HIV Testing: Global Challenges, Global Strategies, Global Impact

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Conference Proceedings

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BACKGROUND

The expansion in availability and utilization of HIV testing is an international health priority. In the twenty-five years since the detection of HIV, testing for the presence of infection has become a cornerstone for prevention and treatment efforts. Central to the global expansion of HIV testing efforts are the protection of human rights to unfettered access and voluntary informed consent.

Over the last several years epidemiologic modeling has suggested that spread of the HIV epidemic may be halted through an aggressive test and treat strategy that seeks to identify persons affected by the disease and offer immediate initiation of antiretroviral therapy. While a test and treat strategy is not without controversy, the idea of universal voluntary testing is integral to any and all HIV related outreach.

Despite aggressive efforts to increase access to voluntary testing and counseling, the percentage of HIV-infected individuals who are aware of their status is alarmingly low: globally, more than half of all people who are HIV-positive are unaware.

Pragmatic realities surround the capabilities and limitations of testing technologies, barriers to access, associated stigmas, the linkage between detection and treatment, resource allocations, and health systems readiness. In order to capitalize on the potential of HIV testing as a valuable prevention strategy, new approaches to testing outreach and utilization must be developed and shared.

CONFERENCE GOALS

HIV Testing: Global Challenges, Global Strategies, Global Impact was held on July 17th, 2010, in Vienna, Austria, one day prior to commencement of the XVIII International AIDS Conference.

The one-day conference was sponsored by the Center for HIV Identification, Prevention and Treatment Services (CHIPTS) in collaboration with the National Institute of Mental Health and the Ford Foundation. As the fourth of five annual meetings looking at the social and behavioral implications of emerging biomedical interventions for HIV prevention, the conference brought together leaders in program implementation and biomedical, behavioral, and economic research to identify and discuss opportunities and challenges in global HIV testing efforts.

Andrew Forsyth, Project Officer for the National Institute of Mental Health, and Mary Jane Rotheram, Director of CHIPTS, opened the conference and welcomed participants and presenters to an assemblage aimed at the identification of challenges, strategies, ethical issues, public policies, and cost-effectiveness of HIV screening and testing as prevention tools.

BRIAN WILLIAMS, PHD
South African Center for Epidemiological Modelling and Analysis (SACEMA), Stellenbosch, South Africa

As a leading researcher recently retired from the World Health Organization and a co-founder of the South African Centre for Epidemiological Modelling and Analysis, Dr. Williams opened the conference with an overview of the potential of a universal and aggressive test and treat strategy to eliminate HIV.

In the 25 years that we have knows about HIV, we have spent $150 BN USD and published more than 50,000 academic papers, yet we have failed significantly reduced the transmission of the virus, Dr. Williams cautioned. While mortality rates have dropped slightly due to increased access to antiretroviral therapy (ART), the growing global prevalence of HIV indicates that new strategies must be adopted in order to curb the spread of disease.

Using advanced epidemiological modeling, Dr. Williams and a team of WHO researchers explored the feasibility of eliminating the HIV epidemic through universal treatment of HIV-infected individuals[1]. In order to curb the epidemic, transmission must be reduced by a factor of seven: if the risk of infection is $1/7^{th}$ (15 percent) of what it is now, transmission will be reduced by 85 percent and spread of the virus could be halted. By offering universal voluntary testing and counseling and providing an option of immediate ART initiation for people found to be HIV-positive, it should be possible to achieve this level of reduction. The success of such a strategy hinges critically on the extent to which ART reduces transmission.

Treatment as prevention, in the forms of universal application of a test and treat strategy with annual HIV testing, has the potential to reduce transmission of HIV by up to 80 percent. Biomedical prevention intervention, such as male circumcision and vaginal microbicides, have been shown to decrease transmission by up to 37 percent while behavioral interventions can decrease transmission by approximately 32 percent. A combination of male circumcision, behavioral intervention, and the universal test and treat strategies has the potential to produce a 92 percent reduction in transmission - eight percent greater than the 85 percent transmission reduction needed to eliminate HIV in the population.

Results from the epidemiologic modeling raise two essential questions: how frequently to test and when to commence ART? Using data presented in a 2009 paper he co-authored, Dr. Williams presented a compelling argument for the initiation of an annual testing and immediate treatment strategy in South Africa. The WHO currently recommends commencing ART at a CD4 count of 350/uL: a strategy that is expected to reduce (but not eliminate) mortality, incidence, and prevalence

[1] Granich RM, Glicks CF, Dye C, De Cock KM, Williams BG. Universal voluntary HIV testing with immediate antiretroviral therapy as a strategy for elimination of HIV transmission: a mathematical model. Lancet 2009; 373: 48-57.

by 2040 while necessitating maintenance of ART provision to infected individuals. In contrast, the epidemiologic model illustrates that immediate commencement of ART at any CD4 count could eliminate incidence by 2020, reduce mortality rates, and greatly decrease the number of people requiring ART treatment by 2040. Annual testing and immediate treatment is not only projected to eliminate incidence and prevalence, it incurs the lowest long-term costs.

The benefits to a universal test and treat strategy are not limited to HIV. In South Africa, tuberculosis (TB) is a major cause of morbidity and mortality and its co-incidence with HIV is well documented. TB increases exponentially as CD4 counts decline and ART decreases the risk of TB by 60 percent. A test and treat strategy has the potential to halve the rate of TB in HIV-positive individuals in the short term and HIV-related TB in the long term.

A universal test and immediate treatment strategy is not without concern and Dr. Williams discussed arguments related to the health effects on individuals, drug resistance, logistical practicalities, and costs. Recent evidence indicates that the adverse effects of early-initiation of ART on both individual health outcomes and on drug-resistance are minimal while the acceptability of treatments are high. Furthermore, immediate initiation overcomes some of the inherent problems associated with obtaining CD4 counts in resource-challenged environments and the approach actually results in significant long-term cost savings when compared to current policies of delayed treatment initiation.

Dr. Williams concluded with a proposed three phase implementation strategy to make universal testing and immediate treatment a reality: feasibility studies to investigate compliance, viral load suppression, residual transmission, externalities, and costs; impact studies to look at population incidence and issues of scale; and a well-funded scale-up that is conducted rapidly but with care. "We have the tools, the knowledge, and the wherewithal. The question is, do we have the political will to do it."

TIMOTHY D. MASTRO, MD
FHI, Durham, North Carolina, USA

From his vantage as Vice-President of a large multi-national health and development organization, Dr. Mastro provided an overview of the complex considerations on universal testing strategies to eliminate HIV.

Know your epidemic! Although we know what works for HIV prevention (e.g. condoms, male circumcision, PMTCT, clean injection equipment, and knowledge of status), Dr. Mastro cautioned that transmission dynamics vary across populations and that in-depth understanding of where transmission occurs in a particular environment is critical.

Results from the "Know your Epidemic" project are beginning to document some of the complicated sexual networks that foster differences in transmission dynamics in several Sub-Saharan nations. Due to the complexity of such networks and the nature of the disease, it is imperative to

reach the right people early and with the proper testing technologies. Oftentimes those most at risk for transmitting the virus (individuals with early HIV infection, high viral levels, late stage infection, and/or in active transmission networks) are not the same people that are most willing to test for the presence of infection.

There have been great strides in HIV diagnostic technology in the last decade, Dr. Mastro observed. Whereas the first generation of antigen detecting technologies was capable of detecting the presence of HIV 40-45 days post-infection, current 4th generation combination antibody/antigen are capable of detecting virus 16 days post-infection. Rapid HIV tests utilize 3rd generation technology which detects virus 20-25 days after infection while viral RNA testing has the potential to reduce the delay to about 11 days.

Currently, HIV testing can be categorized into eight different types: client-initiated voluntary counseling and testing (VCT); home-based programs; venue-based programs; routine testing initiated by health care workers; diagnostic requests made as part of a larger blood work-up; required without consent (e.g. military and immigration); blood and tissue donation; and medical research.

Although it is widely documented that HIV-positive individuals substantially reduce their high-risk behaviors after they become aware of their infection, Dr. Mastro stressed that generalized knowledge of status does not have consistent beneficial effects. For HIV-negative individuals, knowledge of status is a mixed picture. Results from three meta-analyses (from both developed and developing nations) indicate that although HIV-negative VCT recipients in developing countries reported that they were less likely to have unprotected sex following the testing, there was not a significant modification of risky behaviors in the developed world. VCT was not associated with reductions in the number of partners in any of the analyses.

Dr. Mastro used data from Kenya to illustrate some of the more pressing challenges to HIV testing efforts. In Kenya, nearly one in 10 married or cohabitating couples is affected by HIV and 61 percent of those couples are sero-discordant. Equally alarming, of all HIV-infected persons in Kenya, 56 percent have never tested for HIV and 28 percent reported a negative result in their last HIV-test. Eighty-four percent of HIV-infected adults were unaware of their status. Home-based, door-to-door, mobile and community based testing programs are being ramped-up in order to combat these unfavorable realities.

Dr. Mastro stressed that the economics of testing are imperative when making programmatic decisions for it will take a huge number of tests and tremendous investment in order to raise global testing efforts to an effective level. Yet, these costs cannot be avoided as HIV testing is the key to prevention, care, and treatment. New strategies will expand HIV testing coverage while new diagnostics may lead to greater efficiency, but a massive scale-up will be required to achieve universal testing. "Proper delivery is imperative and we can't promise something that we can't provide."

BERNARD M. BRANSON, MD
Centers for Disease Control and Prevention Division of HIV/AIDS Prevention, Atlanta, Georgia, USA

As the chief architect for the CDC's activities surrounding HIV testing technologies, Dr. Branson outlined the evolution of HIV testing and the effects that scientific progress has had on the paradigm for disease identification and care.

Currently we are on the fourth generation of enzyme immunoassay (EIA) testing technologies, Dr. Branson explained; and each generation shortened the timeframe of undetectable infection. The first and second generation EIAs detected the presence of IgG HIV antibodies and could identify the presence of the virus 40-60 days after infection. The third generation EIAs added the capability to detect the presence of IgM antibodies and allowed for diagnosis approximately 20 days after infection. Fourth generation technology detects both the presence of HIV antibodies and p24 antigen and can capture the presence of HIV 16 days post infection.

In addition to the fourth generation EIAs, advanced (and costly) RNA testing can detect virus 11 days post infection. While our current technologies are impressive, Dr. Branson noted, the reality is that an 11 day interval between infection and detection still exists – a reality with important consequence. This 11-16 day period of undetectable infection corresponds to the beginning of the acute phase of HIV infection, a period critical in both the transmission of disease and the "capture" of HIV-infected individuals.

Lasting approximately 3 months from the time of infection, the acute phase of HIV plays an important role in transmission of disease. Because viral loads are higher, the risk of transmission is greater. Consequently, acute transmission counts for at least 11 percent and perhaps a lager proportion of all new HIV infections. In addition, at least half of the people with acute HIV infection seek medical care due to symptoms of acute HIV. Because antibody tests cannot detect the presence of their infection and the low likelihood of an HIV RNA test for persons presenting with generalized symptoms, an important opportunity is lost to identify the disease during its most infectious stage. "The reality is that we can't close the interval, even when testing people relatively frequently in areas with high prevalence," Dr. Branson explained. When it comes to our HIV testing programs, "we need to understand what we're missing and what we're really getting at."

Our current testing algorithms have limitations that compound the issues associated with the detection interval. In high incidence populations such as men who have sex with men, current antibody tests (which include both rapid HIV tests and Western blot confirmation) do not detect infection in approximately 10 percent of infected persons who seek testing, persons who are in the acute phase and at highest risk of transmission. The Western blot traditionally used for confirmation is less sensitive during early infection than many widely used screening tests. With

more sensitive, laboratory-based tests for RNA or p24 antigen, delays inherent to centralized screening (e.g turnaround time for tests sent to a laboratory for analysis) reduce the "effective sensitivity" because infected individuals fail to receive their test results.

In 2010, the CDC proposed a new diagnostic algorithm that would take advantage of newer, more sensitive tests and overcome some of the shortcomings of Western blot confirmation and thus reduce the numbers of infected individuals who get tested but remain unaware of their infection. After a reactive 4th generation test (that detects HIV-1 and HIV-2 antibodies and p24 antigen), an antibody test that differentiates HIV-1 from HIV-2 antibodies would be performed. Referral to care (where an HIV viral load would be performed) would be initiated based on detection of the presence of antibodies. Specimens that test positive on the 4th generation test, but negative in the subsequent antibody test would then undergo RNA testing (indicative of acute HIV infection if positive) and patients would be referred for medical care and intensive prevention interventions..

Dr. Branson then discussed the role and future of rapid HIV testing technology. The U.S. Food and Drug Administration (FDA) has approved one oral fluid, two serum/plasma, and four whole blood rapid tests that have been used throughout the United States to increase the numbers of people aware of their status. Not only does rapid testing technology increase the receipt of test results, it also increases the feasibility of testing in acute-care settings with same-day results, and increases the number of venues where testing can be offered to high-risk persons. Yet, Dr. Branson noted, these tests are not without disadvantages, including higher cost, personnel and quality assurance requirements, and lack of easy interface with lab information systems. Perhaps most importantly, most of these rapid tests utilize 2nd generation technology that detects IgG antibodies 40-60 days after infection. In contrast, a 4th generation rapid HIV test that can detect antibodies and p24 antigen is now available that can detect infection as soon as 20 days after infection.

Cautioning that "there is no perfect test," Dr. Branson concluded his presentation with an overview of the future of HIV testing technologies. Point of care RNA detection technology is on the horizon: tabletop assays, using blood taken from a finger-stick, will be evaluated in clinical trials over the coming year and handheld, battery-operated, microfluid-based assays are currently under development and expected to be tested in clinical trials within the next five years.

ZUNYOU WU, MD, PHD, MPH
National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention, Beijing, China

Dr. Wu began the session on ethical issues related to HIV testing by focusing on three areas with specific relevance to the HIV epidemic in China: late testing, the testing of spouses of heterosexual HIV-positive individuals, and the testing of spouses of HIV-positive MSM.

Late stage disease diagnosis, due to late testing, is one of the largest problems facing Chinese health officials. In 2009, more than 20,000 individuals were diagnosed with AIDS. For more than 15,000 of those individuals, the diagnosis marked the first time they had been tested for HIV. In the same year, more that 80 percent of the 12,287 individuals who died from AIDS-related complications died before they were offered ART. Of the 20 percent receiving treatment, half began their treatment in the late stage AIDS progression. Dr. Wu attributes much of late testing behavior to individual beliefs that they could not be affected by HIV and a desire to avoid confronting reality: the later the disease diagnosis the better.

In addition to the spread of HIV through sexual or IDU networks, China has a unique problem of HIV among blood and plasma donors. Since the 2004 inception of a massive testing campaign for former plasma donors or blood transfusion recipients sponsored by the Chinese Center for Disease Control and Prevention (China CDC), over 15,000 cases of HIV/AIDS have been identified.

The spouses of infected individuals are a major source of concern for public health officials. As stigma remains an important component to the HIV epidemic in China, health officials grapple the reality that spousal notification may not be an option for many HIV-infected individuals. "From a public health point of view we are interested in the number of people being infected," stated Dr. Wu, and oftentimes, the disclosure of results could mean expulsion from the familial networks and community which officials fear could do even more damage by spreading the disease, "... if we do not work with them correctly, they may infect even more people."

HIV within MSM populations was another major topic of concern introduced by Dr. Wu.
In the past few years, the prevalence of disease within MSM populations has increased dramatically. Alarming to public health officials are recent data indicating that 97 percent of Chinese MSM also partnered with females. A survey of 585 MSM indicated that 31 percent were married. Eight percent of those were infected with HIV and 22 percent were infected with syphilis. Dr. Wu explained that MSM generally accepted, and encouraged, testing of their male sexual partners but the same individuals were strongly averse to informing their female partners of their need to test for HIV.

In conclusion, Dr. Wu summarized the ethical challenges facing Chinese public health officials and explained that much comes down to the need to protect women who are unaware of their husband's engagement in high-risk sexual relationships. "Without a successful HIV testing program, treatment as treatment and treatment as prevention will not work."

JEREMY SUGARMAN, MD, MPH, MA
Johns Hopkins University, Baltimore, Maryland, USA

As a leading scholar in both theoretical and empirical medical ethics, Dr. Sugarman presented the ethical values in conflict in HIV testing.

HIV testing is central to enhancing prevention of HIV infection and treatment for those infected with the virus. Broad moral claims are often made to justify the implementation and expansion of HIV testing programs, yet HIV testing is not value free.

Multiple strategies have employed different constructs (e.g. mandatory, universal, opt-out) to achieve the goal of increased testing, noted Dr. Sugarman. However, the act of testing itself carries a series of unanswered empirical claims about what is going to work in practice.

In clinical care, HIV testing is performed in order to help the patient identify and manage infection. In public health settings, the focus shifts to the health of the population. In research testing is utilized to determine what works best for treatments, prevention, and even different testing strategies themselves. In each of these three realms, separate ethical systems or frameworks are commonly employed and different ethical requirements are emphasized. With respect to different HIV testing strategies, the central ethical question becomes "what ethical framework or frameworks might be employed to help determine appropriate testing policies…which best protect the rights and interests of those being tested while also addressing the enormous burden of HIV infection?" The answer depends, in part, upon the domain in which the question is being asked.

Within a clinical setting, ethical considerations emphasize the interests of the individual, Dr. Sugarman explained. The discipline of medicine is focused on taking care of people and centers around beneficence (the act of doing good), non-malfeasance (no harm to individuals), and egalitarian justice wherein equality among individuals is generally privileged. In the clinical setting, shared medical decision making, along with informed consent in specific circumstances, are applications of some of these principles.

Ethics in public health are similar but the focus shifts from the individual to the population. Beneficence exists but the focus is on the health of communities rather than the individual. Respect for autonomy is present but the emphasis is on requiring the least restrictive alternatives rather than on individual decision making (e.g. it is less restrictive to observe a patient taking TB medicine than using quarantine, which is reserved for those who will not take the medication under direct

observation). In public health, social justice and a utilitarian approach to population health takes into account aggregate risks and benefits across multiple sectors in a society.

Finally, the ethical framework in the research setting emphasizes the ethical principle of respect for persons in that the rights and interests of individuals are paramount since research is not conducted to provide benefit to the individual. Beneficence is also important in research ethics but the balancing involves the expected benefits of the knowledge to be gained against the risks born by the subjects.

Warning that the ethics of HIV testing are often discussed without consideration to the sphere in which they lie, Dr. Sugarman posed the following, "what do we do in those settings where we have muddling of which ethical approach to use because we are as a practical matter working across spheres?" First, we must be sensitive to the normative aspects of the testing practice. There will be different expectations for what will happen in the process of HIV testing in a public health setting compared to a doctor's office, and these expectations need to be acknowledged and honored, Dr. Sugarman noted. Policies and systems can be helpful in clarifying such expectations and community engagement could be utilized to effectively craft these policies. Informed consent is often an integral element.

Dr. Sugarman described that there are two senses of consent – autonomous authorization and social rules of consent. The idea of autonomous authorization stems from a "littered history" in which individuals were subjected to uninformed and unauthorized medical procedures. As a result, obtaining specific informed consent for all major medical procedures is imperative. Social rules of conduct refer to institutionalized norms such as special consent forms or the presence of witnesses during the informed consent process. Such rules are put in place to both remind providers what ethics demands and to facilitate doing a good job.

Obtaining informed consent is a three step process. First, the person giving consent must exceed the threshold criteria of having adequate decision making capacity and being positioned to make a voluntary choice. "Informed consent is largely, but not completely, a cognitive act," Dr. Sugarman explained. Having adequate decision making capacity means that the individual must be able to absorb information, use it, process it, make a rational decision about it, and then be able to express that choice. For those with decision making capacity, it is important to ensure they are positioned to make a voluntary choice. Special consideration must be paid to those people with less power in society and relationships - oftentimes women, children, and those dependent on care are not in the position to make a voluntary choice and informed consent becomes a charade, he cautioned.

Second, once the threshold has been met, informed consent requires providing information in a way that is understandable. This includes information about the test as well as benefits and harms. For example, the act and process of testing carries certain context dependent stigmas that can lead to physical, psychological, economic, or social harm. Further, it is of arguable importance to include

information about such issues as potential linkage to care, the capacity to guide personal decisions about care, the ability to deal with both true and false test results, and the implications a result has on behavioral change that affects both the health of self and others.

Dr. Sugarman concluded with strong emphasis on the importance true informed consent for HIV testing. A range of values are in conflict in the HIV testing process and explicit, informed, consent provides a means of negotiating these competing realities.

THOMAS J. COATES, PHD
UCLA Program in Global Health, Los Angeles, California, USA

As the themes in HIV testing continue to evolve, the challenge becomes how to accommodate them all. Nearly a decade after embarking on a study examining the impact of community based provision of VCT, Dr. Coates shared the emerging results from NIMH Project Accept and discussed their implications for the future of HIV testing efforts.

During the 1990s, Dr. Coates was involved in the Voluntary HIV-1 Counseling and Testing Efficacy Study Group - a USAID-funded randomized controlled trial designed to determine the effectiveness of VCT as a preventative tool. Results from the study indicated that not only was VCT associated with a significant reduction in unprotected sex with non-primary partners, it significantly reduced the episodes of unprotected sex in couples co-enrolled in the study, and was determined to be a very cost effective HIV prevention method.

The study resulted in a change in policies and direction of prevention resources at USAID and produced significant information concerning critical components to HIV testing. The researchers concluded that opportunity costs and associated stigmas prevent many from utilizing VCT services. For those that do, confidentiality and counseling are highly valued. Many people enjoy the opportunity to discuss their life circumstances with a trained professional and talk about their reasons for being there. Equally important as the quality of pre-testing services is the significant need for post test support. Ignoring that need is a lost opportunity in prevention. Findings like these, Dr. Coates explained, led to the development and implementation of the NIMH Project Accept – The Impact of Community-Based VCT.

Project Accept is a randomized controlled trial with well over 100,000 participants in four countries in Sub-Saharan Africa and South East Asia (South Africa, Zimbabwe, Tanzania, and Thailand). Designed to compare two approaches to VTC, communities were randomized into either the Standard VCT (SVCT) with clinic based services or the Community-based VCT interventions (CBVCT).

CBVCT is comprised of four elements: community preparation, outreach and mobilization; provision of mobile VCT; post-test support; and ongoing data feedback and field adjustments. This last component was absolutely critical, emphasized Dr. Coates, "it wasn't enough to set up the program and just do it." Data collection and dissemination systems were established to provide the sites with monthly feedback to the sites, which was then used to readjust recruitment and outreach strategies to ensure that recruitment goals were met.

"As with many things, it took time…time to both learn how to reach the community and possibly for the community to accept testing as a mode." stated Dr. Coates "Just to go in and do the testing in a one-shot kind of affair would not have worked. It took time, effort, adjustment, re-adjustments, and new mobilizations to make sure we reached the kinds of goals we were trying to reach."

In the three years of intervention, Project Accept was able to test and counsel 54 percent of individuals aged 16-32 in the CBVCT communities. Dr. Coates was especially pleased at the effect of the intervention on relatively younger clients who may not have been reached otherwise. In addition, the CBVCT did a very good job of reaching men, a demographic group that remains one of the biggest challenges to HIV prevention and treatment efforts. Dr. Coates revealed that the CBVCT strategy was not particularly effective at reaching couples and he believes that home based, door to door testing is a more appropriate strategy to reach this particular population.

For all age groups, repeat testing was more common in the intervention sites, indicating that the program is effective at inculcating a culture of repeated testing in order to remain informed about personal HIV status. While more people tested positive at standard VCT sites (probably because people seeking such services were more symptomatic), the CBVCT identified a greater number of infections because of the larger numbers of people tested. In addition to the aggregate number of newly diagnosed cases, Dr. Coates stressed the impact of testing on prevention for HIV-negative individuals.

Currently in its 10th year, Project Accept is in the final stages of post-intervention data collection and evaluation. A random sample of 18-32 year olds is being selected from intervention communities – 13,000 of whom will participate in an extended behavioral survey and the reminder in a more condensed version. 50,000 blood samples are being collected to determine HIV incidence and qualitative and cost-effectiveness components are currently underway. At study commencement there was concern that a decade of research might conclude with antiquated results. However, unfortunately, the pace of change isn't as rapid as we might like it to be and the results will still be relevant.

What has become apparent as the decade-long study comes to a close is the impact of mobilization, post-test support, and local access on enhanced uptake of HIV testing. Delivered in conjunction with one another, these services can have a significant impact on HIV testing behaviors and service utilization.

In spite of all of the emerging successes, Dr. Coates cautioned that the big question still remains: will large scale community-based VCT significantly reduce HIV incidence? The post-intervention data from Project Accept currently under collection and analysis will provide us with some of the answers in the next two years.

BRUCE FORGRIEVE, MBA
Shout-it-Now, Cape Town, South Africa

"The power of marketing works. Branding works. It gets the message across about what people need to know and what they need to do. It increases sales, changes behavior, makes people buy their products. It also works in the fight against HIV."

Silicon Valley veteran and founder of the South Africa-based Shout-It Now, Mr. Forgrieve, spoke to the power of marketing in the efforts to encourage and expand HIV testing among young people.

Shout-It-Now was founded in 2007 by a consortium of businesses leaders and social scientists who came together to try a different approach in curbing the spread of HIV in young people. By leveraging technologies, celebrity, and rewards, Shout-It-Now aims to educate about, and encourage, HIV testing in school-based settings.

Shout-It-Now partners with schools, businesses, South African celebrity spokespersons, and utilizes MTV-style videos to engage school children in online education programs. Shout-It-Now teams go into schools, set up tents with computers, and give students the opportunity to partake in an online HIV curriculum. Following the online portion, students are given the opportunity to meet with HIV testing counselors and test for HIV (as well as screen for TB). HIV-negative individuals are encouraged to stay that way and positive individuals are linked to a health care provider to initiate care and treatment.

"Then we do something very different," explained Mr. Forgrieve, "we give them a prize or reward for doing it." Incentivizing participation takes away the associated stigmas: they can tell their friends that they're not worried about their HIV status, they are merely testing in order to receive the incentive.

A 2008 pilot with 3500 South African students far exceeded expectations. Ninety-five percent of students were able to effectively utilize the online program and 88 percent of the students who watched the video then went for a voluntary HIV test. In addition, there was a 13 percent knowledge increase, and a 92 percent increase in the number of people who decided to submit to an HIV test as a result of participating in the online program. After the successful results, Shout-it-Now garnered additional funding from several prominent institutions, including the CDC, and educated and tested more than 30,000 students in 2009. Through the use of massive scale-up and franchise strategies, Shout-it-Now aims to reach one million children in the next three years.

Mr. Forgrieve credits much of the program's success to the fact that it is both data and technology driven: not only is it based on a comprehensive data set that captures South African students attitudes and beliefs towards HIV education, but the technology allows the program to go to scale quickly and easily while keeping up with changes in said attitudes and behaviors.

VLADIMIR MUSATOV, MD, PHD
Botkin Hospital for Infectious Diseases, St. Petersburg, Russia

Dr. Musatov provided an overview of HIV testing in Russia based on his experience as an infectious disease physician, advocate, and advisor to the Global Fund's implementation in the Russian Federation.

The HIV testing network within the Russian Federation is vast. Each year approximately 21 million people are tested for HIV and there are approximately 550,000 people "officially" living with the disease but unofficial estimates put that number closer to 1.5 million. Within the city of St. Petersburg alone, approximately 500,000 of the 4.4 million inhabitants are tested for HIV annually.

The Russian Ministry of Health (MOH) has established formal recommendations for obligatory testing of at-risk populations. These include blood and plasma donors, certain categories of medical staff, pregnant women (twice during gestation – one at initial visit and the second after the 30th week), babies born to HIV-infected mothers, foreigners (migrant workers and students), and all citizens entering the military or education system. The MOH also suggests testing for all patients with opportunistic infection, unknown HIV status, or tuberculosis; patients at STD and drug clinics; MSM; commercial sex workers; individuals with multiple partners; prisoners; and people who have come into contact with HIV-infected individuals.

Although the MOH states that all people who receive an HIV test should receive pre and post test counseling, Dr. Musatov cautioned that this is merely a formality. Typical pre-test counseling usually consists of being told that a test will be administered while post-test services for HIV-positive individuals consists of little more than the provision of information about a specialized HIV clinic.

Dr. Musatov's hospital, the Botkin Hospital - St. Petersburg Infectious Diseases Clinic, is the largest in the Federation. More than 30,000 patients are seen each year and programs provides specialized services for 4500 PLWHA. The Botkin Hospital also provides laboratory services for the two mobile clinics operated by the Humanitarian Action Charity Foundation – an organization that provides support for vulnerable populations such as commercial sex workers and street children.

Dr. Musatov noted that official and independently collected data vary greatly. Official data state that seven percent of intravenous drug users are HIV-positive while direct testing efforts find the prevalence to be in the range of 20-25 percent. While the MOH does not collect or obtain official statistics for commercial sex workers or street children, Dr. Musatov's research puts the estimates at 48 percent and 37 percent, respectively.

Although there are apparent problems with the official statistics, Dr. Musatov credited the MOH recommendations with the identification of many infections that may have gone undiagnosed otherwise. In 2009, more than 450 HIV-infected women gave birth within St. Petersburg. Among these, 60 percent were initially diagnosed during mandatory pregnancy screenings. Of the 636 patients diagnosed at the Botkin Hospital, 24 percent were detected early and 16 percent were cases with AIDS defining conditions.

In conclusion, Dr. Musatov summarized some of the greatest barriers to comprehensive testing in the Russian Federation. Firstly, there is a lack of information and many people are unaware that they could be affected by the pandemic. Second, many people are trying to move past prior drug additions and work hard to forget past risk behaviors. Thirdly, many positive individuals have difficulty acknowledging, accepting, and acting on their diagnosis. Lastly, there is the ever present need for physical and human capital to scale up competent and effective testing efforts.

YU FEI
Chengdu Gay Care Organization, Chengdu, China

As a section manager for one of China's most prominent community based organizations (CBO), Mr. Yu spoke to the development of a CBO initiated HIV testing-program that works in collaboration with the Chinese Center for Disease Control and Prevention (Chengdu Municipal CDC) to increase HIV testing in the MSM community.

The Chengdu Gay Care Organization (CGCO) was founded in 2002 in order to assist with HIV prevention, gay culture development, and gay rights promotion, largely in response to the low utilization of HIV testing in Chengdu's gay community. Although the China CDC had established testing centers in the city, they were underutilized by the MSM population, Mr. Yu reported. There was an overwhelming feeling of neglect for the MSM lifestyle in the counseling process, while the hours of operation prohibited the willing from attending. Many of those who received an HIV test did not return for their results.

In response to these barriers, the CGCO devised four distinct strategies to increase HIV testing in Chengdu's gay community: 1) make VCT sites more convenient in terms of location and hours of operation; 2) combine intervention work with testing initiatives and utilize gay venue networks, personal networks, and the internet to reach marginalized populations; 3) provide supportive and adequate counseling that utilizes experienced and professional gay counselors; 4) establish a "First Counseling Responsible System" that ensures that same counselor follows their clients through the entire testing process – from pre-counseling, to testing, to providing results, and (when necessary) follow-up services for positive individuals. This system was designed to establish trust between the client and the providers, assist with administrative tracking, and help ensure that people are enrolled into care and treatment services.

Program effects have been well documented and in the two years of CGCO operation, Chengdu's HIV testing utilization has expanded greatly. The number of MSM testing for HIV rose from 243 in 2007 to 1,456 in 2009; the rate of return for confirmatory testing increased from 38 percent to 85 percent in the same time period; and the rate of return for successful follow-up services increased from 33 percent to 92 percent. Mr. Yu stressed the importance of cooperation with health officials, and explained that all of the laboratory work and data reporting went through the Chengdu Municipal CDC.

Scale-up has begun in three more Chinese cities with similar gay-rights activist groups and data is beginning to show success. Of course, this work is not without barriers, Mr. Yu explained. Currently, CGCO funding depends completely on external resources that come mainly from international partners. There is a shortage of human resources and an outmoded reliance on blood-drawn testing that is not only frustrating to clients but creates unnecessary strain on VCT providers. Finally, the lack of CBOs throughout the country prohibits expansion of this successful model into many regions affected by similar barriers to testing utilization.

CHERIF SOLIMAN, MD
FHI, Cairo, Egypt

In Egypt, a nation with low HIV prevalence, hidden and outlawed at-risk populations, and a severe lack of health-related funding, the challenges to implementing HIV testing programs are great. Dr. Cherif Soliman presented an overview of some of the unique challenges facing testing efforts in Egypt and what organizations like his have accomplished in the complex operating environment.

One of the most formidable challenges to the provision of HIV testing in Egypt is the macro environment. Stigma, culture, political relationships, corruption, and the lack of technical capacity make it difficult to institute programs as they should be instituted.

Equally as challenging is the lack of dedicated resources for HIV prevention, testing, care, and treatment. Within Egypt HIV prevalence is still low, yet there are signs of concentration among certain groups (e.g 6.2 percent prevalence among MSM). In light of other public health concerns the disease is not a priority and neither the government nor funding agencies are interested in investment in HIV, Dr. Soliman believes. He went on to explain that what limited funding exists is usually invested in generalized risk-reduction awareness campaigns.

In 1995 Egypt established a comprehensive HIV care and treatment program that included a VCT component. Critical to these efforts was collaboration among organizations and cultural adversaries. Everyone had been engaging in individual and un-coordinated efforts, Dr. Soliman explained, and the first priority was bringing groups together to develop a national and conjoined platform.

Once the major administrative hurdles were overcome, and the system had been established, leaders were more than dismayed by the fact that the most at-risk populations (MARPS) didn't utilize the services. It was established that the providers were the barriers to service utilization and once again, groups were brought together. Religious leaders, providers, and individuals from the MARPS came together in the same room to develop mutually beneficial solutions and increase service utilization.

Dr. Soliman went on to explain that promotion of HIV testing within MARPS still remains a challenge. From a client perspective, there is lack of trust about government services. In response, organizations like FHI utilize peers to encourage VCT: MSM to MSM, sex worker to sex worker, IDU to IDU. Collaborations with community members have led to a beneficial diversification of services. Fixed clinics have become mobile, disparate services have been integrated, and outreach efforts are now combined with comprehensive care.

The fact that interaction with many MARPS groups is illegal presents one of the greatest administrative hurtles in Egypt. Homosexuality and prostitution are outlawed and it is a crime to interact with individuals in these populations. "How do we work in a place with no legal protections even for providers?" Dr. Soliman asked. To get around this obstacle, providers state that their efforts are focused on IDU under the government hospice and harm reduction messaging encompass safe practices for all "risky behaviors."

Despite efforts to overcome some of the macro-level barriers and to ensure that the national HIV prevalence remains low, Egypt still faces many challenges. Female participation in all prevention activities (including testing) remains alarmingly low, technical capacity is lacking (only one laboratory in the country performs confirmatory testing), and there are a limited number of NGOs who are willing to work with MARPS.

Most discouraging to many potential service providers are the sustainability requirements being imposed by external funding agencies. "In a place where everything is hidden and provider salaries are low, how can we talk about sustainability?" posed Dr. Soliman, "…it is impossible to have income generating activities in a place providing services for high risk populations but funding agencies demand it. I can promise you that many VCT providers will close soon because they can't meet funding agency requirements for sustainability." What is needed are strong, flexible funding agencies, intermediaries to translate the information, and technical implementers who can understand, respect, and adapt to these complex operating realities.

JAMES G. KAHN, MD, MPH
University of California, San Francisco, USA

As mounting evidence indicates that an aggressive test and treat strategy has the potential to end the HIV epidemic, the demand for economic analyses of this exciting prevention modality grows. Dr. James Kahn of the University of California, San Francisco presented his research on the estimated cost and cost-effectiveness of ART for prevention in South Africa.

Based on South African health systems data, Dr. Kahn's model investigated cost and cost-effectiveness of a universal test and treat model in which HIV treatment is initiated at various CD4 levels. Outcome measures included trends in HIV incidence and prevalence, deaths, disability adjusted life years gained, cost, and cost-effectiveness. While most cost-effectiveness analyses are based on five to 20 year intervals, this model extended the time horizon to 40 years to better capture the benefits over time.

Key cost inputs were obtained from current expenditures by prominent HIV/AIDS funding agencies and recent prevention efforts in neighboring nations. Costs related to ART were based on the PEPFAR costing schematic, while expenditures related to hospitalizations came from the WHO. Costs of community-based HIV testing were extrapolated from recent outreach efforts in Kenya and Uganda and adjusted to South African wages (the model relied on the assumption that demonstrated community based strategies are efficacious and can be extended). Costing estimates also included a human rights component that included support, monitoring and evaluation, legal representation, and annual independent audits.

Additional key inputs included the assumption of a five-year scale up timeline, annual HIV testing, an ART coverage of 80-90 percent that reflects refusal and drop-out rates, transfer costs from first to second line drugs, and a purposefully conservative estimate on the effect of ART on HIV transmission rates.

Intervention scenarios integrated both ART initiation and external prevention modalities. Four different ART initiation scenarios were modeled: the current standard (CD4 <200); CD4 <350; CD4 < 500; and all CD4 levels. Two different prevention scenarios were investigated: current prevention efforts and an enhanced prevention strategy that incorporates other biomedical interventions (i.e. male circumcision) that result in a lower baseline HIV incidence. Comparisons were made across ART scenarios and within the levels of prevention.

Dr. Kahn reported that each of the model's early ART initiation scenarios resulted in significant cost savings over the next forty years, when compared to the status quo. Initiating treatment at a CD4

count of less than 350 is projected to result in a nearly $4BN of net-savings while an initiation at all CD4 levels is expected to save nearly $14BN.

Initially, lowering the level of CD4 initiation in a test and treat strategy results in an initial cost increase because 1) people will be testing more and 2) the strategy involves the ART initiation in large numbers of HIV-positive individuals who aren't sick and therefore costs associated with treatment are not offset by a decrease in hospitalization expenditure. Although beginning treatment for all HIV positive individuals regardless of CD4 count incurs the greatest initial costs , within 10 years this strategy yields the lowest annual costs. The more intensive the initiation strategy, the greater the drop in discounted annual cost: larger numbers of people on ART translate into fewer hospitalizations, slower progressions to more expensive disease stages, and greater number of new infections averted.

Dr. Kahn cautioned that although this is a very costly strategy, it is imperative to look at the estimated cost savings. Within the framework of the current prevention scenario, a universal test and treat strategy is expected to cost nearly $62 BN over the next forty years; however, this is approximately $14 BN less than a test and treat strategy at current ART initiation levels. The existence of a cost savings, in conjunction with an overall health benefit (reduction in the number of deaths), eliminates the need to calculate cost-effectiveness ratio. He went on to explain that "this analysis that suggests that you're saving money and saving lives. In cost effective and economic parlance this means it's a dominant strategy: it's both better and cheaper."

Although the analysis resulted in net savings for all levels of ART initiation, these figures depend on the model's assumption that drug prices reflect the PEPFAR pricing schematic. Currently, South Africa is paying approximately 20 percent more than the lowest available price for HIV medications. Using the actual costs in South Africa, universal ART maintains a net savings but ART initiation at CD4<350 and CD4<500 incur net costs. However, with cost-effectiveness ratios of $188.5 and $9.07, respectively, initiating ART at these levels is considered to be extremely cost-effective under WHO standards.

Of course, epidemic modeling is not a perfect science, Dr. Kahn warned. As a tool it is inherently imprecise as many assumptions are made and the future is uncertain. The scale up of testing and expansion of ART provision will be difficult to achieve. The model is based on other models of service expansion but large-scale development will be limited by costs and human resources. The reductions in hospital usage were difficult to capture and reprogram and subject to substantial levels of uncertainty. Moreover, the model has purposefully excluded any costs and savings outside of the health care system including the examination of broader economic effects such as the benefits to having a healthier and more productive workforce.

Despite these limitations, there is strong evidence that the expansion of a universal test and treat strategy will not only yield tremendous health benefits in areas affected by the HIV epidemic, but it

can sharply reduce costs over the next four decades. Although there is likely to be an initial increase in expenditure a robust test and treat program will breakeven in less than a decade and has the potential to save $14 BN over the next 40 years.

ROCHELLE WALENSKY, MD, MPH
Harvard Medical School, Boston, Massachusetts, USA

The HIV epidemic in the U.S. differs markedly from nations with generalized epidemics both in the populations affected and the medical costs incurred. Even in the U.S. the promise of new strategies is often tempered by the reality of both finite supply and less than ideal demand. Thus, careful scrutiny of resources allocation is warranted. As an expert in both HIV screening programs and cost-effectiveness analysis, Dr. Walensky presented a comprehensive overview of the economics of test and treat strategies.

In the U.S., the increasing HIV prevalence reflective of longer HIV-related survival in the face of steady disease incidence. The proportion of people who are aware of their HIV-status continues to increase as well. A decade ago it was estimated that 1/3 of HIV-positive people were unaware of their status. Today that proportion is estimated to be approximately one in five. Despite this decreasing ratio, the fact remains that those who remain unaware of their HIV-positive serostatus responsible for more than 50 percent of all new infections. Dr. Walensky noted that "clearly, as we can make new HIV diagnoses, we can potentially decrease the number of new infections that are out there."

In the aggregate, screening and testing programs are expensive and require a large dedication of upfront resources. Are the benefits worth the costs? Cost-effectiveness analysis has become a tool that decision makers can use to allocate limited funding to the more beneficial interventions. A screening strategy evaluated as "cost effective" (CE) doesn't necessarily mean that it is cheap and that it saves money, explained Dr. Walensky. CE means that the additional benefit is worth the additional cost. To obtain a CE ratio, the increased cost of an intervention or service (compared to no strategy) is divided by the additional health benefits derived (usually expressed in quality adjusted life years (QALYs)). That number is often then compared on a sliding scale that is based on the appropriate Gross Domestic Product (GDP), a a potential benchmark to gauge value. The WHO has deemed something "very cost effective" if the CE ratio is less than 1 x GDP per capita for a given country and "cost-effective" is the ratio is less than 3 x GDP per capita for that country. For the US, these benchmarks may be approximated at < $43,000/QALY and <$129,000/QALY, respectively.

Two separate analyses published side-by-side in the New England Journal of Medicine (2005) – led by A. David Paltiel[2] and Gillian Sanders[3] – were among the first to report the cost effectiveness of

[2] Paltiel AD, Weinstein MC, Kimmel AD, et al. Expanded screening for HIV in the United States---an analysis of cost-effectiveness. N Engl J Med 2005;352:586-95.

HIV screening in the U.S. Paltiel's research estimated that testing individuals in high risk populations every five years had a CE ratio of $50,000/QALY gained and even a one-time HIV test is in the general population is marginally cost effective at $113,000/QALY. In a concurrent and independently conducted model, Sanders' analysis included the effects on testing on transmission and determined that HIV screening in populations with one percent HIV prevalence would be "very-cost effective" with a CE ratio of $15,000/QALY.

It is one thing to determine if a particular intervention is cost-effective is but it's quite another to state a threshold of what society is willing or able to pay. Finite resources demand that thresholds have to be created, the value of saving a life has to be determined, and no one really likes to do that, Dr. Walensky explained. "It is very nice for me to be standing up here and say that we should be paying for it because it's worth it but how is this all going to happen?"

In the U.S., public financing for HIV care and treatment services is derived primarily from three sources: Medicare, Medicaid, and the Ryan White Care and Treatment Act (including the AIDS Drug Assistance Program). Both Medicare and Medicaid are entitlement programs with strict eligibility criteria (e.g. income, age, or disability status) and provide care and treatment for HIV-infected individuals. The Ryan White program accounts for $2.2 BN of the $10.8 BN annual allocations for HIV programming, and includes all of the discretionary funds that many jurisdictions rely on to implement testing programs. This funding source has remained essentially flat for the last eight fiscal years.

Using data recently reported by Martin, et al, Dr. Walensky explained that if the U.S. population was screened every five years, testing would comprise approximately 20 percent of the anticipated $2.7 BN increase in costs of HIV care over the next five years. Considering the impact of expanded screening efforts on discretionary programs, and the facts that current public funding streams for ART are already taxed and budgetary allocations have not increased in nearly a decade, the reality is somewhat sobering. Dr. Walensky emphasized that she wasn't implying that it shouldn't be done, only that it demands a lot of thought, analysis, and additional resources devoted to the care and treatment of those who will be identified.

A successful test and treat program model requires navigating a pathway of four sequential and multiplicative processes: someone has to be offered a test, they have to accept, they have to receive their results, and they must be linked to care if found to be HIV-positive. Each step must be completed and failure in any one step results in overall failure of the process.

Using data from her own research, Dr. Walensky explained that an optimized program with 80 percent of patients being offered the test, 60 percent accepting, and 80 percent of those linking to care, has an "index of participation" of only 38 percent (80*60*80). An idealized program, with a 90

[3] Sanders GD, Bayoumi AM, Sundaram V, et al. Cost-effectiveness of screening for HIV in the era of highly active antiretroviral therapy. N Engl J Med 2005;352:570-85.

percent rate across the board, results in a 73 percent index of participation (90*90*90). Alarmingly, a base case that is rooted in actual data from Washington D.C. indicates a 9.4 percent index of participation (31 percent offered, 60 percent acceptance, and 50 percent linked to care).

Using this base case index of participation of 9.4 percent, Dr. Walensky and her team modeled the impact of test and treat strategy in Washington D.C. Annual screening with immediate ART initiation has the potential to increase the life expectancy in HIV-positive people by 1.1 years and reduce the number of secondary HIV cases by 15 percent in five years. Results of sensitivity analyses illustrate the importance of effective testing programs in a test and treat strategy. The impact on the decrease in community viral load (and, therefore, likely transmission) improves as the index of participation increases. A participation index of 73 percent (the idealized program with 90 percent rate of offering, accepting, and linking to care) is required for a test and treat strategy to decrease the time spent with transmissible viral load at the community level by approximately 50%.

Dr. Walensky concluded with a reminder that a disproportionate number of new HIV cases in the U.S. are the result of undiagnosed HIV-infection. While HIV screening programs have been demonstrated to be cost effective, their affordability depends on levels of public investment and will come at a cost to existing HIV services. Finally, the "pathway of participation" in any HIV testing program has critical implications for the preventative effects of a universal test and treat strategy.

EDWIN D. CHARLEBOIS, PHD, MPH
University of California, San Francisco, USA

Globally, tuberculosis (TB) is the number one cause of death in HIV-positive individuals. The WHO has called for all TB patients to be tested for the presence of HIV-infection but this remains an act much easier said than done.

Due to the nature of transmission of both diseases, TB and HIV infections cluster in families; thus, there is a pressing need to expand testing to household members of infected individuals. Dr. Charlebois presented the preliminary findings from a randomized controlled trial seeking to identify effective family-based HIV and TB testing strategies in Kampala, Uganda.

The background research for the NIMH-funded Project ACCEPT uncovered two general categories of barriers to HIV testing – logistical (e.g. locale, time, money) and psychological (e.g. stigma and fear of results). In response, Dr. Charlebois and his team developed a multi-level strategy to increase uptake of HIV testing services by new TB patients seeking treatment at a Kampala TB Control Center. To overcome logistical barriers, HIV VCT services were co-located in the facility where patients were seeking care and free and rapid HIV tests were employed. At the group level researchers took advantage of clusters in family groups and sought to test the households of TB-infected patients. To address psychological barriers, good counselors were employed and trained to address issues of associated stigmas and provide strong linkage to care.

To test the strategy, NIMH funded a five-year study (2006-2011) with three aims: 1) integrate same-day rapid HIV VCT for TB patients at a TB Control Center; 2) conduct a randomized controlled trial of home-based vs. clinic based VCT for TB evaluation patients (the focus of this particular presentation); and 3) evaluate linkage to care for TB patients newly diagnosed with HIV.

The randomized controlled trial allowed for a direct comparison of two strategies to test household members for TB-infected individuals who were receiving outpatient treatment, explained Dr. Charlebois. Participants in the home-based VCT arm were offered home VCT services for all household members and a ride home in a study vehicle. Participants in the clinic-based VCT arm were given information sheets to take home and encouraged to bring household members to the TB clinic for HIV testing. Patients were ensured that transportation costs would be covered and priority would be given to household members for VCT services.

In order to be eligible for participation, the TB patient had to agree to be tested for HIV at the clinic, live within 20 kilometers of central Kampala, and have one or more household members with unknown HIV status. Participants in both arms had up to one month to get household members

tested. Three hundred and seventy four participants were stratified by HIV status (304/374 were HIV-negative) and more than 1000 individual household members were included in the trial.

Dr. Charlebois reported that overall, approximately 58 percent of the time the intervention was successful in engaging household members in HIV testing. The percentage was significantly higher in the home-based VCT (74 percent of household members) when compared to clinic-based VCT (40 percent). Among index patients who tested positive for HIV referral rates for household members were lower than the overall average (66 percent of household members in home based VCT and 37 percent for clinic-based VCT). Dr. Charlebois noted that only 19 percent of enrolled participants tested positive for HIV and as the study continues, the results are likely to change.

To date, the study has identified newly-diagnosed HIV-infection in 4.1 percent of all household participants. The general HIV prevalence in Uganda is 4.6 percent and Dr. Charlebois explained that many people in the households who tested positive were already aware of their status (and therefore not categorized as newly-diagnosed). There was a larger yield of newly diagnosed individuals in houses with HIV-positive index patients but that difference was not statistically significant at the .05 level. 62.5 percent of individuals newly diagnosed with HIV were spouses of HIV-positive index patients.

Dr. Charlebois has drawn some important implications for family testing strategies from these preliminary results. First, the results allow us to strongly conclude that home-based testing is a more effective recruitment strategy for the testing of household members than clinic-based VCT. Second, the number of household residents is positively associated with VCT uptake in the home-based strategy. Third, the highest yield in new identifications was among spouses of HIV-positive TB patients. Last, the study has uncovered a host of important considerations when engaging in home-based testing. Privacy is critical and often presents a challenge in tight living conditions. Household members (especially men and children) are often unavailable during typical working hours and home visits should be made available on evenings and weekends to increase participation. Finally, home-based testing has exponential benefits to the community as awareness is raised and inquisitive neighbors often encourage their own family members to engage in VCT services.

SHANNON HADER, MD, MPH
District of Columbia Department of Health, Washington DC, USA

The last four years have seen major changes in Washington DC, not the least of which has been a major strategic shift in the fight against HIV. As Director of HIV/AIDS, Hepatitis, STD and TB Administration, Dr. Hader was instrumental in bringing about a transformation in approach to HIV testing efforts within the municipality.

With a prevalence of 3.2 percent, Washington DC has the highest rates of HIV in the United States. Elements of generalized and highly concentrated epidemics combine to create a very high burden of

disease across populations and throughout the city. The complexity and scale of the epidemic have forced public health leaders to transition from traditional, individual-based, HIV prevention strategies to community-wide prevention efforts that not only engage and empower community members but identify and utilize existing systems to increase knowledge, service provision, and uptake. At the root of this challenge is ensuring that large numbers of people who need to get tested have the opportunity to know their status.

In Washington DC, the HIV epidemic is distributed across heterosexual, MSM, and IUD populations, but demographic characteristics of these populations differ dramatically. The affected heterosexual population is characterized by low levels of education and income while the affected MSM population is just the opposite (demographic information about the affected IDU populations are pending). What the MSM and heterosexual infected populations share is a concentration in older members of the communities. In both populations, the greatest burden of disease lies in people over 30 years old and 7.6 percent of all 40-49 year olds are HIV-positive.

These populations also share an alarmingly high number of HIV-positive people who are unaware of their status. In a recent National HIV Behavioral Survey that surveyed and tested over 1800 at-risk individuals, almost half of the HIV-positive respondents were unaware of their status. Of those, 72 percent had visited a medical provider in the last 12 months and fewer than half were offered an HIV test at their last medical visit. These data provide insight into not only who is known to have HIV, but who has HIV and is unaware of their status, and present critical opportunities to focus on HIV testing where people were already engaging in medical care, Dr. Hader explained.

In 2006, Dr. Hader and her team initiated "From Provision to Promotion," a three pronged HIV testing scale-up strategy in Washington DC. First, outreach efforts began with new policy advocated that HIV testing be routinely offered in medical settings. An intensive HIV testing campaign began in collaboration with medical providers, community based organizations, HIV-focused comprehensive health center, the Department of Corrections, Hospitals, and Managed Care Networks.

Second, an emphasis was placed on medical settings in efforts to maximize available resources. Dr. Hader's team recognized that providers created one of the biggest barriers to testing. After decades of being told that HIV testing wasn't their responsibility or right, providers were not offering HIV tests to patients. At the same time many patients not only wanted to be offered the test, but they also were unaware that they *hadn't* been tested. An "Ask for the Test Offer the Test" campaign was targeted to providers and patients. Modeled on direct to consumer marketing strategy utilized by pharmaceutical firms, the campaign encouraged the public to ask for the test while simultaneously supplying providers with information about the test and encouraging them to offer the service. To better liaise and follow-up with providers, partnerships were established with the Global Business Coalition on AIDS, TB and Malaria and Pfizer (which does not provide any testing materials or ARVs to the Department of Public Health). Pfizer drug representatives integrated HIV testing

materials into their own product promotion and assisted in disseminating the information throughout the community.

Lastly, efforts were made to change the paradigm about the expected results of testing. Outreach highlighted the importance of linkage to care and providers were educated about their responsibilities in establishing those connections. Patient navigator services were expanded, CBOs were incentivized to prioritize linkage to care, and government provided patient materials were re-worked to ensure that HIV-positive individuals were aware of not only their own, but their providers', roles and responsibilities.

"When we implement systematically we can capture more people," Dr. Hader explained. Four years after the program began, data are beginning to illustrate the impact on testing utilization and on public health. There has been a 335 percent increase in publicly-supported HIV tests. The median CD4 count at first diagnosis rose from 216 in 2004 to 343 in 2008. The number of HIV-positive individuals who are linked to care within three months has increased by 37 percent, a number that emerging data indicate is even higher for publicly funded partners. The number of newly diagnosed AIDS cases dropped by 40 percent and the number of people dying from HIV in Washington D. C. has dropped from 379 in 2004 to 274 in 2007.

The success of the program has not been without its challenges and Dr. Hader was quick to point out that much work remains to be done. Provider and client perceptions about the disease can always be improved. At the client level low perceptions of HIV risk continue to be a problem (especially in heterosexual women), while more providers need to adopt a non-risk based testing model that doesn't discount the risks to women and older populations. Equally as important, explained Dr. Hader, is the need to adopt newer, cheaper, and more advanced testing technologies. Finally, there is an overarching goal to become more strategic. An area like Washington DC with its high prevalence and complex demographics needs a population-based study with seromarkers to better capture the shifting successes and missed opportunities.