THE HIV CARE CONTINUUM AND THE 2015 UPDATE TO THE NATIONAL HIV/AIDS STRATEGY

Ronald P. Hattis, MD, MPH *ronhattis@beyondaids.org* Secretary, Beyond AIDS Foundation Assoc. Clinical Prof., Preventive Medicine, Loma Linda University November 15, 2015



Objectives

- The participant will be able to:
- 1. Discuss updated national goals for HIV prevention and treatment
- 2. Utilize HIV treatment for prevention
- Guide patients through the HIV Care Continuum

WELCOME FROM BEYOND AIDS

- Beyond AIDS is a US-based non-profit membership organization pursuing public policies and laws that can reverse the course of the global HIV epidemic through sound public health policy
 - Sounded unrealistic when founded in 1998; now within reach
 - Dues \$50; \$25 students; \$75 couples; non-deductible
- The subsidiary Beyond AIDS Foundation is a public charity dedicated to education, research, and promotion of effective approaches for prevention of HIV
 - Donations are tax-deductible
 - Operates internship/fellowship program
- References not included in slides available in Web documents from government or at Beyond AIDS Website: <u>www.beyondaids.org</u>

MAIN METHODS TO PREVENT HIV INFECTIONS

- Infection and exposure form a cycle that can be broken
 - Block exposure, or protect exposed person from infection
- Reduce infectiousness of infected person
 - Viral suppression by antiretroviral treatment
 Key to the HIV Care Continuum
- Prevent infectious material from source from exposing other person
 - Abstinence from sex or from needle sharing; "sero-sorting"
 - Condoms, gloves to create a physical barrier
 - Safe handling of blood, needles in health care
- Make the exposed person less susceptible to infection
 - Prophylaxis: pre-exposure (PrEP); post-exposure (PEP)
 - Circumcision help protects exposed males
 - Vaccine, vaginal microbicide needed but not yet commercially available

THE VALUE OF HIV SCREENING FOR PREVENTION

Positive test is the entry into treatment

- Treatment achieving undetectable viral load reduces infectiousness
- Early treatment also improves health outcomes, reduces mortality
- Studies show that persons aware of positive status decrease unsafe behavior

Partners of HIV positives can take precautions

- Partner services can identify exposed persons, either before infection or before transmission
- Known continuing seronegative partners can take PrEP and insist on condoms

Antiretroviral prophylaxis: a defining moment in HIV control



Figure: HIV prevention technologies shown to be effective in reducing HIV incidence in randomised controlled trials¹⁻¹¹ PrEP=Pre-exposure prophylaxis. *Meta-analysis of circumcision trials.

Published Online July 15, 2011 DOI:10.1016/S0140-6736(11)61136-7

"TREATMENT AS PREVENTION"

- Treating the infected person to reduce infectiousness is the mainstay of treatment for TB, syphilis, other diseases
 - Far fewer infected persons to treat than potentially exposed persons
 - Requires prompt onset of treatment, but until 2012 was contrary to treatment guidelines
 - Prior guidelines said to wait for drop in CD4 cell count (in 2001, treatment was to begin at count of 200 = AIDS)
 - Such a decrease in CD4 count could take years
- Research published 2012 showed that ART can make HIV almost non-infectious
 - Concept proposed 16 years earlier, 1996 by Hattis and Jason <u>http://www.beyondaids.org/articles/1996MA~1.PDF</u>
 - http://www.beyondaids.org/articles/WillNewMedicationsReduceInfect iousnessofHIV-1997.pdf

"TREATMENT AS PREVENTION," CONTD.

- 2008: Granich et al. modeling predicted reduction of epidemic with universal testing, immediate treatment to suppress viral load. Available at http://dx.doi.org/10.1016/S0140-6736(08)61697-9
- 2012: HPTN 052 clinical trial showed reduction of transmission to sexual partners of 96% in combination with prevention counseling
 - Cohen, M. S.; McCauley, M.; Sugarman, J. (2012). Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3200068/
- 2015: START and Temprano studies showed better clinical results when antiretroviral therapy was started at CD4 counts over 500
 - INSIGHT START Study Group. Initiation of antiretroviral therapy in early asymptomatic HIV infection. N Engl J Med. Jul 20 2015. Available at http://www.ncbi.nlm.nih.gov/pubmed/26192873 Temprano ANRS 12136 Study Group. A trial of early antiretrovirals and isoniazid preventive therapy in Africa. N Engl J Med. Jul 20 2015. Available at http://www.ncbi.nlm.nih.gov/pubmed/26193126

Science 2011 Sto

BREAKTHROUGH OF THE YEAR

HIV Treatment as Prevention

AAS

THE VIRAL REPRODUCTIVE RATIO, R₀

- R₀ is the number of new cases that result during an initial cases's period of infection (which for HIV is lifetime, or until virus undetectable or no exposures)
 - If R₀=1, disease is stable; if >1, disease prevalence increases (exponentially at first, till susceptibles exhausted)
- \square $R_0 = Infections/contact * contacts/year * years/source$
 - Years/source is number of years source remains infectious (ended by death, viral suppression, or cessation of exposure)
- To reduce HIV in population, **R**₀ must be <1
 - Average case should be detected before transmission, then transmission must be reduced to below replacement levels (<1 new case per existing)
 - "Treatment as prevention" makes this achievable

ORIGINS OF THE HIV CARE CONTINUUM CONCEPT

- In 2011, Dr. Edward Gardner (a nominee for Beyond AIDS Foundation's "Nettie Award" for 2015) used previous studies to estimate dropouts at every stage of reaching viral suppression
- □ *Clin Infect Dis.* (2011) 52 (6): 793-800. doi: 10.1093/cid/ciq243
- He estimated that at that time, only 19% of HIVinfected persons in the US had undetectable viral loads
 - Initially called "spectrum of engagement in care" or "treatment cascade," renamed the HIV Care Continuum

HIV TREATMENT SPECTRUM/CASCADE GARDNER, EM, et al., Clin Infect Dis. (2011) 52 (6):793-800.doi: 10.1093/cid/ciq243



Stage of Engagment in HIV Care

CDC'S DUPLICATION OF GARDNER'S WORK

83% of est. 1.15 million infected persons in U.S. had been tested

66% were linked to care (lower if black, young)
Only 33% had received ART (1/2 of those in care)
Only 25% had undetectable or very low viral loads (VL = copies of virus per ml) (3/4 of those receiving ART)

 Separate study by CDC in 2011 came up with similar figures: 80% of infected tested, 62% in care, 36% on ART, 28% virologically controlled

Study based on CDC's National HIV Surveillance system: Hall, I 7/27/12 using 2009 data; used the term "treatment cascade"; available at <u>http://blog.aids.gov/2012/07/hivaids-treatment-cascade-helps-identify-gaps-in-care-retention13tml</u>

HIV CARE CONTINUUM INITIATIVE

 In 2013, President Obama issued Executive Order, creating HIV Care Continuum Initiative

- Endorsed universal screening, ages 15-65, and treatment of all positives
- Assured coverage through Affordable Care Act (ACA)
- "High-impact" grants to serve high-risk population groups
- Research to improve outcomes along HIV Care Continuum

HELPING PATIENTS THROUGH CONTINUUM OF CARE

- Working with patients through the Continuum
 - Screen routinely
 - Link positives to care
 - Initiate treatment as soon as accepted by patients
 - Retain patients in treatment; emphasize adherence
 - Strive for undetectable viral loads

Supplement with other prevention strategies

- Helping high-risk uninfected patients maintain safe/avoid transmission-prone behaviors
- Partner services to detect, screen recently exposed persons
- Counsel and consider PrEP for high-risk negatives

WHAT IS THE NATIONAL HIV/AIDS STRATEGY?

- "The National HIV/AIDS Strategy (NHAS) is a fiveyear plan that details principles, priorities, and actions to guide our collective national response to the HIV epidemic"
 - First released by President Obama on July 13, 2010, the Strategy "identified a set of priorities and strategic action steps tied to measurable outcomes for moving the Nation forward in addressing the domestic HIV epidemic"
- In July 2015, White House released the National HIV/AIDS Strategy for the United States, Updated to 2020
 - Update reflects work accomplished and new scientific developments since 2010 and "charts a course for collective action across the Federal government and all sectors of society to move us close to the Strategy's vision"

STRATEGY'S VISION

The United States will become a place where new HIV infections are rare and when they do occur, every person regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance, will have unfettered access to high quality, lifeextending care, free from stigma and discrimination."

■ This is identical to vision in the 2010 strategy

STRATEGY'S GOALS

- I. Reduce New Infections
- Increase Access to Care and Improve Health Outcomes for People Living with HIV
- 3. Reduce HIV-Related Health Disparities and Health Inequities
- 4. Achieve a More Coordinated National Response to the HIV Epidemic
 - These are the same 4 goals as the 2010 NHAS, but implementation is different
 - Influenced by HIV Care Continuum concept (to be discussed), aiming ultimately at viral suppression to reduce transmission as well as improve health
 - Some targets/indicators for high-risk groups, others now for all

Source: https://www.aids.gov/federal-resources/national-hiv-aidsstrategy/overview/

INDICATORS OF PROGRESS (NEW)

INDICATOR 1

 Increase the percentage of people living with HIV who know their serostatus to at least 90 percent (unchanged)

INDICATOR 2

 Reduce the number of new diagnoses by at least 25 percent (unchanged)

• INDICATOR 3

- Reduce the percentage of young gay and bisexual men who have engaged in HIV-risk behaviors by at least 10 percent (new)
 INDICATOR 4
 - Increase the percentage of newly diagnosed persons linked to HIV medical care within one month of their HIV diagnosis to at least 85 percent (changed from three months to one)

• INDICATOR 5

 Increase the percentage of persons with diagnosed HIV infection who are retained in HIV medical care to at least 90 percent (new)

INDICATORS OF PROGRESS, CONTD.

INDICATOR 6

Increase the percentage of persons with diagnosed HIV infection who are virally suppressed to at least 80 percent (new)

INDICATOR 7

 Reduce the percentage of persons in HIV medical care who are homeless to no more than 5 percent (more aggressive)

INDICATOR 8

Reduce the death rate among persons with diagnosed HIV infection by at least 33 percent (new)

INDICATOR 9

 Reduce disparities in the rate of new diagnoses by at least 15 percent in the following groups: gay and bisexual men, young Black gay and bisexual men, Black females, and persons living in the Southern United States

INDICATOR 10

 Increase the percentage of youth and persons who inject drugs with diagnosed HIV infection who are virally suppressed to at least 80 percent

NEW OPPORTUNITIES FOR PREVENTION

- The HIV prevention toolbox has grown. Based on scientific and technological advances in the past five years, new guidelines and recommendations have expanded the number of options for prevention."
 - Centers for Disease Control and Prevention (CDC) has issued guidance to providers recommending PrEP be considered for those at substantial risk for HIV.
 - Guidelines from the U.S. Department of Health and Human Services (HHS) now recommend that all persons with HIV be offered treatment not only for their own health, but also because antiretroviral treatment significantly reduces the risk of HIV transmission to others.

NEW OPPORTUNITIES FOR PREVENTION, CONTD.

- U.S. Preventive Services Task Force (USPSTF) recommends that all people aged 15 to 65 years, and all pregnant women, be screened for HIV.
- CDC has also provided guidance for the adoption of new testing technologies that enhance the ability to diagnose HIV soon after infection, broadening the window of opportunity for effective interventions during the acute phase of infection a time when HIV is most likely to be transmitted to others.

COMPARISON WITH ORIGINAL 2010 NHAS

- One year ago (10/14), Beyond AIDS representatives met with HHS officials in Washington to urge updating the NHAS
 - We were told there were not yet plans for this
 - Eight months later, update was issued
- Changes since 2010 when first NHAS was issued
 - Treatment guidelines recommended waiting to treat till CD4 count had dropped below 500; changed to offering to everyone in 2012
 - Studies showing 96% reduction in transmission if viral load suppressed were not published until 2011
 - CDC had recommended universal screening in 2006, but USPSTF did not endorse recommendation until 2013

COMPARISON WITH 2010 NHAS, CONTD.

- Both old and new plans called for 90% of infected persons to know their status
 - 2010 goal was not met by 2015, reset for 2020
 - According to CDC, 12.8% of infected Americans do not know status
 - Universal screening, ages 15-65, endorsed by USPSTF, also by President in HIV Care Continuum Executive Order, 2013
- 2010 NHAS called for increasing linkage to care after diagnosis, with few details

This would not have meant initiating antiretroviral treatment

- New plan assumes those linked with care will be offered treatment
- 2010 NHAS called for 20% increase in proportion of virally suppressed blacks, Latinos, gay/bi men
 - Would have raised suppression from 25% to 30%
 - New plan aims at 80% suppression rate for all

SOME "EXTRAS" THAT BEYOND AIDS ADVOCATES IN UPDATED NHAS

Reducing new infections

- Risk-appropriate counseling for persons testing negative as well as positive (safe sex, PrEP, no needle sharing, etc.)
- Routine outreach to all testing positive, for linkage to care, partner services, risk reduction

Access to care/improving outcomes

- Monitoring of treatment initiation, retention, viral suppression (e.g., expanded public health surveillance)
- Reducing disparities/inequities
 - Tracking, outreach by providers for intensive assistance when missed appointments or unsuppressed viral loads
- More coordinated federal response
 - Expand public health tracking to include positive, negative, and missed viral loads, drug resistance patterns/trends

UNAIDS 90-90-90 PROGRAM

Developed 2014, adopted 9/15/15; Reference: http://www.unaids.org/sites/default/files/media_asset/JC2686_WAD2014report_en.pdf

■ By 2020, global goal:

- Identify 90% of infected persons
- Get 90% of identified patients on antiretroviral treatment
- Of patients on treatment, 90% to be virally suppressed
- Of all infected persons, 73% to be virally suppressed
- By 2030, "end the HIV epidemic" as a global health threat
 - Intensify to 95-95-95 in 2030
 - 2015-2030 prevent 28 million infections, 21 million deaths
 - 90% decline from 2010 levels
 - 15x return on investment

GOOD NEWS, BAD NEWS

Positive steps	Limitations
CDC is issuing some grants to states for "data to care" (linking HIV positives)	Not all states yet receiving, and money often not getting to all local levels (esp. California)
Routine testing ages 15-64 should now be covered by Affordable Care Act (ACA) plans and Medicare	Coverage may be rejected if correct diagnostic code is not used (even though no diagnosis is needed), and 10/15 switch to ICD-10 codes adds confusion
CDC recommendations on testing, partner services, outreach to positives coming closer to those of Beyond AIDS	Since recession, most states and counties have lost large percentage of public health funds, not yet restored, so can't afford to implement the recommended programs
Treatment of HIV is simpler, with more once-a-day regimens	Drugs still very expensive, and states have less AIDS Drug Assistance (ADAP) money to cover patients who are still uninsured (including through ACA)
NEWS: In September 2015, World Health Organization revised treatment recommendations to offer meds to everyone infected, from 2013 recommendation to treat at CD4 count under 500; 90-90-90 program adopted	Many countries still waiting till drops to 350; it will take several years to get resources to treat everyone (if achieved by 2020, computer modeling predicts "end of HIV epidemic as a global health threat" by 2030). Will require standardized system of reporting, commitment by each individual country, and funding invoctment