Considering TLC+ in California: Proceedings of a Think Tank on HIV Testing, Linkage to Care, Plus Treatment

California HIV/AIDS Research Program
and
The California Conference of Local AIDS Directors

Prepared by: Susan Strong,

Project Facilitator, California HIV/AIDS Research Program, October 2010

EXECUTIVE SUMMARY

In spite of the fact that there is still no cure for HIV or AIDS, emerging scientific evidence is pointing to an exciting new possibility for reducing or even ending the HIV epidemic in our lifetime. The driving force behind this possibility is the fact that HIV-infected people on effective HIV treatment regimens, have low levels of the virus in their bloodstream and are far less likely to pass the virus on to others than those who are untreated. And, if enough people in a specific community or population could be HIV tested, linked to treatment, and achieve low viral load levels, transmission of the virus could be reduced to a fraction of current levels. In time, perhaps transmission of the virus could even be eliminated. Researchers and policymakers are calling this new approach **TLC+** (Testing and Linkage to Care Plus Treatment).

The specific goals of TLC+ are twofold: the first is to increase the number of HIV-positive people who know their serostatus and are engaged in care and treatment to improve their individual health outcomes and, second, to reduce the incidence of HIV infection.

With all of its promise, significant questions and barriers surround full implementation of TLC+. Does the approach really work? Is it possible to involve a high enough percentage of persons with HIV in treatment so that the viral load level of an entire community could be reduced? What new resources would be needed to implement such an approach, and where will they be found? Can implementation of TLC+ be cost-effective or even result in cost savings? What policy and systemic changes would be needed to make TLC+ a reality?

To begin to shape answers to these questions, the California HIV/AIDS Research Program (CHRP) and the California Coalition of Local AIDS Directors (CCLAD) co-sponsored a statewide Think Tank on May 18, 2010 called **Considering TLC+ in California**. The purpose of the Think Tank was to begin to discuss implementation of TLC+ in California and to identify the key issues that need to be addressed in order to move forward. A total of 64 planners, policymakers, treatment and care providers attended the meeting.

While the Think Tank was not intended to establish a consensus on TLC+, the session did unearth a number of themes, critical thoughts, issues, and questions regarding the approach. Among these are the following:

- A growing body of research suggests that reducing community HIV viral load within a given population is associated with a reduction in new HIV infections. Dr. Moupali Das and colleagues at the San Francisco Department of Public Health (SFDPH) and the University of California, San Francisco (UCSF) have shown that as the community viral load decreased in San Francisco from 2004-2008, there were accompanying reductions in newly diagnosed and reported HIV cases.

- TLC+ has the potential to serve as a new organizing principle in California to move to another level in fighting HIV. TLC+ may also provide an important new opportunity to integrate HIV planning, policy, and funding at the federal level in

order to support states and counties in moving forward with an integrated HIV strategy.

- As HIV prevention shifts to focus more on those infected, TLC+ may offer a new platform for advocacy to improve the HIV services system by ensuring the continuing relevance of and need for the Ryan White CARE Act.

According to Think Tank participants, **key barriers** to implementation of TLC+ in California include the following:

- ❖ Lack of routine HIV screening at all levels, especially in private practice settings, for all populations;
- ❖ Lack of resources and models to implement comprehensive testing and treatment linkage on a broader level;
- ❖ Ongoing HIV stigma and fear of HIV testing and treatment;
- ❖ Lack of awareness of HIV testing and treatment resources;
- ❖ Lack of integration between HIV and sexually transmitted disease, TB, Hepatitis C testing, and other health-related systems;
- ❖ Lack of data-driven targeting of HIV testing and treatment linkage resources;
- ❖ Lack of integrated data systems to share information related to HIV testing and treatment, including community viral load levels; and
- ❖ Lack of organized public / private partnerships and statewide planning efforts to develop effective ways to implement TLC+.

Specific elements of TLC+ that could potentially be **implemented now** to begin to move toward this model include the following:

- ❖ Offer routine HIV testing in a greater range of settings and venues;
- ❖ Provide more extensive training to non-HIV-specific physicians and healthcare providers in order to normalize HIV testing and ensure linkage to treatment;
- ❖ Create expanded linkages between testing and treatment providers in order to provide immediate linkage to care for persons who test HIV-positive or who test as preliminarily positive before confirmatory testing; and
- ❖ Continue to clarify treatment guidelines and standards at the national level that define expanded HIV testing and treatment as part of the standard of general medical care, as well as HIV/AIDS care.

Specific **practice changes** that could help make TLC+ a reality in California include the following:

- ❖ Incorporate TLC+ in the new national HIV/AIDS strategy in order to expand resources for HIV testing, care linkage, treatment, and treatment retention, and expand co-location or linkage of HIV testing and care services wherever possible;
- ❖ Provide routine HIV testing in urgent care, private practice, and community health center settings;

- Expand targeted outreach and testing for those persons who are at very high risk but not accessing the care system;
- Expand surveillance resources and linkages to enable community viral load mapping throughout California, and to track all HIV testing conducted in the state;
- Expand provider education on how to assess HIV risk and how to counsel patients to undergo HIV testing and access care;
- Integrate the work of HIV and STD programs throughout the state;
- Involve the broadest possible range of public and private providers and agencies in local and statewide TLC+ planning efforts; and
- Develop new messages to help overcome stigma related to HIV testing, treatment, and populations at highest risk for HIV infection.

Specific **policy changes** that could help make TLC+ a reality in California include the following:

- Enhance collaboration and integration of federal funding for HIV through federal agencies such as the Centers for Disease Control & Prevention (CDC), Health Resources and Services Administration (HRSA), and the Substance Abuse and Mental Health Service Administration (SAMHSA);
- Advocate for new standards for HIV testing and treatment through agencies such as the Joint Commission, the National Quality Health Council (NQHC), the National Committee for Quality Assurance (NCQA), and the US Prevention Services Task Force;
- Create new statutes expanding access to surveillance data by planners, providers, and policymakers;
- Provide better integration of HIV surveillance and reporting within the overall health system; and
- Implement immigration reform to remove barriers to care for undocumented persons.

Key research questions that could help move TLC+ forward in California include the following:

- Conduct research to determine the impact and cost-effectiveness of TLC+ on reducing new HIV infections;
- Fund pilot studies to identify and test TLC+ best practices focusing both on impact and cost-effectiveness;
- Assess HIV testing practices and barriers to testing with the goal of normalizing HIV antibody testing;
- Assess different methods to locate and identify persons who are unaware of their HIV infection;
- Study what motivates people to initiate HIV testing and/or treatment;
- Focus research on hard to reach populations who continue to fall out of care, including substance users, the homeless and those with mental health issues;
- Research issues of HIV testing, treatment, and support in correctional settings;

- Develop best practice guidelines for retention and re-engagement in HIV care;
- Explore HIV and aging issues in the context of TLC+;
- Study and promulgate best approaches for reducing stigma focused on persons at-risk for HIV, including stigma related to HIV testing, treatment;
- Develop enhanced cultural competency training and support tools for providers;
- Conduct formative research to develop effective messaging promoting the benefits of early HIV treatment at both the community and provider level; and
- Expand the use of viral load testing to better predict HIV transmission risk.

BACKGROUND

HIV prevention and treatment providers and researchers have long focused on the goal of identifying as many persons living with HIV as possible, particularly in early stages of HIV infection. The rationale for this goal has been twofold: First, starting antiretroviral therapy (ART) early can dramatically improve patients' long-term health by limiting opportunistic infections and slowing or preventing the onset of AIDS. Second, the experience of learning one's HIV status often has a significant impact on HIV risk behaviors, both by making individuals aware of the risk their behavior poses to others and by generating a greater focus on personal health and wellness. Additionally, expanded testing also helps experts identify where the HIV epidemic is spreading fastest, and among which populations.

However, emerging research suggests an additional important rationale for expanded HIV testing that may have the potential to dramatically curtail or even eliminate HIV infections in the future. This rationale centers on growing scientific evidence showing that persons with low or non-detectable levels of the HIV virus may be far less likely to transmit the virus than those with higher viral load levels, regardless of HIV risk behavior. The fact that suppressed viral load may reduce or limit transmission of HIV has led researchers and planners to consider whether strategies in which larger numbers of persons with HIV are tested and linked to treatment could have a progressive effect on reducing new cases of HIV infection. As more individuals achieved reduced or non-detectable viral load levels through HIV treatment, would the result be fewer new HIV infections over time within that community? Could such an approach eventually lead to the reduction or even eradication of new HIV cases in some populations?

The barrier to achieving this goal lies in the fact that low viral load levels in large populations can only achieved through high levels of testing, followed by regular use of antiretroviral therapy by the vast majority of HIV-infected individuals in that population. This requires systems to test, effectively link and retain HIV+ persons in treatment and care. These barriers have existed since the onset of the epidemic; however, achieving these goals on a broader community level requires a more concerted effort than has existed previously. Key issues include the following:

- At the present time, neither financial resources nor legislative mandates exist to make mass HIV testing possible across entire populations. HIV prevention providers are strapped for resources, and have faced dramatic funding reductions over the past

several years. And, while HIV antibody testing is becoming more normalized, objections still exist to widespread testing, reflecting concerns about stigma related to HIV, and being identified as a population at risk for HIV.

- HIV drug treatments are expensive, and the current system is already burdened to the breaking point by the cost of financing medications for uninsured and low-income persons with HIV. A significant increase in the number of new persons in treatment would potentially add to this burden. Of note, early comparisons of HIV treatment costs to costs for other diseases, such as diabetes and breast cancer, indicates that HIV treatment costs are within ranges considered acceptable for these other illnesses.

- Some debate still exists in the medical community regarding when persons with HIV should begin treatment. As data becomes clearer, medical provider standards of care for initiation of treatment will further clarify treatment initiation timelines. Further, additional medications and scientific breakthroughs will improve understanding of this question.

- There is a concern that, by informing individuals that being on treatment reduces the risk of viral transmission, a false sense of security might be created leading in turn to increased risk behaviors and/or inconsistent treatment adherence by some individuals.

- There is strong evidence to suggest that individuals may be most infectious during the period immediately following HIV infection. This complicates the task of preventing HIV transmission by linking persons to care, since confirmation of HIV positive status is not usually accomplished in early days or weeks after exposure.

- In addition there is the fact that insufficient evidence currently exists to fully demonstrate whether a population-based approach to HIV prevention would be truly effective. Early research is promising, though critical questions remain. There has also not been time to conduct research into the costs of such an approach, and whether other approaches, such as expanded funding for behavior-based HIV prevention efforts, might be more cost-effective in reducing HIV in the long run.

Yet in spite of these hurdles, this new approach to HIV prevention – an approach that has also been known as "Test and Treat" - holds exciting potential, and has become an area of great interest to HIV planners and policymakers. In addition to its potential to dramatically reduce new cases of HIV infection, the approach would certainly result in more people being diagnosed and linked to HIV care at an earlier stage of infection, which would in turn lead to enhanced health outcomes for many more persons with HIV. Application of the model could also help reduce stigma related to HIV, while encouraging more consistent and frequent HIV testing and treatment. The CDC is engaged in a much needed and significant expansion of HIV testing nationally, which has the potential to result in great improvement in the individual health outcomes of HIV-positive people and reduction in HIV incidence. The National Institutes of Health (NIH) is also conducting research in Washington, D.C. and the Bronx, New York to determine the potential benefit of HIV treatment for prevention

(HPTN052) and of the feasibility of Test and Treat programs as a possible tool for prevention (HPTN065).

In December 2009, the San Francisco-based policy leadership group Project Inform and the New York-based treatment advocacy group Community HIV/AIDS Mobilization Project (CHAMP) convened a multi-disciplinary group of 54 HIV/AIDS experts to discuss whether implementation of a Test and Treat strategy could help the US reduce new HIV infections while increasing the number of Americans who know their HIV status and receive appropriate treatment. Based on a review of available data and existing programs, the Project Inform/CHAMP Think Tank participants recommended a new strategy called "**Testing & Linkage to Care Plus**," or "**TLC+**" (the "Plus" referring to Treatment) as part of the National HIV/AIDS Strategy. The TLC+ strategy has significant potential to support the three goals of that strategy, which include: a) increasing the percentage of HIV-positive Americans who are engaged in care and treatment and optimizing their health outcomes; b) reducing disparities in the health outcomes of populations impacted by HIV disease; and c) reducing HIV incidence.

OVERVIEW AND PROCEEDINGS OF THE THINK TANK

To explore the implications of the "Testing & Linkage to Care Plus Treatment" (TLC+) framework for the State of California, and to examine the issues involved in a potential movement toward TLC+ in our state, the California HIV/AIDS Research Program (CHRP), in conjunction with the California Conference of Local AIDS Directors (CCLAD) developed and organized a day-long, statewide Think Tank on May 18, 2010 entitled "**Considering TLC+ in California".** The TLC+ Think Tank was conceived as part of CHRP's **Visioning Change Initiative**, which has received major funding from the Evelyn and Walter Haas, Jr. Fund**.** Visioning Change is a multi-year effort to re-invent HIV prevention and care in California involving HIV planners and policymakers in activities to explore emerging HIV trends and issues throughout the state.

Held at the conference center of The California Endowment in Oakland, the TLC+ Think Tank was attended by **64** participants from throughout California, representing both public and private organizations encompassing the state's prevention, care, policy, and research communities. Many persons attending were CCLAD members; other participants represented the State Office of AIDS, researchers from campuses of the University of California, private medical providers, policymakers, consumers, and HIV prevention and treatment groups. The meeting was facilitated by Susan Strong, a highly respected HIV planning expert, and included presentations by noted HIV researchers and leaders.

The goals of the TLC+ Think Tank were for participants to: a) increase their knowledge and capacity to implement TLC+ and/or its key elements in local jurisdictions throughout California; and b) develop specific research, practice, and policy recommendations for TLC+ implementation in California.

TLC+: A Primer

Dana Van Gorder, Executive Director of Project Inform, presented an introductory session which built upon an earlier computer and phone-based webinar, presented on May 11, 2010. Mr. Van Gorder noted that while we have made great progress in fighting the HIV epidemic we still have a long way to go. Out of 1.1 million people currently living with HIV across the US, an estimated 448,000 of them are not engaged in care and treatment that could save their lives and reduce new HIV infections. Meanwhile, 56,000 new HIV cases occur in the US annually, and people are entering treatment at progressively later stages in their HIV infection.

Considering TLC+ in California
Meeting Agenda
May 18, 2010

10:00 – 10:30 – Welcome & Introductions

10:30 – 10:45 – TLC+: A Primer

10:45 – 12:00 – Small Group Discussion: TLC+ Challenges in California

12:00 – 12:30 – Lunch

12:30 – 1:30 – Panel Discussion: Outreach and Linkages to Care

1:30 – 1:45 – Synthesis of Morning Small Group Work

1:45 – 3:00 – Small Group Discussion: TLC+ Implications in California

3:00 – 3:30 – Break

3:30 – 4:15 – Summary of the Day's Discussions with Final Questions

4:15 – 4:30 – Next Steps and Wrap-Up

Mr. Van Gorder emphasized that, despite these daunting statistics, there have been many encouraging changes in our approach to HIV, changes that may present an opportunity for us to utilize TLC+ as an organizing principle for galvanizing more effective responses to the epidemic. For example, while we still do not have a cure for HIV, we have very good treatments that have demonstrably improved the health and quality of life of persons living with HIV. We also have made a great investment – with CDC support – to expand HIV testing in the US, and there is some indication that we are seeing a payoff in terms of identifying new HIV cases. There is also substantial evidence that treatment itself can be an effective means of HIV prevention, and, while there is still not conclusive scientific proof, at a theoretical and practical level we have seen that if a patient is adequately treated for his or her HIV infection, overall HIV incidence can be reduced. Further, the recent passage of health care reform may additionally increase the number of persons with access to medical providers, testing, and treatment over the next half decade.

TLC+ could serve as an organizing principle to help California move to the next level in fighting the spread of HIV. He noted that TLC+ may also provide an important new opportunity to integrate HIV planning, policy, coordination, and funding at the federal level in order to support states and counties in moving forward with an integrated HIV strategy.

Mr. Van Gorder also presented information related to the question of when it is best to begin antiretroviral therapy in persons with HIV, a question that is based in part on the ambiguity that continues to exist in federal treatment guidelines. He cited ongoing studies, including studies being conducted in San Francisco on community viral load, which indicate that TLC+ may be an extremely cost-effective approach to community-wide HIV prevention and also noted that it could be an opportune time to push for TLC+ as part of a convergence of policy factors, particularly as part of the emerging National AIDS Strategy being developed by the White House Office of National AIDS Policy. TLC+ may provide us with a clear and organized framework for prioritizing and sensibly allocating HIV planning and funding on a national level.

On July 13, 2010, **President Obama** released the first domestic **HIV/AIDS Strategy (NHAS).** The strategy has three goals: 1) decrease the number of new HIV infections in the US, 2) link all identified HIV-infected Americans to high quality HIV care and promote optimized health outcomes for these individuals, and 3) decrease health disparities for Americans impacted by HIV disease, especially peoples of color and members of the LGBT community. Along with the NHAS, he issued an implementation plan with clearly defined and quantifiable goals, and federal department directives in order to successfully enact the strategy. Monitoring of ongoing success with the plan was assigned to the Presidential Advisory Council on HIV/AIDS, which includes four Californians—Michael Horberg (Kaiser Permanente), Naina Khanna (WORLD), Mario Perez (LA County Department of Public Health), and Phil Wilson (The Black AIDS Institute).

A key element of NHAS is making sure every American knows their HIV status, which means greater routine HIV testing. For Americans who are HIV-infected, NHAS also calls for greatly improved linkages to quality HIV care. NHAS recognizes that quality HIV care includes consideration of earlier antiretroviral treatment, as this improves patient outcomes and lowers risk of HIV transmission.

TLC+ Challenges in California: First Small Group Exercise

Following the opening presentations, small groups were formed consisting of an average of 8 participants each. The groups were asked to discuss two specific questions in regard to TLC+ implementation in California .and to determine their top three responses / issues for each question as identified through the discussion. Responses to group discussion around these two questions are presented in full as Attachment A.

1. **In an ideal world, where resource limitations are not an issue, what are the challenges you would expect in implementation of TLC+, especially in terms of detection and linkage to care?**

In response to this question four major themes were identified:

A. Significant client level barriers that remain to be addressed, reduced, and/or removed. These include fear of HIV, stigma related to HIV, basic survival issues, especially for those with multiple complicating factors (homelessness, drug use, poverty, etc.), issues related to racism, and fear of the healthcare system.
B. Provider barriers, including: projections which demonstrate a clear shortage of medical, nursing and allied health services providers well into the future, lack of provider knowledge of HIV, fear of disclosing a positive test result, and shortage of co-located testing/treatment facilities.
C. Access barriers including: non-availability of testing and treatment services in areas where the most difficult-to-reach populations reside, inadequate funding to allow wide-spread outreach and testing for all, and various policy and procedure changes that will be required to actualize the linkage to care.
D. Policy barriers that include: silo'd resource streams, including separate programs and funding for prevention and treatment activities which prevent collaboration and development of strong linkages, HIPPA confidentiality issues that interfere with logical linkage steps and inter-jurisdictional issues that may work against establishment of a statewide, comprehensive system.

2. Given current resources, what are the critical components of TLC+ that you think you could (or are) implement(ing)?

In response to this question five major themes were identified:

A. Expand provider education and training in relation to HIV testing and treatment, including expanding the HIV testing and risk assessment skill set of existing staff in complementary fields such as STD prevention, substance abuse treatment, mental health, and pregnancy prevention.
B. Redirect HIV testing resources to ensure that testing is more readily available in areas where clients at highest risk are found.
C. Proactively work with HRSA and Region IX providers to support expanded HIV screening, linkage to care, and retention services.
D. Expand needle exchange programs.
E. Engage key non-medical community gatekeepers in the TLC+ effort, particularly to expand outreach to disproportionately-affected at-risk communities and to expand the number of culturally competent providers conducting HIV outreach and care linkage.

Outreach and Linkages to Care: Afternoon Panel

This panel was facilitated by Michael Horberg, MD, MAS, FACP, and Director of the HIV Interregional Initiative at Kaiser Permanente. Other panel members included Moupali Das, MD, San Francisco Department of Public Health and University of California San Francisco, and Davey Smith, MD, Bridges Program at the University of California San Diego. Dr.

Horberg explained that the purpose of the panel was specifically to explore the complex issue of the care linkage component of the TLC+ model.

Dr. Moupali Das began by explaining that the San Francisco HIV Prevention Section long-term goal is to end new HIV infections in San Francisco, with a shorter-term goal of reducing new infections by **50%** by the year 2015. San Francisco's focus is on high-risk groups - particularly men who have sex with men (MSM), injection drug users (IDUs), and male-to-female transgender persons who have sex with men – as well as on reducing HIV disparities. To reduce viral load levels and HIV transmission in the city, the Prevention Section has focused on five key areas: 1) expanding HIV awareness; 2) prevention with positives; 3) structural changes; 4) expanding needle exchange; and 5) expanded HIV testing, particularly through social network-based testing. The Section's current prevention targets are to link persons to care within three months of HIV diagnosis and to create a norm for at-risk persons to be tested for HIV every six months.

Dr. Davey Smith described an extensive HIV testing and care linkage program at the University of California San Diego which targets high-risk individuals with the goal of identifying their serostatus and linking them to care as early in their HIV infection as possible. A unique feature of the program involves offering HIV nucleic acid testing to extremely high-risk clients who initially test negative for HIV. Because nucleic acid testing can identify persons with acute HIV infection up to 12 days prior to the development of HIV antibodies, this approach could help identify more individuals with HIV earlier in their infection, and hopefully influence their risk behaviors during the time they are most infectious. According to a study of the program in San Diego conducted by Morris, et al. (2010) use of nucleic acid testing among a group of 3,151 testing clients

Providing Early Evidence of the Potential Effectiveness of TLC+: San Francisco's Community Viral Load Model

San Francisco has pioneered a technique for mapping **community viral load (CVL)** which may prove to be a critical new tool for targeting resources and assessing the success of HIV prevention efforts. Through this technique, the HIV/AIDS surveillance section of the public health department calculates the average of all individual viral loads in a geographic area or among different subpopulations. In this way, the city can explore the geographic distribution of viral load levels throughout the city in order to target HIV prevention strategies to the communities most at risk. These findings can also be updated and tracked over time, as persons in care receive regular viral load testing.

In a recent study authored by Moupali Das et al. (2010) decreases in community viral load over time from 2004-2008 were associated with reductions in new HIV infections during that time period. This finding provides important evidence for the potential of TLC+ interventions to reduce new HIV infections on a communitywide level by consistently providing antiretroviral therapy to a high percentage of HIV-infected community residents.

Source: Das M, Chu PL, Santos G, Scheer S, Vittinghoff E, McFarland W, Colfax, G, Decreases in community viral load are accompanied by reductions in new HIV infections in San Francisco, *Plos One*, Online data source, 5(6), June 2010. www.plosone.org

increased the HIV detection yield by 23%.[1] The program also utilizes internet and voicemail systems to inform clients of their HIV status in order to bring them into care. The project's Bridge program works to immediately link individuals to care, while persons identified as being at high risk are cycled back for HIV testing every 6 months.

Dr. Michael Horberg noted that Kaiser Permanente (KP) conducts an extensive and aggressive HIV testing program which encourages high risk patients to undergo frequent testing. While there is no mandatory HIV testing at KP they do work to educate and encourage physicians to order more HIV tests, particularly among high-risk patients, and to incorporate HIV risk assessment into regular physician visits. This includes recommending that physicians test for all STDs when one STD is identified. In part because it is an integrated system with linked medical records, the organization has had success in linking persons to care, with 93% of all HIV-positive individuals linked to care within 3 months of a positive test. KP also strives to assign care coordinators to all HIV-positive persons in each of the system's medical centers who are often present with the primary care physician when the initial HIV diagnosis is presented. The coordinator will then link the patient to an HIV specialist physician for their first medical visit. KP has been able to follow an HIV specialty model of care effectively, and has a long-term retention rate greater than 75% among its HIV-positive patients.

Following their presentations, panel members responded to a series of questions regarding programmatic issues in relation to TLC+. One question asked which specific challenges panel members are currently seeing in their systems. Dr. Smith noted that their biggest challenge is financial. The Bridge program is maintained through a combination of funds: staff must spend a significant amount of time and energy seeking resources to sustain it. Moupali Das noted that in addition to funding, their biggest challenge involves addressing stigma and disparities in HIV testing rates. They also face the problem of "syndemics" – multiple endemics among groups such as gay men, the mentally ill, substance users, and the homeless. By focusing on key drivers of HIV - especially substance use - her program hopes to address those syndemics through a focus on highest risk groups. Dr. Horberg noted that the biggest challenge is simply trying to get physicians to order the HIV test. Physicians aren't necessarily trained on how to talk to people about substance abuse and HIV risk behaviors and often "don't like to hear questions they can't answer." This issue extends to physicians asking older patients about their HIV risk behaviors.

Dr. Das noted that San Francisco General Hospital maintains a "Positive Health Access to Services and Treatment (PHAST)" which utilizes a successful care retention model. The PHAST team is made up of a group of clinicians and social workers who assist San Francisco General Hospital Emergency Department clinicians in disclosing positive results and who physically walk newly-diagnosed persons to the HIV specialty clinic, Ward 86, at San Francisco General Hospital. The program also carries out "matchmaking," which assigns patients to providers based on personality, demographic characteristics, and other

[1] Morris SR, Little SJ, Cunningham T, Garfein RS, Richman DD, Smith DM, Evaluation of an HIV nucleic acid testing program with automated internet and voicemail systems to deliver results, *Annals of Internal Medicine*, 2010;152:778-785.

factors. The PHAST also works with all hospitalized HIV positive patients to ensure appropriate linkage to treatment and relevant care services upon hospital discharge. Additionally, the SFDPH STD Clinic Partner Services program evaluated its partner notification system in terms of how many sexual partners of HIV-positive individuals must be talked to in order to identify one new HIV-positive person. All HIV-positive individuals diagnosed at City Clinic were offered partner services, and it is hypothesized because of the higher background prevalence of HIV in the sexual networks of newly diagnosed individuals at City Clinic, the rate is 21 individuals per new HIV infection identified, which means that the cost of finding each new HIV infection through the partner notification program is approximately $7,000. By contrast, the rate nationally is 35 individuals or more. This suggests that the Partner Services program is a highly cost-effective and efficacious way to identify new HIV-positive individuals by eliciting the partners of recently identified HIV positive individuals. This approach is highly effective in other communicable diseases such as syphilis and tuberculosis.

Dr. Smith conducted an analysis of their early testing program and found that for every new HIV-positive individual their program identified they in turn prevented a total of 2.3 infections within next 6 months. Meanwhile, for clients linked to care through the Bridge program, they found that 75% of clients remained in care 12 months following initial linkage versus 50% of clients prior to the Bridge program. Dr. Horberg noted that at Kaiser, among those diagnosed with an STD other than HIV, 56% received an HIV test within 90 days – a percentage they are working to increase – while 92% remained in care within 3 months of initial care linkage.

An additional question involved the resources that would be needed by each program to move closer to an effective TLC+ model. Dr. Smith noted that with additional funds, he would move the Bridge program into more provider agencies in the community, including non-profit agencies serving specific ethnic minority populations. He would also conduct a cost-benefit analysis of the nucleic acid testing program for persons with acute HIV infection. Dr. Das would want to make structural and policy changes, such as making HIV and STD screening and referral a standard of care. She would also advocate for universal health care coverage for people living with HIV as well as non-harassment policies for possession of drug paraphernalia. She would also want to make sure that every door is the right door for accessing HIV testing and care. Dr. Horberg would utilize the influence and resources of both the National Committee for Quality Assurance (NCQA) and the Joint Commission to influence health policy, especially for physician groups and insurers. Creating standards of care through both of these groups' recommendations is the surest way to ensure physician adoption of best practices and approaches, Dr. Horberg asserted.

Another question focused on co-location of care and prevention services and the difficulties involved in finding and linking new HIV-positive patients to care. Dr. Das noted that finding people and engaging them in care is extremely resource intensive, taking extensive time and energy. However, prioritizing people who are at highest risk for transmission may have an effect on new infections. Dr. Smith believes that co-location of care and prevention is absolutely critical, allowing people who have just tested positive to immediately be tested

for and receive their CD4 / viral load data. It's also good to have partner services attached. Dr. Smith observed that we are often complicit as a medical community in making HIV exceptional – we treat it as a separate test, so people think HIV is somehow "bad." If we can start treating HIV as if it isn't any different than any other diagnostic test, perhaps we can overcome some of the stigma and resistance.

A question was asked about the challenge of developing successful co-located systems – what is the role of county health departments in thinking differently about what co-location means? Dr. Das noted that there might be a way to make things more co-localized without true co-location, such as not requiring a confirmatory HIV test prior to being linked to care, and then having patients receive their confirmatory test at the medical facility to which they've been referred. Dr .Smith noted that "researchers are horrible PR people" and he would like to charge CHRP and others with developing ways to translate academic research to policy.

TLC+ Implications in California: Second Small Group Exercise

In this section, groups were asked to discuss two additional questions related to TLC+ implementation in California. Each group was asked to identify its top three policy recommendations and top three research questions. Recommendations are summarized below:

1. **What are the practice and policy changes at local, state, or national levels that will be necessary to fully implement TLC+ strategies in CA?**

In response to this question, the following key themes around practice and policy changes are identified below. (Please see Attachment B for the complete list).

A. Expand funding for HIV testing, outreach and patient retention services.
B. Co-location of HIV testing, treatment and care services whenever possible.
C. Increase provision of routine HIV testing in urgent care, private practice and community health centers.
D. Build more knowledge of HIV testing, care and risk assessment at the level of non-HIV specific medical care providers.
E. Significantly improve coordination and collaboration between HRSA and CDC in regard to HIV policy.
F. Advocate for new Joint Commission standards on HIV testing and linkage to care.
G. Encourage bodies such as the National Quality Health Council (NQHC) to support routine HIV testing.
H. Support AIDS Drug Assistance Program (ADAP) funding in jails and prisons.
I. Create new reimbursement streams for routine HIV testing and linkage to care programs, including bridge-style programs that utilize service navigators.

2. Thinking about information gaps, possible linkage strategies, policy changes, and other information, what are the research questions that should be pursued to fully understand the potential results of TLC+ implementation?

Many ideas and themes emerged related to this question. Following are a few of the key areas of discussion. (Please see Attachment B for the complete list).

A. Conduct and continue research to determine if TLC+ is a more impactful and cost-effective approach to HIV prevention than current models, including assessing its impact on new HIV infections averted and determining whether there is a direct correlation between TLC+ and community viral load.
B. Assess HIV testing practices and barriers to testing, particularly in relation to medical providers, non-network providers, and new versus long-term HIV practitioners, and with the ultimate goal of "normalizing" HIV antibody testing.
C. Evaluate the impact of intensive HIV testing efforts in specific communities and share resource outcomes that compare universal versus targeted HIV testing efforts.
D. Study and promulgate best approaches for reducing HIV stigma, including stigma related to HIV testing, treatment, and risk behaviors.
E. Conduct formative research to determine why individuals are not in care and/or do not know their HIV status in order to target effective interventions.

Dr. Thomas Coates: Summary Session

The think tank concluded with a final session summarizing the findings and outcomes of the day's activities while providing an opportunity for group discussion. Dr. Thomas Coates, of the Center for HIV Identification, Prevention, and Treatment Services, University of California, Los Angeles, provided an overview of the substance and themes of the day's discussions, as well as contextual comments about the issues and the status of HIV in America today. Key themes discussed included:

- California is a very diverse state (population distribution, geography, cultural/ethnicity, and many other factors). If TLC+ is to be successful in this state, there will need to be a diversity of models to address needs in different regions and populations.
- TLC+ models will need to be evaluated in order to ascertain if they are working or not. Real-time data, including the ability to map "hot spots," and viral load levels across California, will be needed to identify gaps, issues and problems.
- Other research questions about TLC+ will need to be addressed. For example, what level of community saturation of reduced viral loads will result in reduction of virus transmission? Is TLC+ a successful model to bring hard-to-reach and out-of-care populations into medical services?
- There are many calls for increased funding for HIV prevention, support and care. The next reauthorization of the Ryan White Treatment Modernization Act may be particularly challenging given the National HIV and AIDS Strategy and White House focus on HIV, among other factors. Securing increased funding will require targeted decisions and compelling case-making from the field.

- There will be a need for community engagement and mobilization around the idea of treatment as prevention, and a large share of this effort will need to involve expanded community and provider education. In 2010 and beyond, the new norm will need to be, "Yes, HIV medications work, and it's in your best interest to know your serostatus and get treated."
- Today's "perfect storm" of change – a convergence of the state budget crisis, a general push to make HIV prevention more medically oriented, and new scientific approaches - taken together indicate that the behaviorally-based prevention intervention world won't be in existence in its current form in five years;

In final summary comments, Dr. Coates noted that the Think Tank's work had brought his thoughts back to the earliest days of the HIV epidemic, and to initial responses to HIV. What made efforts successful then and over time has been the focus on specific action targets, which allowed activists, care givers, PLWH/A, policy makers and others to channel energy more effectively. Today, we can definitely look back and see that an incredible amount of change has happened, that there are more rational laws on the books, and that there has been scientific advancement. We can be proud of past and current work and can look forward to a future of "harnessing the power of an earthquake" as the epidemic – and the HIV world – continues to evolve.

Attachment A:
Responses to Questions from Small Group Discussion # 1

Question 1: Major Challenges to TLC+ Implementation in California

Client level barriers:

- Pervasive stigma related to HIV and HIV-related risk behaviors
- Fear of receiving an HIV diagnosis
- Lack of engagement in a regular care system
- Negative impressions or mistrust of the healthcare system
- Survival issues such as food and housing overriding an HIV focus
- Substance abuse and mental health issues
- Lack of awareness of HIV resources or treatment options
- Fear of HIV medications or a belief in HIV-related conspiracy theories
- Fear of disclosure of residency status

Provider Level Barriers:

- Lack of integration of sexual health and HIV testing at multiple levels
- Provider bias regarding who should be tested
- Lack of sufficient providers to deliver HIV care and treatment with expertise
- Lack of culturally sensitive and competent providers
- Lack of integration of routine HIV testing within traditional medical settings
- Lack of provider education regarding how to discuss and deliver HIV testing, care and services to patients
- Lack of clearly defined systems for linking HIV-positive persons to HIV specialist care
- Need for educating and training of non-HIV providers regarding HIV clinical issues, testing and stigma
- Shortage of human and financial resources to conduct expanded HIV testing and treatment
- Lack of peer navigation services to help clients deal with the HIV system
- Complexity of documenting HIV diagnosis and/or treatment
- Shortage of co-located HIV testing and treatment services

Access Barriers:

- Organizing TLC+ will be a daunting challenge that requiring extensive new public / private partnerships, new funding and protocols, new public policies, and key leaders and champions
- Linkage to care is challenging and labor intensive, often requiring hands-on peer navigators to be effective
- Testing and care venues are usually located in separate facilities, and require additional steps for clients to access treatment
- In order to be effective, clients must not only be linked to care, but must receive support for

medication adherence and retention in care

System and Policy Level Barriers:

- Linkage to HIV care is not currently defined as a reimbursable care activity
- HIV resources are not currently allocated on a strategic, system-wide basis, so that resources can be placed where they will have the greatest impact on TLC+ goals
- HIV resource streams are often kept separate, which can prohibit or deter initiatives to integrate HIV prevention, care linkage, treatment, and support
- The HIV care system is still often separated into prevention and care "silos", and the HIV system itself is not integrated with the broader healthcare system
- HIPAA, confidentiality, and consent systems may need to be modified to allow for greater information-sharing across the system
- Jurisdictional differences will make it difficult to implement a statewide TLC+ strategy, including differences in infrastructure, capacity, resources, populations, and geography

Question 2: Critical Components of TLC+ that Could be Implemented Now

- Implement routine HIV testing in a greater range of settings and venues through application of new CDC testing guidelines
- Integrate federal and state funding streams to allow for coordinated planning and resource allocation
- Consider the use of prevention resources to support care linkage and retention, including a potential SAMHSA set-aside
- Expand provider education and training in relation to HIV testing and treatment, including expanding the HIV testing and risk assessment skill set of existing staff in complementary fields such as STD prevention, substance abuse treatment, mental health, and pregnancy prevention
- Preserve eligibility for state ADAP for jails
- Situate discharge counselors in emergency rooms for those who test positive
- Normalize the discussion of HIV with medical providers through education
- Begin more concerted effort to address cultural barriers in relation to testing and linkage to care
- Focus on linking individuals to care at the time of a preliminary HIV positive test result
- Focus HIV testing on sexual and social network members of HIV-positive individuals
- Redirect HIV testing resources to ensure that testing is more readily available in areas where clients at highest risk are found
- Proactively work with HRSA and Region IX providers to support expanded HIV screening, linkage to care, and retention services
- Expand needle exchange programs
- Engage key non-medical community gatekeepers in the TLC+ effort, particularly to expand outreach to disproportionately affected at-risk communities and to expand the number of culturally competent providers conducting HIV outreach and care linkage
- Expand and promote peer-based programs for encouraging testing and care linkage
- Begin to develop and share best practices and results related to TLC+ with the broader medical, healthcare, and social service communities

- Create new treatment guidelines that support the goals of TLC+, including clarifying recommendations regarding early administration of antiretroviral therapies
- Increase HIV treatment resources by leveraging the new high-risk pool that will be created under health care reform
- Incorporate HIV quality measures regarding testing
- Create new requirements that all HIV testing sites be administratively integrated with medical sites and vice versa
- Utilize zip code-based community viral load data and extensively share this data with medical and prevention providers on a regular basis

Attachment B:
Responses to Questions from Small Group Discussion # 2

Question 1: Practice and Policy Changes Needed to Implement TLC+

1A. Recommended Changes in Practice to Implement TLC+:

- Expand funding for HIV testing, testing outreach, and patient retention services
- Ensure co-location of HIV testing and services wherever possible
- Provide routine HIV testing in urgent care and community health center settings
- Build more basic knowledge of HIV testing, care, and risk assessment at the level of non-HIV-specific medical care and physicians
- Provide extensive provider training on HIV testing and patient risk assessment, including developing a statewide provider training curriculum
- Expand the availability of partner services programs in non-public agencies and programs
- Combine HIV and STD testing services wherever possible
- Develop and promulgate practice standards for sexual health and risk assessment, HIV testing, and initiation of HIV treatment
- Create integrated structural "prompts" for regular HIV testing in the medical setting
- Have patients self-complete comprehensive HIV risk assessment at initial intake
- Involve the broadest possible range of public and private providers and agencies in local TLC+ planning efforts and in planning at the state and federal level
- Solicit input on implementation of TLC+ from local health jurisdictions, agencies, and providers
- Develop comprehensive statewide plans for rollout of TLC+ that includes resource analysis
- Build new systems and networks for closely connecting all components of the TLC+ system, potentially utilizing the patient-centered medical home model
- Provide training and support to "routinize" HIV testing and risk assessments and to address treatment barriers, including incorporating cultural competency factors
- Use Bridge-type connector models to link persons to care and engage more providers and community referral sources in those connection systems
- Strengthen referral systems to HIV specialists
- Create a strategy to rebuild and replenish HIV specialty care capacity through recruitment of new HIV physicians

- Expand scope and accuracy of automated HIV reporting capacity to support increased funding
- Increase utilization of newer technology, including telemedicine approaches for exurban and rural jurisdictions
- Consider aggregating low prevalence / low incidence counties for both services and funding
- Differentiate between services rendered to those who have fallen out of care versus those who are diagnosed, and develop appropriate responses to each group
- Expand patient education related to the of remaining in care
- Combine HIV and STD testing services on a comprehensive basis
- Maintain the Ryan White CARE Act even with the advent of healthcare reform
- Expand integration of HIV surveillance & reporting systems within the broader public health system
- Create appropriate metrics for TLC+ strategies
- Integrate relevant HIV and non-HIV health health programs in order to maximize resources and coordinate efforts to link low-income persons to health services

1B. Recommended Changes in <u>Policy</u> to Implement TLC+:

- Significantly improve coordination and collaboration between HRSA and CDC in regard to HIV policy
- Advocate for new Joint Commission standards on HIV testing and linkage to care
- Encourage bodies such as the National Quality Health Council (NQHC) to support routine HIV testing
- Support AIDS Drug Assistance Program (ADAP) funding in jails and prisons
- Expand the availability of HIV testing in corrections facilities
- Create new reimbursement streams for routine HIV testing and linkage to care programs, including bridge-style programs that utilize service navigators
- Support policies mandating expanded levels of HIV testing in local health jurisdictions
- Monitor progress of the Early Treatment of HIV ACT (ETHA) and develop alternative care system if not passed
- Evaluate Ryan White CARE Act Part A and Part B prioritization and allocation processes
- Monitor and advocate for changes to relevant monitoring and accrediting standards including US Preventive Services Task Force (USPSTF) HIV screening guidelines
- Incorporate a new measure related to HIV testing and linkage to care in the Healthcare Effectiveness Data and Information Set (HEDIS) and new standards endorsed through the National Committee for Quality Assurance (NCQA)
- Streamline HIV funding
- Remove redundant HIV testing and reporting requirements
- Utilize surveillance data more extensively to monitor and guide HIV allocations
- Implement immigration reform to remove barriers to care for undocumented individuals
- Reduce or eliminate the five-year waiting period for Medi-Cal/Medicaid benefits for legal immigrants
- Create a new State statute to allow use of surveillance data for case management
- Create integrated prevention and care plans developed by local jurisdictions in cooperation with the State Office of AIDS

- Coordinate federal HIV funding at the state and local level, including funding through HRSA, CDC, and SAMHSA
- Create new funding mandates that tie support to infrastructure capacity to deliver TLC+
- Create new requirements mandating formal administrative linkages between HIV testing and care sites
- Simplify training and requirements for HIV testing to make it more widely available
- Provide better integration of HIV surveillance and reporting within the broader public health system
- Explore public/private partnerships to roll out TLC+ in the context of a changing healthcare environment
- Work closely with local, state, and national elected officials to propose essential policy changes to support TLC+ implementation

Question 2: Potential Research Topics or Subjects to Help Develop and Implement TLC+

- Conduct and continue research to determine if TLC+ is a more impactful and cost-effective approach to HIV prevention than current models, including assessing its impact on new HIV infections averted and determining whether there is a direct correlation between TLC+ and community viral load
- Perform a gap assessment related to services linkage from state incarceration to county/community-based care and propose directives to augment linkages based on the findings of this assessment
- Assess HIV testing practices and barriers to testing, particularly in relation to medical providers, non-network providers, and new versus long-term HIV practitioners, with the ultimate goal of "normalizing" HIV antibody testing
- Evaluate the impact of intensive HIV testing efforts in specific communities and share resource outcomes that compare universal versus targeted HIV testing efforts
- Define what constitute "effective linkage to care" in the case of HIV, including appropriate timeframes, ideal type of provider, and resource needs
- Initiate a study on what motivates people to initiate HIV testing and/or treatment, including exploration of mediating factors such as social networks, cultural background, age, gender, and invidual versus community health
- Fund pilot studies to idenity and test TLC+ best practices focusing both on impact and cost-effectiveness
- Identify and disseminate appraoches to overcoming barriers to TLC+ among providers and within communities
- Focus research efforts on hard to reach populations who continue to fall out of care, incluidng substance users and persons with mental illness
- Research issues of HIV testing, treatment, and support in corrections settings
- Explore different methods for incentivizing HIV care among high-risk populations, such as cash incentives when client viral loads remain below a specified level over time
- Develop effective TLC+ evaluation and assessment strategies
- Develop best practice guidelines for retention and re-engagement in HIV care
- Determine next steps for beginning to implement what we have begun to learn about the

effectiveness of community viral load appraoches
- Explore HIV and aging issues in the context of TLC+, including segmenting HIV risk factors among specific elder populations
- Study and promulgate best approaches for reducing HIV stigma, including stigma related to HIV testing, treatment, and risk behaviors
- Develop enhanced cultural competency training and support tools for HIV-related providers
- Develop effective messaging promoting the benefits of early HIV treatment at both the community and provider level
- Expand surveillance of community viral load reporting and drug resistance
- Conduct formative research to determine why individuals are not in care and/or do not know their HIV status in order to target effective interventions
- Increase utilization of new technology
- Ensure that individuals conducting partner counseling and referral services are the same individuals linking those individuals to care
- Evaluate current service delivery models and outcomes to determine whether HIV needs to be remain a "specialty care" area
- Assess the need for expanded linkages between HIV and STD testing in local jurisdictions
- Expand the use of viral load testing to better predict HIV transmission risk
- Provide continuous monitoring of the specifics of all HIV tests in CA
- Incorporate quality assurance measures to determine the effectivenss of all public and private HIV treatment and prevention providers
- Develop and promulgate best practice guidelines regarding case management, including assessing the effectiveness of peer-based versus non-peer-based staff

Attachment C
Considering TLC+ in California

Planning Committee:

Edwin Charlebois, PhD, CAPS, University of California San Francisco

Grant Colfax, M.D. HIV/AIDS Prevention and Research Director, San Francisco Public Health Department

Julie Cross, Health and Disability Policy Consultant, Los Angeles

Terry Cunningham, Chief, STD, HIV and Hepatitis Branch, Public Health Department, San Diego

Nettie DeAugustine, Chairperson, California Conference of Local AIDS Directors

Anne Donnelly, Director of Public Policy, Project Inform

Kevin Farrell, Executive Director, Center for HIV Identification, Prevention, and Treatment Services, University of California Los Angeles

Michael Horberg, M.D., MAS, Director HIV/AIDS, Kaiser Permanente and The Permanente Federation

Steve O'Brien, MD, Director, East Bay AIDS Program, Oakland

Arlene Leibowitz, PhD, School of Public Affairs, University of California Los Angeles

George Lemp, PhD, Director, California HIV/AIDS Research Program

Sophia Rumanes, MPH, Chief HIV Prevention Services Division Office of AIDS Programs and Policy, Los Angeles

Jennifer Sayles, MD, MPH, Office of AIDS Programs and Policy, Los Angeles

Wayne Steward, PhD, CAPS, University of California San Francisco

Robert Whirry, Robert Whirry Associates, Program Development Consultants, Los Angeles

Staff:

Peter Agron, PhD., Clinical Research and Grants Program Manager, California HIV/AIDS Research Program

Bart Aoki, PhD, Assistant Director, California HIV/AIDS Research Program

John Mortimer, PhD, Project Officer, California HIV/AIDS Research Program

Susan Strong, Strong Consulting, Program Manager to the Visioning Change Initiative of CHRP