that increase HIV-positive individuals' ability to engage in and maintain participation in care and treatment. Providers note that approaching HIV-positive people by initially promoting primary care is more likely to engage them in services than promoting treatment, about which patients may be fearful and for which they may not be fully prepared. Ultimately, however, the notion of care clearly includes, but is not limited to, HIV treatment. Other key components of HIV care include regular monitoring of viral load and CD4, STI and hepatitis C screening, and mental health and substance abuse counseling, if needed.

Think Tank participants also agreed that, while still not without potentially serious long-term side effects, HIV treatment has made significant advances in recent years with regard to tolerability and effectiveness. Updated Federal treatment guidelines announced only days before the December Think Tank resulted, in part, from an improved side effect profile of many medications, and the documented benefits of initiating treatment earlier in HIV disease for most patients. While the Think Tank did not seek to take a position on the revised Guidelines, participants generally welcomed the movement toward earlier initiation of treatment and felt that

it is time to promote the benefits of treatment with HIV-positive people as soon as they are ready for that conversation. At the same time, participants agreed that patients must always be fully informed about both the potential benefits and risks of prolonged HIV treatment in order to make appropriate individual choices about when to initiate therapy.

Think Tank participants were not resolved as to how great a reduction in incidence might be achievable as a result of TLC+, and concluded that the impact on incidence will be very difficult to measure, as are the impacts of other prevention interventions on incidence. However, it was also agreed that the combined effects of increased serostatus awareness, reduction in viral burden resulting from increased entry into treatment and behavioral counseling of HIV-positive individuals – all components of TLC+ - could be expected to reduce transmission events. Importantly, all of the elements of TLC+ are the same ones that should be offered to an HIV-positive person whether the goal is to improve his or her individual health outcomes or to reduce incidence at a population-wide level.

Poverty, racism, homophobia and other forms of oppression render targeted groups more vulnerable to high HIV/AIDS prevalence and other negative health outcomes. TLC+ is an important tool for moving quickly to address health disparities for gay men and other men who have sex with men, particularly gay men of color; women, particularly women of color; and male-to-female transgenders, groups that are disproportionately impacted by lower rates of participation in care and treatment, poorer health outcomes and higher incidence. Additionally, men who have sex with men, who have been shown to have fifty times the rate of HIV infection compared to the general population, necessitate an immediate strengthening of care, treatment and prevention programming.

It was also agreed that TLC+ must not comprise the nation's only approach to HIV prevention. Additional evidence-based primary prevention programs should be continued and brought to scale; some in close coordination with TLC+. It is worth noting that an important element of TLC+ is behavioral counseling, or prevention with positives, which seeks to engage HIV-positive people in safe sex and syringe use, in addition to care and treatment, that will help them to avoid transmitting HIV to others. This component of TLC+, as well as social marketing, may help mitigate behavioral disinhibition that could result from increased treatment of HIV-positive people. Transmission risk behaviors among HIV-positive people should be measured and appropriate messages developed with community input to help address any misconceptions about the role of treatment in prevention.

Think Tank participants felt strongly that, while an HIV-positive person might be advised upon choosing when to start treatment that taking medications as soon after infection as possible might help them to prevent transmission, treatment should generally be initiated in keeping with Federal guidelines. However, providers might wish to discuss earlier initiation of treatment with HIV-positive patients who report that they regularly engage in behaviors that are likely to transmit HIV, and work to link those patients to prevention with positives counseling.

Consistent with the belief that HIV testing, care and treatment should be promoted and even encouraged, Think Tank participants also concluded that informed consent, voluntariness and choice must underlie our approach to the domestic epidemic, and be at the core of the TLC+ strategy.

4. Key Barriers to the Potential Impact of TLC+

The Think Tank highlighted a set of issues that serve as significant barriers to strengthening the health outcomes of HIV-positive people and that will reduce the potential effects of TLC+ if they are not addressed in additional provisions of the National HIV/AIDS Strategy:

Stigma and discrimination continue to act as powerful barriers to people's willingness to be tested for HIV and to engage in care and treatment if they are HIV-positive. It is not a coincidence that the groups most vulnerable to HIV and AIDS are also among the most marginalized in American society. Major national efforts, including visible Presidential leadership, are needed to address these issues and to convey to individuals at structurally elevated risk for HIV that acting on their health needs is vital even in the context of stigma and discrimination. These efforts can and should include a national campaign to reduce HIV-related stigma. Additionally, because some HIV-positive people fear that knowledge of their serostatus could subject them to prosecution for engaging in sex, state laws that criminalize sexual behavior of HIV-positive people should be opposed or repealed because of their potential deterrent effect on HIV testing and entry into care without any known public health benefit.

Strengthened medical provider participation – In addition to the time consuming legal requirements some providers indicate they face in order to test patients for HIV and other resource limitations, many primary medical providers fail to encourage patients to be tested for HIV and to follow up in helpful ways due to HIV-related stigma and difficulty in assessing who may be at risk for infection. Some providers are uneasy about approaching patients regarding sexuality, sexual identity, drug use and other social and behavioral factors associated with HIV and AIDS. A significant national effort that includes national medical associations and medical schools must be launched to establish standards of care regarding the routine and universal offering of HIV testing, care and treatment, and to encourage providers to follow them. Presidential leadership is also necessary on this point. Efforts to encourage the easing of informed consent requirements in those states that have not yet done so, and potentially to mandate offering of HIV tests in some clinical settings, should be considered in order to increase participation in HIV testing.

Strengthened community education about HIV – Similarly there is evidence that many people at risk for HIV are failing to be tested or to enter care and treatment based on a serious misunderstanding of several facts. First, some individuals do not understand that if they test HIV-positive, it is possible to take steps to effectively deal with HIV and protect their lives. Others have outdated impressions about the current state of HIV pharmaceuticals which, far from being perfect, are without many of the side-effects that until recently accompanied HIV

treatment and caused many HIV-positive individuals to delay or avoid treatment. Some people are unaware that they can obtain HIV care and treatment and other services at no or low-cost. A significant national campaign is needed to help people at risk for HIV infection better understand the benefits of knowing their serostatus and of addressing HIV disease, and even to promote treatment while also valuing the importance of individual choice.

HIV testing must always be reimbursed – State and/or federal legislation requiring all private and public sources to reimburse is needed to ensure universal access to testing. The Office of National AIDS Policy has commissioned a study of this issue and other structural barriers to HIV testing by a panel of the Institute of Medicine.

A guaranteed source of financing must be made available to accomplish TLC+ - The current effort to increase awareness of HIV status is laudable, but it will also become problematic if people who learn they are HIV-positive are unable to access affordable or no-cost care and treatment. Adequate resources do not even exist to assure that all *currently* diagnosed HIV-positive Americans are able to receive affordable or no-cost care and treatment. Without a guarantee of access, the United States will never be able to fully control this epidemic. National healthcare reform, establishing HIV care and treatment as an entitlement program, or significant increases in Ryan White and other HIV funding will be essential to the success of this goal. It is also critical that Congress and the President act swiftly to prevent the current growth of waiting lists for the AIDS Drug Assistance Program, the joint federal/state program that provides HIV medications to low-income Americans, which is an essential resource for accomplishing TLC+.

5. Action Steps Resulting from the Think Tank

To advance the recommendations resulting from the Think Tank, participants have formed a National TLC+ Work Group, the goals of which are to:

Communicate the results of the Think Tank to the President, President's Advisory Council on HIV/AIDS, Office of National AIDS Policy and leadership of key federal HIV/AIDS agencies in order to secure inclusion of TLC+ in the National HIV/AIDS Strategy;

Coordinate with key national organizations that have the ability to further define TLC+ and support its implementation by state and local health agencies;

Develop a website to describe TLC+ and assemble best-practices from across the country that can be replicated by state and local health agencies to advance its implementation; and

Make presentations regarding TLC+ at major national HIV/AIDS conferences to educate and engage providers and community members in its implementation.

6. Think Tank Participants

Dana Van Gorder, Project Inform, Chair

Walt Senterfitt, PhD – Community HIV/AIDS Mobilization Project (CHAMP), Co-Chair

Michael Allerton, MS – The Permanente Medical Group, Kaiser Permanente
Judith Auerbach, PhD – San Francisco AIDS Foundation
Katy Caldwell – Legacy Health Services, Houston
Laura Cheever, MD - HRSA
Ryan Clary – Project Inform
Myron Cohen, MD – University of North Carolina
Grant Colfax, MD – San Francisco Department of Public Health
Chris Collins, MPP – American Foundation for AIDS Research
Moupali Das Douglas, MD MPH – San Francisco Department of Public Health
Oscar de la O – Bienestar, Los Angeles
Carl Dieffenbach, PhD - National Institutes of Health
Anne Donnelly, MA – Project Inform
Richard Elion, MD – Whitman Walker Clinic
Cindra Feuer – AIDS Vaccine Advocacy Coalition
Donna Futterman, MD – Adolescent AIDS Program, Montefiore Hospital, Bronx, New York
Matt Golden, MD MPH – University of Washington
Roy Gulick, MD – Cornell University
Shannon Hader, MD MPH – Washington, D.C. Department of Health
Shelley Hayes, JD – American Bar Association
Jen Hecht, MPH – Stop AIDS Project
Kathie Hiers – AIDS Alabama
David Holtgrave, PhD – Johns Hopkins University
Richard Jefferys – Treatment Action Group
Nnemdi Kamanu Elias, MD MPH - Washington, D.C. Department of Health
Naina Khana – Women Organized to Respond to Life Threatening Diseases
Peter Kilmarx, MD – U.S. Centers for Disease Control & Prevention
Marguerita Lightfoot, PhD – Center for AIDS Prevention Studies, University of California SF
Ron MacInnis – International AIDS Society
Kenneth Mayer, MD – Brown University
Marlene McNeese-Ward – Urban Coalition for HIV Prevention Services
Lisa Metsch, PhD – University of Miami
Jacques Normand, PhD - National Institute on Drug Abuse
David Paltiel, PhD – Yale University
Murray Penner – National Alliance of State & Territorial AIDS Directors
Jim Pickett - AIDS Foundation Chicago
Diane Rausch, PhD – National Institute of Mental Health
Monica Ruiz, PhD, MPH – Forum for Collaborative Research, George Washington University
Michael Saag, MD – University of Alabama Birmingham
Matt Sharp – Project Inform
Josh Thomas – Community HIV/AIDS Mobilization Project
Melanie Thompson, MD – AIDS Clinical Research Center, Atlanta

Craig Washington – AID Atlanta, Inc.
Andrea Weddle, MSW – HIV Medicine Association
Tiffany West Ojo - Washington, D.C. Department of Health
Vera Yakovchenko – Department of Health & Human Services
A. Toni Young – Community Education Group, Washington, D.C.

(Participant's organization names are included for identification purposes and do not necessarily reflect support from their agencies)

For further information, contact dvangorder@projectinform.org