Proposal for a Revised National HIV/AIDS Strategy

Developed by the Beyond AIDS Scientific Committee; endorsed by the Beyond AIDS Foundation Board, 10/19/14
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Prevention strategies proven to be effective for some other communicable diseases lacking a vaccine, such as tuberculosis and syphilis, have focused on control of infection at the source (the infected person). This control includes identification of infected persons through screening and surveillance, behavioral and barrier measures to prevent new exposures, treatment to prevent or stop infectiousness as well as to achieve clinical benefit, and testing and prophylactic treatment of recently exposed persons (Wetmore, 2010).

HIV prevention strategies during the first 3 decades of the epidemic, including the initial National HIV/AIDS Strategy (NHAS) released in 2010, on the other hand, generally consisted of a variety of measures directed primarily toward populations at risk rather than infected persons (Yehia, 2011). This limitation was unavoidable for many years, due to unique pre-test requirements that limited identification of cases (CDC, 2006), lack of HIV reportability to public health, and guidelines that deferred treatment during the early years of infection. The 9 implementation targets of the NHAS did include goals of increased diagnosis, earlier linkage to care, increased retention in care, and increased viral load suppression for 3 population groups, but it did not provide for a seamless transition of infected individuals through these stages. The 2013 Presidential HIV Care Continuum Initiative (Obama, 2013) increased the focus on universal screening for infections, continued to stress linkage to care and retention in care, and added universal treatment of HIV-infected persons to achieve more rapid viral suppression. However, the specific measures listed in the initiative still by and large targeted risk groups rather than directly working with infected individuals.

However, 4 prerequisites have been met over recent years, for a prevention strategy that permits interruption of transmission at the level of each infected person:
a) Recommendations for universal screening of adolescents and adults (CDC, 2006; Moyer 2013);
b) Surveillance systems that include all HIV infections (German, 2001; Gallagher, 2007);
c) Evidence from ecological, observational, and experimental studies and mathematical modeling that the most effective prevention method is antiretroviral treatment with viral load suppression, i.e., treatment as prevention (TasP) (Nachega, 2014; Cohen, 2011; Granich, 2009); and
d) Treatment guidelines that expand antiretroviral therapy to all infected persons (HHS 2012, Marrazo, 2014).

The building blocks are thus now in place for an updated national strategy that would predominantly emphasize interruption of the chain of transmission at the source, through enhancement of the Care Continuum for each infected individual. Universal suppression of the virus and hence of viral transmission could drive U.S. HIV incidence rates steadily downward for the first time, while simultaneously achieving improved health outcomes. To be truly effective for prevention and control, such a strategy would need to include identification of and outreach directly to all infected persons and/or their providers; initiation and maintenance of antiretroviral treatment; and continual suppression of viral load, while

providing optimal clinical care. It would also need to be complemented by essential public health-related components such as surveillance of infections; addressing barriers and disparities in care; monitoring and management of the Care Continuum; prevention services as part of care for infected persons; and partner services. Any increased costs for the first few years would be more than made up by steadily lower future costs due to reduction of the epidemic.

We therefore recommend such a revision to the 2010 National HIV/AIDS Strategy, to be promoted and supported with adequate public funding, and with a high emphasis on the rights, confidentiality, voluntary cooperation, and dignity of persons living with HIV. The following table of essential elements for this revised strategy correlates the main subdivisions of the 2010 NHAS with the stages of the Care Continuum.

GOALS: **STAGES OF CARE CONTINUUM:**	***REDUCING NEW INFECTIONS***	***INCREASING ACCESS, IMPROVING OUTCOMES***	***REDUCING HEALTH DISPARITIES***	***COORDINATED NATIONAL RESPONSE***
IDENTIFICATION/ DIAGNOSIS	○ Universal, routine, opt-out screening should be provided to all adolescents and adults, initially and at intervals complementary to risk factors, with integrated linkages to care for those testing positive, except in anonymous testing situations (CDC, 2006; Moyer, 2013). ○ Post-test counseling and information, including measures to avoid transmission, should be provided at testing sites to all persons testing positive, with invitations or referrals for further follow-up counseling provided, especially for those who cannot emotionally process full information when results are presented. Referral sources for prompt evaluation and care should be discussed. ○ Post-test information on measures to avoid infection (e.g., condoms, with option of PrEP if they are unlikely to be used), with availability of counseling, referrals, and repeat screening based on risk, should be offered at publicly funded testing sites to all persons testing negative who can be accessed for such services (amended 11/30/14; USPHS, 2014).	○ Surveillance of the demographics of recent new positives and evolving transmission patterns, as well as well as risk behavioral surveillance data (e.g., NHBS) if available, should guide the targeting of future screening and risk behavior reduction efforts. ○ Conveniently accessible testing sites, and home testing, should be assured for disadvantaged populations.	○ Training should be made widely available to providers, on universal screening recommendations and their culturally competent implementation.	○ The Centers for Disease Control and Prevention (CDC), and the U.S. Preventive Services Task Force (USPSTF) should maintain, update, and urge universal implementation of the latest recommendations for universal screening of adolescents and adults, and the methods and confirmation algorithms used (Branson, 2006; CDC, 2014; CDC, 2006; Moyer, 2013). ○ State legislation/ regulations should be sought as needed to require laboratories to report aggregate

	○ Sera from recently-exposed and highest-risk persons testing negative, whose new-onset infections might be missed by even the best antigen/antibody screening methods, should be submitted for pooled HIV RNA testing (Pilcher, 2013). ○ HIV reporting and other surveillance activities should be universally recognized as an integral and essential component of prevention. All legal and institutional barriers to the use of reporting data for prevention purposes should be eliminated. ○ Community HIV education for the general population, and that targeted to high-risk populations, should be focused on specific public health objectives: 1) Promoting or including HIV screening with the education as the entry point for newly discovered HIV infections into the HIV Care Continuum. 2) Similarly promoting or including combined or coordinated screening for HIV, other STDs, and viral hepatitis. 3) Promoting safe behavior that can prevent not only HIV but other STDs and bloodborne pathogens as well. ○			numbers of negative tests done, in order to permit surveillance of overall testing and positivity rates. ○ CDC should survey and monitor distribution of testing sites and testing rates, to optimally serve populations at increased risk. ○ Surveillance-driven updating (at least annual) of the targeting of screening and prevention should be a condition for CDC funding.
LINKAGE TO CARE	○ Laboratory reporting of positive tests to the local public health agency should trigger automatic, prompt, and routine initial outreach services, consistently and adequately funded in all local jurisdictions nationwide. This outreach should assure that the following linkages, services, and referrals take place, should be provided for all individuals confirmed as testing positive, and/or to the providers of those tested under the providers' care: (Aziz, 2011;	○ Barriers to initial linkage in care should be reduced, including by colocation or integration of HIV diagnostic and treatment services, or by actively offered transportation assistance.	○ Treatment facilities should be made available in neighborhoods populated by disadvantaged, high-risk population groups.	○ Federal funding from CDC for surveillance and outreach should be available in all geographic and demographic areas. States should be held accountable, as a condition of funding, for assuring that services are

	Christopoulos, 2011; Zaller, 2011; Marks, 2010, CDC, 2008). 1) Linkage to care by healthcare providers who are knowledgeable about HIV management and prevention, if not already arranged. 2) Counseling on measures to prevent transmission, if not already provided, including the importance of viral suppression, safe sexual practices, informing of partners; and for drug users, non-sharing of "works," access to clean needles, and drug treatment. 3) Initial partner services by disease intervention or other public health specialists, or by properly trained healthcare personnel as permitted by law, to identify likely source partners and the most recently exposed partners, including confidential notification and opt-out testing of possibly exposed individuals. ○ Estimated duration of infection, based on history and laboratory assays (Laeyendecker, 2013), should be utilized to guide the timeframe for initial partner tracing. ○ Partners who test HIV positive should be provided with all of the same counseling and care services of the source patients. Those who test HIV negative should be counseled on condom use, with option of PrEP (e.g., until patient's viral load becomes undetectable, if exposure will be ongoing). ○ Partners who are injection drug users should also be counseled on disinfection and non-sharing of "works"; screening for hepatitis B and C, non-sharing of "works," access to clean needles, and drug treatment.			available in all local jurisdictions.

RETENTION IN CARE	○ Surveillance/monitoring of persons testing positive should track their subsequent progression through the Care Continuum. This can be achieved by a combination of efforts by providers (and as a condition for Ryan White funding for care and/or as billable services) and public health agencies. Accountability for the performance of this function should be a condition of public reimbursement. ○ Ongoing assessment about new partners should be provided in the course of care, with referral (as above) or performance of follow-up partner services, including confidential notification, counseling, and opt-out testing for contacts. New partners identified in the course of care should be provided with prompt testing, counseling, and follow-up services, just as for partners identified initially (CDC 2008). ○ Other Prevention with Positives components should be provided through collaboration of providers and supportive HIV/AIDS services with Ryan White funding, including accessible condom distribution; screening and treatment of other STDs, hepatitis B and C, and tuberculosis; prevention of mother-to-child transmission; reproductive health care; and referral to other services as needs arise during care. ○ Prevention case management should be provided as needed.	○ Maintenance of continuous HIV care, including integrated prevention measures, should be optimized by competent providers and support resources, including the monitoring of treatment adherence, with simplification or adjustment of regimens as needed (Gardner, 2011; Doshi, 2013; Hart, 2007; Yuan, 2006). ○ Referral services should be available to specialists, support groups, ADAP, case management cross-trained in prevention, substance abuse treatment, mental health services, housing assistance, prevention with positives, and other programs (historically funded by the Ryan White CARE Act) as appropriate (Giordano, 2011; Conviser, 2002; Tobias, 2007; Bradford, 2007; Thompson, 2012). ○ Transportation assistance should be available to patients having difficulty returning to treatment facilities, or accessing referral specialists.	○ Active community outreach should be provided to patients missing appointments, and closely tracked referrals to new sources of care for those who require a change in provider.	○ HRSA should require cross-training of Ryan White case managers to provide prevention case management, including ongoing counseling on maintenance of condom use, treatment adherence, and other measures to prevent transmission. ○ HRSA should continue to administer traditional programs provided by the Ryan White CARE Act, which are not covered by the Affordable Care Act. ○ The U.S. Preventive Services Task Force, CMS, and other appropriate agencies should review preventive services needed by HIV positive persons, so that these can become benefits under the Affordable Care Act. ○ Ancillary measures provided by the Ryan White program should be maintained for persons and for services not covered by the Affordable Care Act

				(e.g., support groups, socio-economic assistance, and case management). ○ All possible efforts should be pursued to extend prevention and treatment services provided through the Ryan White CARE Act as benefits of both Medicaid and the ACA exchanges.
TREATMENT WITH ANTIRETRO-VIRAL DRUGS	○ Prevention messages should be fully incorporated into ongoing care and treatment, and provided with the best evidence-based approaches including routine assessment and brief counseling during clinical visits, regarding sexual and drug-related behavior and treatment adherence, with referrals as appropriate. ○ Monitoring of the offering and initiation of antiretroviral treatment should be provided, either by public health agencies or by contracted HIV/AIDS agencies, and publicly funded.	○ Prompt offering/initiation of antiretroviral treatment, and assurance of continuous treatment availability, should be available. ○ Providers should monitor for and address antiretroviral medication adverse effects.	○ Provider training should be increased for culturally competent care (adapting to the local context), identification and treatment of comorbid mental health diagnoses, and concomitant substance use. ○ Primary care providers who do not treat HIV should be urged to refer all HIV patients to competent providers who do.	○ HRSA, in cooperation with CDC and NIH, should assure that recommendations for treatment of all infected persons are widely disseminated and promoted to patients and providers, as the standard of care. ○ Coverage of treatment through the ADAP program should be maintained for persons with HIV who are not covered by Affordable Care Act, and for any treatments not covered by ACA exchange plans.
VIRAL SUPPRESSION	○ Monitoring of viral load suppression, with resistance testing and adaptation of treatment when indicated, should be performed by providers, with the aim of achieving	○ Federal grants and other public funding for care and case management should hold recipients accountable	○ Patients whose viral loads are not fully suppressed should be provided with special	○ HRSA should include monitoring and follow-up of detectable viral loads in the funding and

	undetectable viral loads or lowest viral levels possible, to prevent transmission as well as the development of viral resistance. ○ Detectable viral loads reported by laboratories should be tracked in state public health surveillance systems, brought to the attention of providers when levels remain elevated or tests are missed, compared with reported infections to determine suppression rates, and correlated with transmission patterns.	for monitoring of viral loads.	intensive assistance, both medical and related to adherence, to help achieve undetectable levels. ○ Special programs to enhance viral suppression should be provided for population groups with the lowest rates, but should involve work directly with individual patients.	accountability of HIV treatment funding. ○ CDC should promote surveillance of viral RNA, missed viral RNA testing, resistance tests, and CD4 levels, and should include this service in prevention grants to states. ○ State legislation/ regulations should be sought to enact laboratory reporting of all viral load, genotype, and CD4 testing regardless of results, in those states not yet providing this.

References

Aziz M, Smith KY. Challenges and successes in linking HIV-infected women to care in the United States. Clin Infect Dis 2011; 52 (Suppl 2): S231-S237.

Bradford JB, Coleman S, Cunningham W. HIV System Navigation: an emerging model to improve HIV care access. AIDS Patient Care STDS 2007; 21(Suppl 1): 549-58.

Branson BM, Handsfield HH, Lampe MA, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. MMWR Recomm Rep 2006: 55 (RR-14): 1-17; quiz CE1-CE4.7.CDC. Results of the Expanded HIV Testing Initiative – 25 jurisdictions, United States, 2007-2010. MMWR 2011; 60: 805-810.

CDC. National HIV Testing Day and New Testing Recommendations. MMWR. 2014; 63(25): 537

CDC. Recommendations for Partner Services Programs for HIV Infection, Syphilis, Gonorrhea, and Chlamydial Infection. MMWR, 2008; 57(RR09):1-63

CDC. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Adults in Health-Care Settings. MMWR 2006; 55(rr14): 1-17.

Check Hayden E. 'Seek, test and treat' slows HIV. Nature. 2010; 463:1006.

Christopoulos KA, Das M, Colfax GN. Linkage and retention in HIV care among men who have sex with me in the United States. Clin Infect Dis 2011; 52 (Suppl 2): S214-S222.

Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med 2011; 365:493-505.

Conviser R, Pounds MB. The role of ancillary services in client-centered systems of care. AIDS Care 2002; 14(Suppl 1): 53-8.

Doshi RK, Malebranche D, Bowleg L, Sangaramoorthy T. Health Care and HIV Testing Experiences Among Black Men in the South: Implications for "Seek, Test, Treat and Retain" HIV Prevention Strategies. AIDS Patient Care STDS 2013; 27: 123-133.

Gallagher, K. M., Sullivan, P.S., Lansky, A., and Onorato I.M. (2007). Behavioral surveillance among people at risk for HIV infection in the U.S.: The National HIV Behavioral Surveillance System. *Public Health Reports*, *122*(Suppl 1), 32–38

Gardner EM, McLees MP, Steiner JF, Del Rio C, Burman WJ. The spectrum of engagement in HIV care and its relevance to test-and-treat strategies for prevention of HIV infection. Clin Infect Dis. 2011; 52: 793-800.

German, R. R., Lee, L. M., Horan, J. M., Milstein, R. L., Pertowski, C. A., & Waller, M. N. (2001). Updated guidelines for evaluating public health surveillance systems: Recommendations from the Guidelines Working Group. *MMWR. Recommendations and Reports: Morbidity and Mortality Weekly Report*, *50*(RR-13), l1–35

Giordano TP. Retention in HIV Care: what the clinician needs to know. Top Antivir Med 2011; 19: 12-16.

Granich RM, GIlk 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.

Hart E, Curtis H, Wilkins E, Johnson M. National review of first treatment change after starting highly active antiretroviral therapy in antiretroviral-naïve patients. HIV Med 2007; 8: 186-91.

Laeyendecker O, Brookmeyer R, Cousins M, Mullis C, Konikoff J, et al. HIV Incidence Determination in the United States: A Multiassay Approach. JID 2013:207, 232-239.

Marazzo J M, del Rio C, Holtgrave D R, et al. HIV prevention in clinical settings: 2014 recommendations of the international antiviral society-USA panel. Journal of the American Medical Association 2014; 312(4):390-409

Marks G, Gardner Ll, Craw J, Crepaz N. Entry and retention in medical care among HIV-diagnosed persons: a meta-analysis. AIDS 2010; 24:2665-2678.

Moyer VA. on behalf of the U S. Preventive services task force. screening for HIV: U.S. preventive services task force recommendation statement. Ann Intern Med. 2013;159(1):51–60.

Nachega JB, Uthman OA, del Rio C, et al. Addressing the achilles' heel in the HIV Care Continuum for the success of a test-and-treat strategy to achieve an AIDS-free generation. Clin Infect Dis 2014; 59 (Suppl 1): S21-S27.

Obama B. Accelerating Improvement in HIV Prevention and Care in the United States through the HIV Care Continuum Initiative. Federal Register 2013; 78(138): 43057-43059

Pilcher C D, Louie B, Facente S, et al. Performance of Rapid Point-of-Care and Laboratory Tests for Acute and Established HIV Infection in San Francisco. Plos One. 2013; 8(12): e80629

Taege A. Seek and treat: HIV update 2011. Cleveland Clinic J Med. 2011; 78: 95-100.

Thompson MA, Mugavero MJ, AMico KR, et al. Guidelines for improving entry into and retention in care and antiretroviral adherence for persons with HIV: evidence-based recommendations from an International Association of Physicians in AIDS Care Panel. Ann Internal Med 2012; 156: 817-833.

Tobias C, Cunningham WE, Cunningham CO, Ounds MB. Making the connection; the importance of engagement and retention in HIV medical care. AIDS Patient Care STDS 2007; 21(Suppl 1): 53-8.

US Public Health Service. Pre-exposure prophylaxis for the prevention of HIV infection in the United States – 2014. Available at: http://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf. Accesses 23 September 2014.

Wetmore C M, Manhart L E, Wasserheit J N. Randomized controlled trials of interventions to prevent sexually transmitted infections: Learning from the past to plan for the future. American Journal of Epidemiology. 2010; 32(1): 121-136.

Yehia B, Frank I. Battling AIDS in America: An Evaluation of the National HIV/AIDS Strategy. American Journal of Public Health 2011; 101(9): e4-e8.

Yuan Y, L'Italien G, Mukherjee J, Iloeje UH. Determinants of discontinuation of initial highly active antiretroviral therapy regimens in a US HIV-infected patient cohort. HIV Med 2006; 7: 156-62.

Zaller ND, Fu JJ, Nunn A, Beckwith CG, Linkage to care for HIV-infected heterosexual men in the United States. Clin Infect Dis 2011; 52 (Suppl 2): S223-S230.