Substance Use, Mental Health, and HIV: Integrating Treatment as Prevention

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Conference Proceedings

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Kevin Fenton, MD, PhD
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Dr. Kevin Fenton opened the conference with a plenary speech that highlighted the current state of the HIV epidemic in the United States, the integration of treatment as prevention within the current context of worsening health inequalities, and the importance of health equity, which he defined as "the absence of systematic or unfair disparities in health among population groups in a social hierarchy, or with different levels of social advantage or disadvantage."

Noting that recent advancements in treatment as prevention were some of the most exciting developments to emerge in the HIV prevention field in many years, Dr. Fenton cautioned that these new technologies may worsen health inequalities if implementation is not careful and deliberate. "As we think about new technologies, and new biomedical technologies, it is critical that we focus not only on interventions delivered within the health care sector, but we think about the wider range of health inequalities and what we need to be doing to address these issues."

Dr. Fenton based his overview of the HIV epidemic in the US on data released by the Centers for Disease Control and Prevention (CDC) in early August 2011. Approximately 1.2 million Americans are living with HIV, with one in five affected individuals being unaware of their status. While there is an overall stabilization of HIV incidence in the US, alarming trends in population subgroups exist: incidence is increasing among men who have sex with men (MSM), and in particular, young Black MSM. A key feature of the CDC's incidence data is the tremendous burden of disease on African Americans and Latinos relative to Whites in the US. Characteristics of newly infected individuals illustrate the stories of health inequalities: 44% of new infections are in African Americans, 32% in Whites, and 20% in Hispanic/Latinos. In addition, the epidemic is becoming increasingly concentrated in younger people 13-29 years old.

Increasing prevalence with stable incidence probably means that the transmission rate for HIV is declining, explained Dr. Fenton. With more people living with HIV, we would expect greater numbers of onwards transmissions, and therefore, increasing incidence. Stable incidence indicates that 1) people living with HIV are taking steps to prevent the onward transmission of disease and 2) we are beginning to see the population level effects of the highly effective antiretroviral therapies (ART).

The new data from the CDC also indicate geographic concentration of the epidemic. Fifty-four percent of people living with HIV/AIDS live in five states and 90% reside in one of 23 States. Despite the fact that 95% of Americans who are living with HIV/AIDS are either MSM of all races, African Americans and Latinos, or Injection Drug Users, there exists clear evidence of the concentration in urban, socioeconomically disadvantaged communities where the prevalence of HIV is high regardless of one's risk group, race, or ethnicity.

Dr. Fenton employed the Social Determinants of Health Model to illustrate the very complex reality of HIV in the US and to better elucidate the factors associated with worsening health inequalities in the most affected populations. The Social Determinants of Health Model postulates that the social

and economic conditions in which a person lives and one's position in that social hierarchy are as important to health outcomes as individual characteristics such as behaviors and biological factors.

As an infectious disease epidemiologist, Dr. Fenton proposed a few "friendly amendments" to better capture the realities of HIV transmission in the US and the inequalities that exist: 1) Individual level factors that influence social positioning should include sexual orientation and homelessness; 2) As we are talking about an infectious disease, we need to add to the model the background prevalence of disease - a huge driver of incidence and the main reason why we're seeing an increase in incidence in young MSM. "Study after study has demonstrated that young Black MSM have equal or lower rates of high risk behavior than their White or Hispanic counterparts. But they are having these lower risk behaviors within the context of higher background prevalence;" 3) Structural factors need to include the correctional system, which is a huge driver of HIV in the US, racism and homophobia which determine so many experiences in the health care sector, and residential segregation which affects who has access to what kinds of interventions and opportunities within the United States.

Bringing the discussion back to treatment as prevention, Dr. Fenton stressed the importance of addressing the implications of advancing biomedical technologies within the context of health inequalities and the limitations of service delivery within the healthcare sector.

Recent scientific discoveries have made it absolutely clear that treatment *is* prevention and there are a range of proven interventions that can be confidently added to the prevention toolkit. While additions to the toolkit change the way we think about individual level drivers, time and resource limitations mean that a blanket approach will not do and the most effective interventions for those most a risk must be prioritized. Within the current economic realities, limited resources must be targeted, used wisely, employed differently, and targeted strategies must be made unapologetically.

"Because we know better we must do better," stressed Dr. Fenton, "if we believe that the determinants of HIV are multilayered, then it behooves us to ensure that we have a multilayered prevention portfolio." In a transforming environment, there are opportunities to partner differently, to do different kinds of work, and to integrate technologies in more effective and more deliberate ways. Effective integration is imperative in order to address health inequalities.

A combination of interventions is essential and so is the translation of clinical efficacy into real world effectiveness for communities living with HIV in the United States. How we use these novel biomedical strategies depends on the phase of the epidemic and interventions must be scaled to assure appropriate coverage and impact while being delivered in culturally relevant and competent ways.

Social attitudes are important as they shape how interventions are taken up and implemented in communities. These new tools are being implemented in a dynamically changing social environment and HIV is no longer a major item of concern in the US population, not even among those populations who are at greatest risk of acquiring the disease. Recent data from the Kaiser Family Foundation show that fewer than 6% of Americans consider HIV a major health concern, down from 44% in the 1990's.

The good news is that affected groups are more likely to have higher population awareness and concern about issues related to HIV. Unfortunately, the same data suggest that while awareness is

higher, the overall majority of the communities hardest hit fail to have adequate levels of concern, given the urgency of the epidemic, warned Dr. Fenton.

The effects of social attitudes are not limited to individual and community level behaviors. Reduced concern at the community level makes it far more challenging to maintain a national dialogue. It makes it difficult to maintain population level awareness, interest, and advocacy about HIV. In turn, it becomes more challenging to think about, fund, and scale up new interventions. The attitudes of the population are likely to be shared with, and shape, the attitudes of the policy makers and political leaders who are critical in determining the way programs are funded, led, supported, and delivered. This reality has particular impact on HIV programming as populations most affected by the disease are already disenfranchised.

As we move forward with this promising and exciting phase in HIV prevention, it is crucial to remain keenly attentive to issues surrounding health equity, expressed Dr. Fenton. Cautioning that while some have expressed a desire to charge forward with our new tools and technologies, we need to be mindful of health equity concerns. He cautioned that new technologies will take time to scale up and it would be fallacious to think that they are going to be implemented today, tomorrow, or next week. The challenge becomes accelerating the diffusion of interventions while remaining mindful of both health equity and competing health care priorities.

HIV does not exist in isolation: other infectious diseases such as syphilis, gonorrhea, and tuberculosis are common in HIV affected populations. At the same time, we need to think about who currently has access to ART and who is, or has the potential, to be virally suppressed. There are over 9000 people on waiting lists for ARVs. The majority of states with ADAP waiting lists are in the Southern states – exactly where the HIV epidemic is most concentrated.

The current methods of health service delivery are also critical components to the health equity issues associated with treatment as prevention. Dr. Fenton stressed that these interventions are complex and often times rely on a health system that is already failing to reach and serve at-risk communities. If the new interventions more likely to be taken up by those who already have access, issues of inequalities have the potential to be compounded, he warned.

As the root causes of these inequalities are complex interaction between social and structural determinants, biomedical interventions which only address one component of the root causes of health disparities have the potential to fail. Implementation without proper contextual support is dangerous and can add to health inequities. Dr. Fenton cautioned that, unfortunately, we continue to fail to learn lessons from history: *a priori* design and implementation of programs are too often the case and programs fail as a result.

Fortunately, we also have an opportunity to do it right. The prevention, treatment, and care interface needs to be explored and a "smart HAART" rollout needs to be employed. Demonstration projects are important as are deliberate planning processes that address health inequities. The potential to infuse health equity issues into our public policies, communications, and community engagement exists and the CDC has begun to integrate issues of health equity perceptions into every conversation.

In conclusion, Dr. Fenton explained that the devil is, indeed, in the details. It is essential that processes surrounding the implementation of treatment as prevention are completed with the

mindset of health inequities at the fore of our thinking and not in the back. As we move forward, we need to ensure that we do not worsen health inequities. Integration of treatment as prevention will only be successful if health equity remains a primary concern and we maintain a balanced portfolio of individual, community, and societal level interventions.

SESSION ONE: TREATMENT AS PREVENTION FOR SUBSTANCE USERS AND MSM

Steven Shoptaw, PhD
UCLA Department of Family Medicine |Los Angeles, California

As a clinical and research psychologist specializing in addiction therapy, Dr. Shoptaw expressed sincere enthusiasm about the dizzying successes in combination prevention that have come to fruition in the last several years. The potential for biomedical interventions that can be employed in tandem with behavioral interventions has created a very different playing field in HIV prevention.

Substance users play an important role in the transmission of HIV yet they are often excluded from the discussions and the research surrounding HIV prevention, explained Dr. Shoptaw. It is critical to include drug-using populations whose behaviors put them at risk for HIV, regardless if they take part in behaviors that some might find objectionable.

In the greater population of MSM, the use of assertive ART as prevention for both HIV positive and negative individuals has to be coupled with behavior change to facilitate the adherence that ensures efficacy. Indeed, the very act of taking a pill every day is a behavioral act and interventions that promote pill-taking can be as efficacious as the effects of the pills themselves.

What remains to be articulated is whether the concept of treatment as prevention works for substance using MSM. To date, this group has been systematically excluded from participation in research. "Where are substance using MSM in the data when we hear about successful treatment as prevention?" They are generally not there, explained Dr. Shoptaw. If you run a randomized control trial with a goal of establishing clinical efficacy, you are not likely to include substance users who are believed by investigators to be non-adherent and unpredictable in their behavior.

In addition to issues surrounding the inclusion of substance abusers in clinical trials, there are also ethical issues that remain unaddressed. There may be objections to providing HIV-negative substance abusers with ART, a medication that is not available to all HIV-positive individuals who want it. Should we allocate ART to people who are engaging in behaviors deemed objectionable on a social level? It is a valid question that warrants attention and needs to be attended to. The HIV prevention community has dealt with this sensitive issue is by ignoring it and making recommendations for the general population, remaining silent on addressing the needs of those who engage in "objectionable" behaviors. Post-exposure prophylaxis (PEP) provides an example of the long time lag between recommendations/protocols for on-the-job exposure in contrast to recommendations for those whose exposure resulted from risky sexual behaviors.

While much remains to be discovered regarding treatment as prevention, there has been solid research that provides information about HIV-positive substance abusers who have access to ART. Studies show that crack cocaine use has a significant and negative correlation with health outcomes

(increasing viral loads, decreasing CD4 counts, and increasing morbidity and mortality) in HIV-infected women.

Other studies have illustrated significant negative impacts of methamphetamine use on immune parameters (e.g. CD4 counts) but those same studies indicate that the negative effects are "completely swamped and washed away by the impact of ART." The science remains indefinite, explained Dr. Shoptaw, as one study showed viral suppression in HIV-positive MSM receiving ART showed was observed for all men, excepting those who appeared with a positive urine drug screen for recent methamphetamine use.

Finally, there is strong evidence that opioid therapy for injecting opiate users can boost adherence to ART indicating an increased relevance of combination therapy for opiate injectors. Integrating HIV care within the context of addiction medicine can increase the positive outcomes for both addiction and HIV diseases.

Although there are not a lot of data on treatment as prevention in substance using MSM, there is more information available about substance abuse treatment as HIV prevention. Treatment programs are not just treating addiction. Reductions in drug use from treatment also increases cognitive functioning, decreases the sharing of paraphernalia, reduces exchange of sex for drugs, promotes more frequent contact with health care providers, and improves access to information. All of these have profound positive and sustained changes in behaviors.

Needle exchange programs have been shown to be extremely cost-effective interventions with significant positive impacts on HIV seroprevelence in communities. Their successes are to be lauded but it is important to remember that the majority of those at greatest risk for HIV, MSM, do not inject the substances they use. In the United States, methamphetamine use is an important driver of the HIV epidemic.

The use of methamphetamines is correlated with a two to four fold increase in risk for HIV transmission, explained Dr. Shoptaw. Recreational meth-using MSM are in the lower 20% of incident infection while chronic meth-using MSM who are not seeking treatment have about 42% of prevalent HIV infection. Data from drug treatment clinics indicate that three out of five MSM who seek outpatient treatment for their addiction are infected with HIV and a full 86% of MSM who enter residential treatment facilities are HIV-positive.

"Brains not on methamphetamine make healthier sexual decisions than brains on methamphetamine," stated Dr. Shoptaw. Methamphetamines change the probability of infection by changing characteristics of behaviors: episodes of unprotected sex, increased likelihood of engaging in sex with someone with other STIs, and increased exposure to viral mucosa and people with high viral loads. Therefore, keeping people off drugs is more cost-efficient than dealing with the downstream sequela. By lowering risk behaviors and allowing people to make better decisions about their health, HIV transmission dynamics can be positively affected.

Dr. Shoptaw concluded his presentation with a return to the idea of combination treatment as HIV prevention within the context of substance using MSM. As emerging evidence indicates biomedical and behavioral interventions to HIV prevention can be effective, the challenge becomes the integration of appropriate elements with substance abuse treatment strategies to best assist members of the substance using communities avoid HIV infection.

Irene Kuo, PhD, MPH
George Washington University School of Public Health and Health Services |Washington, D.C.

Dr. Kuo presented an overview of treatment as prevention in HIV infected substance users, with an emphasis on Washington D.C, a municipality with one of the highest HIV prevalence rates in the country and an innovative and aggressive public health strategy to bring the epidemic under control.

In the United States, as well as many nations around the world, injection and non-injection drug use are driving factors in HIV transmission. The effectiveness of ART in drug users – especially in injection drug users - is well established. Also established is the comparatively late initiation of ART and suboptimal adherence rates. Therefore, it becomes imperative to get more substance users engaged and adherent to ART and HIV care.

Dr. Kuo outlined three major components to treatment as prevention strategies particular to this population: 1) Identification of unknown HIV infections and immediate linkage to care; 2) Engagement and retention in care; and 3) Linkage and access to substance use treatment to facilitate that engagement and retention in HIV care.

While the first two components have much in common with strategies designed to promote treatment as prevention in non-substance using populations, this population has a unique need (and perhaps opportunity) to integrate HIV care with substance abuse treatment programs. Drawing from a recent publication in Health Affairs by Valkow and Montaner, Dr. Kuo reported on the importance of comprehensive and integrated treatment for both conditions. Not only is it important to integrate substance use treatment with HIV care, she explained, it is important to incorporate HIV testing and linkage to care into substance use programs. Recent data indicate that nationwide, only 60% of drug treatment programs offer HIV testing.

With substance abuse being an important driving factor in HIV transmission of the epidemic, the question becomes "how do we get more substance users engaged, retained in, and adherent to HIV care?" Using her intimate knowledge of treatment as prevention activities in Washington DC, Dr. Kuo drew on activities within the city to provide applied examples.

With a prevalence rate of 3.2%, the US capital is home to a generalized epidemic and, like many parts of the world, substance use is a major driver of the disease. A baseline prevalence study conducted in 2007 indicated that 59% of high-risk heterosexual study participants reported binge drinking in the last 12 months, 28% had ever engaged in injection drug use, and 28% reported using crack cocaine.

Washington, DC was selected to participate in the HIV Prevention Trials Network HPTN 065 endeavor to evaluate the feasibility of an enhanced test, link to care, plus treatment approach for HIV prevention. While this intervention has the potential to produce important gains reducing community viral load, substance users and people with serious mental disorders were excluded from study participation, so it is unknown if these types of interventions are applicable and/or effective in substance using populations.

Dr. Kuo shared some of her experiences with the D.C. Partnership for HIV/AIDS Progress, a collaboration between the National Institute of Allergy and Infectious Diseases, the DC Department of Health, and George Washington University.

As a lead researcher on a qualitative needs assessment, Dr. Kuo investigated substance use and mental health treatment needs and the impact of those needs on HIV care. The study revealed both facilitators and barriers to care. Facilitators included centers with integrated care, provider structure, and non-judgmental attitudes toward substance use. Barriers to patient adherence in the continuum of HIV care included competing basic needs and stability in housing. Dr. Kuo stressed the finding that when people have to worry about different things, they place a lower priority on initiation and retention in HIV care and treatment.

Emphasizing that there are different approaches to increasing engagement and retention in care, Dr. Kuo closed with a recapitulation of some of the methods that can and should be employed to effectively promote treatment as prevention in substance users. Integrated care, assistance in meeting basic needs, customized treatment plans, increased capacity for HIV care providers to deal with substance use disorders, and proactive linkage to care are all essential elements to stopping HIV transmission.

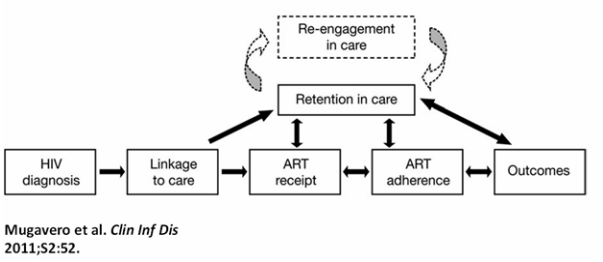
SESSION TWO: TREATMENT AS PREVENTION FOR MENTAL HEALTH PROVIDERS

Cynthia Grossman, PhD
Secondary Prevention Program at the National Institute of Mental Health Division of AIDS Research | Bethesda, Maryland

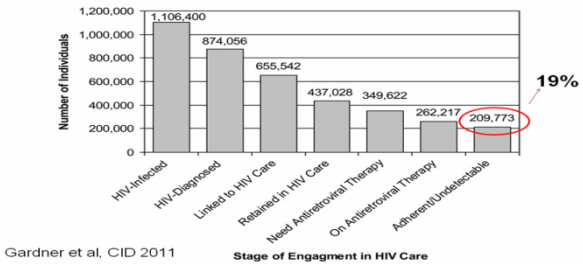
Dr. Grossman, Program Officer for the Secondary Prevention Program at the National Institute of Mental Health Division of AIDS Research, provided an overview of the intersection of HIV and mental health and implication of the relationship on treatment as prevention strategies.

Changes in the prevention landscape have created both promise and challenge. With a goal of drastic reductions in the transmission of HIV, the test and treat strategy provides a framework for engaging infected individuals in care and maintaining their viral suppression over time. However, significant challenges remain in getting people into testing, getting those who test positive engaged care, and supporting maintenance of adherence over a long period of time.

Utilizing a models employed by researchers Gardner and Mugavero, Dr. Grossman highlighted the cascade of initiation and maintenance of HIV care and treatment when the desired outcome is viral suppression. From diagnosis through receipt of and adherence to ART, the cascade appears linear, simple, and achievable but, Dr. Grossman cautioned, there is a lot of complexity built into a simple picture.



Mugavero et al. *Clin Inf Dis* 2011;S2:52.



Gardner et al, CID 2011

Currently an estimated 19% of people living with HIV in the United States have an undetectable viral load. The cascade illustrates not only the stages of engagement in HIV care but how important it is to maintain a high percentage of persons who progress from one stage to the next.

Embedded in Gardner's paper is a modeling paradigm in which numbers are modified to hypothesize a scenario in which 90% of people successfully complete each stage of engagement. If 90% of HIV infected people are aware of their status, and 90% of those engaged in care, and 90% of those are retained in care and on ART, 66% of individuals could achieve undetectable viral load levels. While 66% would be a laudable success, 34% of infected people would still maintain a detectable viral load – and that's quite a lot of virus being circulated in the population, cautioned Dr. Grossman. Thus, the challenge to treatment as prevention is that even if only 10% of the patient population is lost at each stage on the HIV care continuum, the final number is further from the desired outcome of undetectable viral load than we would like to see on a population level.

Directing the discussion back to the relationship between mental health and HIV, Dr. Grossman explored some of the factors associated with the loss of people at each stage of the HIV care continuum with a focus on mental disorders and their impact.

Data from a Duke University research team led by Brian Pence indicates that mental illness or substance abuse disorders matter in terms of achieving and maintaining viral suppression in persons infected with HIV. Persons with a 'high' or 'moderate' probability of having a mental illness or substance abuse disorder are markedly less likely to achieve and maintain viral suppression.

Dr. Grossman stressed that is it also important to consider the cascade surrounding mental disorder and treatment on its own, as mental disorders have been shown to be a barrier to HIV care and achievement and maintenance of viral suppression. According to some studies, roughly one-third of people with a mental health disorder will be diagnosed by a mental health specialist. About one-third of those diagnosed will receive treatment. Eighty percent of those who are diagnosed will be retained in care.

In contrast to the availability of HIV data, data on mental health disorders is extremely difficult to obtain. First, compared to national surveillance of HIV, for mental disorders there are not as robust national surveillance databases and clinical systems are not well equipped to track cases and treatment outcomes for mental health disorders at national level. Second, diagnosis of a mental disorder is challenging and there are wide variations in the types of disorders and probability of detection. For example, individuals diagnosed with depression are much more likely to be identified, treated and retained in treatment than individuals living with posttraumatic stress disorder or substance abuse. Lastly, treatments for mental disorders are varied and they are provided in different locations - many people who receive treatment do not do so at a specialty clinic.

While the surveillance systems for mental health and HIV are markedly different, there are commonalities that affect engagement in either type of care. In both systems gaps in care are associated with co-morbidities, lower educational attainment, lower health literacy rates, lack of insurance, and poverty and the associated realities surrounding neighborhood violence, incarceration, and unstable housing. These larger social and structural determinants influence whether people fall out of the steps in the cascade and addressing them will be the challenge to treatment as prevention approaches.

The NIMH is focusing significant effort on understanding the social and structural factors that impede people from obtaining, utilizing, and maintaining care. Financial incentives and economic strengthening approaches are being explored, as well as service integration, health disparities research, and the role of psychosocial barriers such as medical mistrust and stigma.

At both the individual and structural levels, NIMH priorities are being re-aligned to ensure consistency with the National AIDS Strategy and there is a focus on reducing of health disparities and increasing quality of and access to care for those living with the disease. Combination approaches that go beyond the individual level – those that go into the neighborhoods, into the communities, and beyond – need to be integrated with combined behavioral- biomedical approaches.

Adam Carrico, PhD
Center for AIDS Prevention Studies (CAPS) |San Francisco, California

Dr. Carrico rounded out the session on mental health by speaking about psychiatric risk factors for HIV disease progression and highlighting how cost-effective approaches to expanding access to ART requires addressing co-occurring psychiatric conditions.

Psychiatric factors impair HIV disease management and result in incomplete disease suppression, explained Dr. Carrico. Consequently, efforts to change community viral load must engage populations with psychiatric co-morbidities and provide people with adequate treatments to help them control their mental health and substance use disorders.

The literature on the intersection between mental disorders and HIV management contains conflicting assertions. In general, studies with community cohorts illustrate that mental disorders are correlated with hastened disease progression – even after controlling for medicinal adherence – and this evidence is strongest for depressive symptoms and stimulant use (methamphetamines, crack, and cocaine). In contrast, studies that employ HIV clinic based cohorts have found the opposite results. Within these studies, psychiatric co-morbidities are associated with utilization of ART for longer periods as well as longevity. The discrepancies between community and clinic based cohorts may be due to the methodologies, asserted Dr. Carrico. The clinic based studies that obtain psychiatric risk factors from chart review have the potential to confound treatment and diagnosis of mental health and substance use disorders.

To better understand the relationship between mental health and HIV care, Dr. Carrico and a team of UCSF researchers recruited a cohort of homeless and marginally housed HIV infected individuals from the San Francisco community. The NIDA SHADOW Project identified both structural and psychiatric factors that were independently associated with ART utilization. Being enrolled in ADAP and any mental health treatment in the past 90 days were associated with markedly elevated odds of utilizing ART. Street homelessness (sleeping on the street in the past 90 days) and currant stimulant use disorder were associated with substantially lower odds of utilizing ART.

The research team also examined the viral loads of study participants on ART. Among the approximately 15% of participants who experienced severe mental illness (SMI), viral loads were dramatically elevated. Current SMI was associated with a six-fold higher mean HIV viral load.

Decreased odds of ART utilization among stimulant users can mean a lot of different things, explained Dr. Carrico. It could reflect poor engagement or poor access due to stigma in the medical sector. In either case, optimizing health outcomes and boosting the efficacy of test and treat could happen if we provide concurrent psychiatric care. Further research is needed to better understand barriers and facilitators of ART utilization in this population.

Dr. Carrico expanded on a second current research endeavor that utilized data from the NIMH Healthy Living Project, a randomized controlled trial with 936 HIV+ participants that reported engagement in transmission risk behaviors. The UCSF team hypothesized that depression and (at least weekly) stimulant use would predict elevated viral load over a 25 month time period. The data showed that elevated depressive symptoms at baseline were associated with a 39% increase in the odds of ART discontinuation at follow up. Weekly stimulant use was related to a 2.5-fold increase in the odds of intermittent (stopped and restarted at least once) ART utilization. After controlling for self-reported adherence and CD4 count at baseline, elevated depressive symptoms were associated with a 50% higher viral load and weekly stimulant use was related to a 137% higher viral load. These effects of depressive symptoms and weekly stimulant use on higher HIV viral load were mediated by the inconsistent patterns of ART utilization.

These data from the NIMH Healthy Living Project highlight the role of inconsistent ART utilization and provide some compelling evidence that the effects of psychiatric risk factors are largely behavioral. Behavioral interventions are too often focused on getting people to take more medications when they are on them, asserted Dr. Carrico, we need more interventions that are focused on ART persistence, especially in the era of treatment as prevention. Identifying the implementation and treatment gaps for co-occurring psychiatric disorders is crucial. In the context of HIV medical care, in particular, we have a lot of opportunities to triage people and to initiate treatment.

Dr. Carrico concluded his discussion by integrating his findings into the broader clinical and public health perspectives.

Firstly, interventions that address psychiatric risk factors should be promoted. The goal of treatment as prevention is to achieve the greatest possible reductions in community viral load and we do not want to be promoting ART utilization in populations where these medications that are going to be inadequately used or that contribute to the development of resistance.

Secondly, we also need to address mental disorders as key drivers in HIV-related health disparities. Social and other determinants of health, such as racism and homophobia, are often transferred through psychiatric factors: people become depressed and they begin to use drugs. Because psychiatric factors are essentially on the causal pathways, we should view psychiatric treatment as a way to partially mitigate health disparities.

Lastly, it would be worthwhile to provide clear guidance on how to manage psychiatric conditions in the context of HIV medical care. Providers are often forced to rely on their own judgment and could, oftentimes, benefit from evidence-based guidelines.

In summary, interventions targeting implementation gaps for psychiatric diagnosis and treatment in HIV medical care are critical. Co-location is important. Intensive case management works. We also need to migrate towards low threshold and harm reduction based addiction treatment services and

move away from an abstinence-only approach. Conditional cash transfers and contingency management strategies are evidence-based treatments that work and the opportunities for these types of interventions are plentiful.

SESSION THREE: PAYING FOR MENTAL HEALTH AND SUBSTANCE ABUSE DRUGS FOR PERSONS LIVING WITH HIV

Erika Martin, PhD, MPH
University at Albany - State University of New York | Albany, New York

Dr. Martin opened the session on financing of mental health and substance abuse drugs by sharing some of her most recent research on the inclusions of psychotropic medications in state AIDS Drug Assistance Programs (ADAP).

Treating co-morbid mental health and substance use disorders is a very important part of clinical care for people living with HIV. Over half of all people living in the US with HIV have had a psychiatric disorder. Severe mental illness, particularly bipolar disorder and schizophrenia, may increase behavioral risk factors for HIV infection. People who engage in substance use are also more likely to engage in high risk behaviors. Treating mental health and substance abuse disorders are, therefore, important parts of HIV prevention and care.

People living with HIV navigate through a complex funding system for HIV care. Only about 15% of people with HIV have private insurance while the majority relies on Medicaid to cover their costs of care and treatment. Medicare is the second major program that supports people living with HIV and has recently become the largest source of federal funding for HIV care. Both Medicaid and Medicare are entitlement programs, explained Dr. Martin, and the budget automatically expands and contracts in response to underlying need. Both also have strict eligibility requirements which exclude many people living with HIV.

To support those excluded from the established care systems, the Ryan White program was created in 1990 as a payer of last resort for people with HIV. Designed exclusively for HIV care, the Ryan White program targets the uninsured and under-insured people who are not eligible for Medicare or Medicaid because they are not disabled and/or meet low income requirements. The Ryan White program runs and funds the federal ADAP programs, which finance drug assistance for about 30% of people living with HIV in the United States. Unlike, Medicaid and Medicare, Ryan White funding is discretionary which means that Congress sets the budget annually. The program has been flat funded for the last decade, despite a steady increase in demand, creating a chronic resource scarcity.

How mental health and substance abuse services are publicly financed is equally complex. Some of the funding streams include SAMSA block grants, Medicare and Medicaid, State Mental Health Agencies, the Veterans Administration, ADAPs, and correctional facilities. The way that funding streams for both HIV and mental health/substance abuse services are administered at the state and federal levels leads to severe health inequities within the United States: where you live impacts what services are available to you as well as what you can afford.

Dr. Martin presented findings from her own research that sought to determine the mental health indications most likely to be covered on ADAP formularies and the state factors that are associated with early inclusion of mental health drugs.

Regression analysis examined the time to adoption for four categories of psychotropic medications in state ADAP formularies. Seven state level factors were investigated: case burden, the size of the federal Ryan White allocation, political orientation, total taxable resources (a measure of state wealth), whether the state passed a mental health parity law, number of psychiatrists per capita, and the size of the state mental health budget.

The study resulted in four main findings: 1) Antidepressants are the most common psychotropic medicines likely to be included in ADAP formularies; 2) Many states do not routinely cover mental health drugs at all; 3) Federal Ryan White allocation size, state political ideology, and number of psychiatrists per capita were all associated with earlier adoption of mental health drugs; and 4) Wealthier states were more likely to be early adopters of drugs to treat anxiety.

The cumulative number of states that have ever included mental health drugs in their ADAP formularies has increased since 1997. In 1997, 10% of states had adopted drugs to treat at least one mental health indication and this increased to 82% in 2008. While this is encouraging, explained Dr. Marin, this also means that by 2008, one in five states had not included psychotropic drugs on their ADAP formularies. Therefore, the size and scope of drug formularies available to HIV infected individuals is dependent on where a person lives.

As her published research focused on the inclusion of treatments for mental health disorders in state ADAPs but did not include substance abuse medications, Dr. Martin presented preliminary data about the coverage of substance abuse medications. These analyses, prepared specifically for the conference, coded whether ADAP formularies included drugs to treat alcohol, nicotine, and opiod dependency as determined by NIDA's Principals of Drug Addiction Treatment guidelines.

Dr. Martin's preliminary research indicated that by 2008, 66% of states had included at least one substance abuse medication while 33% states had adopted at least two. Drugs to treat tobacco addiction are the most commonly included; however, she cautioned that this may be because many states included Zyban, which is also used to treat depression. Fewer than 33% of states included any drugs to treat opiod addiction and only 25% of states included any drugs to treat alcohol addiction.

Stressing that the both analyses had limitations, Dr. Martin summarized her findings as follows: Although there are a lot of studies about the importance of treating mental health and substance abuse in persons living with HIV there has not been a lot of work about the political factors that affect access to psychotropic medications. Treating mental health and substance abuse disorders is important in implementing the National HIV/AIDS Strategy (which includes lowering transmission and improving quality of and access to care) and it is valuable to think about how broader state and national policies can affect access to medications.

Medicaid expansion as part of national healthcare reform is a real opportunity to increase health care coverage to this population. In addition to the Medicaid expansion, there is a new federal mental health parity legislation that addresses private insurance coverage for both mental health and addiction treatment. Last, the long-standing ban on syringe exchange programs has recently been

repealed and although this is largely symbolic (as no money has been allocated), it signals an important shift in thinking at the national level.

While the potential for structural change exists, there remain some daunting challenges that will affect all publicly financed programs, cautioned Dr. Martin. The recession has led to chronic state budget problems and ADAPs have already been affected: many drugs were dropped on the 2010 formularies and ADAP waiting lists are expanding in many states. The Ryan White program is scheduled to be reauthorized in 2013, but Medicaid expansion will not commence until 2014. It is uncertain if the Ryan White program will continue to be funded at its current rate, if it is going to be fundamentally altered, or if it is going to exist at all. In theory, more people living with HIV will have access to insurance through Medicaid expansions but that does not guarantee access to mental health drugs if Medicaid formularies are limited or restricted. And finally, with the upcoming election cycle it is unknown what is going to happen with federal and state budgets and support for HIV care.

DeAnn Gruber, PhD, LCSW
Louisiana Office of Public Health STD/HIV Program | New Orleans, Louisiana

From her perspective as a State AIDS Director, Dr. Gruber provided a personal account of the challenges and opportunities facing leaders and decision makers as they work to meet the needs of community members living with HIV.

In many ways, the State of Louisiana is an exemplar of the findings of Dr. Martin's research. Louisiana is a poor state with limited general fund support for HIV/AIDS services. Despite strong advocacy and continued education, there has never been general fund allocation to the state's ADAP program, reported Dr. Gruber. Over the last two years, the state budget has completely eliminated the $2.5 million in general fund contribution to the state's AIDS program resulting in dependency on federal dollars and collaborative partners, in order to provide services for HIV infected individuals.

Louisiana has always had a limited ADAP formulary, primarily due to a lack of resources. Until 2007, the only drugs on the formulary were ART. In 2007, a small budgetary surplus allowed a long awaited reassessment of the formulary and presented an opportunity for expansion. A review panel was established and mental health drugs were discussed. There were some who felt it was very important, but the group chose to invest in opportunistic infection prophylaxis.

The state continues to have a very limited and restricted ADAP formulary although in 2008, the eligibility criteria were expanded from 200% to 300% of the federal poverty level. The number of people served grew by 15% and expenditures increased 33%. The dramatic increase in expenditures meant that the program was going to have to be modified again and in June 2010, the very difficult decision was made to close enrollment into the ADAP program and thus become one of 12 states with a waiting list.

The State of Louisiana is faced with many challenges, but Dr. Gruber was quick to assure that public health leadership is committed to making HIV treatment work. Efforts have been made to take advantage of the State's generous Medicaid program by successfully lobbying for the removal of prescription restrictions for HIV+ individuals. Relationships with the Office of Behavioral Health have been improved in order to refer people into their services for treatment and care. The state's

STD/HIV Program has also partnered with local Ryan White Part A recipients (New Orleans and Baton Rouge) to support drug regimens not covered by ADAP, including mental health drugs.

Plans are already being prepared to take advantage of potential opportunities that may arise as a result of health care reform. Although no one is sure what it is going to look like, efforts are being made to identify places where ADAP dollars can be better leveraged, for example, by paying premiums or co-payments for health insurance plans. Dr. Gruber emphasized that similar efforts were being made to implement these types of strategies across the country, especially in southern states that are particularly hard hit by budget crises.

"Yes, we certainly do have an ADAP crisis in our country and the resources are not there to be able to expand formularies…I know that there are other mechanisms and strategies that we will continue to explore and implement on the state level. If it is not ADAP, then it will be another way to get these services provided to people who need them."

AFTERNOON PLENARY: TREATMENT AS PREVENTION, NEXT STEPS

Carl Dieffenbach, PhD
Division of AIDS National Institute of Allergy and Infectious Diseases |Bethesda, Maryland

Dr. Carl Dieffenbach closed the conference with an overview of the fundamental changes to discussion, dialogue, and possibilities in the era of treatment as prevention.

Thirty years into this epidemic, we are in a process of transition from managing an infectious disease to managing a chronic disease. Yes, HIV is an infectious disease but once HIV-infected and identified as HIV+, management of the disease requires a new set of tools that have not been fully embraced. The long term challenge becomes figuring out how to make the transition in an effective way in order to maximize the use of the tools we have available.

If we consider the time frame around exposure and infection there are a number of means to prevent HIV transmission. These include the periods prior to HIV exposure where structural, behavioral, and vaccine based interventions could have the biggest impact. At the time immediately prior to coital exposure, agents like condoms, microbicides, PrEP and vaccination would have the biggest impact. Post exposure PEP, and vaccines would be the tools that might prevent establishment of infection. Now with treatment as prevention we know that ART provision with good follow up and complete viral suppression results in a significant drop in HIV transmission among discordant partners.

Moving forward, the challenge becomes what to do with all of the information. No single strategy is sufficient to tame the AIDS epidemic and we need to utilize a toolkit that is refreshed and kept up to date and employ targeted strategies to reach specific populations. It is not sufficient just to develop and deploy the tool, stressed Dr. Dieffenbach, for people have to be able and willing to take advantage of the activities available to them.

It has been a good run of two and a half years and data from the CAPRISA and iPrEx trials indicate the tremendous influence of behavior on efficacy. CAPRISA illustrated a vaginal microbicide gel with 39% overall effectiveness while the iPrEx trial results showed a 44% reduction in incidence

with oral prophylaxis. The PrEP trials had a profound reduction in those with high adherence but nearly no effect in those with low adherence. Dr. Dieffenbach called attention to the large confidence intervals on each of the studies: The lower bound on CAPRISA showed 6% efficacy. These wide confidence intervals and the lack of demonstrated efficacy that resulted in discontinuation of the FEM-PrEP trials further reinforce the need for the linkage between biomedical and behavioral strategies and highlight the importance of managing the patient as a whole and not just the disease by itself. Both CAPRISA and iPrEx are examples of tools that, if used properly, could have significant effect; but used improperly, could be extremely problematic.

"What we have are a large number of trials with large confidence intervals that really are affected by social, behavioral, and other consequences," and this is the challenge in the next range of trials. How do we make these results more generalizeable? How do we engage the behavioral side to improve the efficacy and narrow the confidence limits?

Dr. Dieffenbach provided an overview of the demonstration projects being administered or planned. The ongoing VOICE trial in South Africa will finally answer the questions about PrEP and microbicides in women. With two study arms (one that provides oral pre-exposure prophylaxis and the other that provides a microbicide gel), the study has the potential to support or refute what was found in CAPRISA and help to nail down questions about Tenofovir and Truvada in women. iPrEx Ole, an open label trial to assess adherence to oral PrEP, is the first step in understanding how to roll PrEP out and demonstration projects are being planned in San Francisco and other major metropolitan areas.

"There remains a dynamic tension in this field, particularly in the areas of PrEP and microbicides. Now that we have some success what do we do with this? Do we optimize what we have or do we move on to the next generation?" It is healthy tension, stated Dr. Dieffenbach, and requires a level of discussion. Should we build upon the current technologies and create rings, implants and injectables based on Tenofovir or do we invest in a more efficacious starting point with a different oral formulation?

Switching gears, Dr. Dieffenbach concluded his plenary discussion with a synopsis of the emerging research agenda as we go forward with a test and treat strategy. Utilizing treatment as prevention, in the form of the test and treat strategy, is a good idea but a highly utopian approach, stated Dr. Dieffenbach. The HPTN052 study convincingly demonstrates that treating the infected individual can have profound influence on linked transmission but there are significant research challenges that will need to be addressed in order to fully understand what it will take to successfully implement a test and treat strategy work in a real world setting.

There exist significant challenges to implementation, understanding the barriers to testing, and ensuring that cost effective and strategies are effectively employed. Stressing the cascade model employed by Dr. Grossman earlier in the day, Dr. Dieffenbach stressed the importance of managing the whole patient and not just the disease, especially when dealing with populations affected by mental health or substance abuse disorders. "We as people who are responsible with implementing the President's National AIDS Strategy need to acknowledge that and need to acknowledge that we need to change many of the things we are doing, particularly in the area of linkage to care." If test and treat, or treatment as prevention, is going to have the kind of eye popping effect that studies shown it is capable of, we are going to have to improve our numbers in each step of the treatment cascade.

Proven prevention strategies are behaviorally dependent and we need to start thinking about the next generations of products – agents that can be better utilized by larger numbers of people. If we can come up with exciting new tools that help us manage that component of the disease, we can get to a point where the tools can control the epidemic. Control and elimination within our lifetime remains our goal.