HIV Screening of Adults and Adolescents

Michele Owen, Ph.D

Division of HIV/AIDS Prevention

Acting Senior Advisor for Laboratory Diagnostics

Disclaimer: The findings and conclusions in this presentation are those of the author and do not necessarily represent the views of the Centers for Disease Control and Prevention **Disclosure**: No relevant financial relationships

National Center for HIV/AIDS, Viral Hepatitis, STD & TB Prevention Division of HIV/AIDS Prevention

Summary of Evidence for 2006 CDC Testing Recommendations

- HIV meets the criteria for screening, and effective treatment is available
- Many patients with HIV visit healthcare providers but their infection goes undetected
- People decrease their risk behaviors when they find out they are infected with HIV
- HIV screening in healthcare settings is cost-effective
- Opt-out screening increases testing rates

http://www.cdc.gov/hiv/pdf/library_slideSet_testing_healthcare.pdf

CDC 2006 HIV testing in Health-Care Settings Adults and Adolescents

- Routine, voluntary HIV screening for all persons 13-64 in health care settings, not based on risk
- Repeat HIV screening of persons with known risk at least annually
- Opt-out HIV screening with the opportunity to ask questions and the option to decline
- Include HIV consent with general consent for care; separate signed informed consent not recommended
- Prevention counseling in conjunctions with HIV screening in health care settings is not required

CDC 2006 HIV testing in Health-Care Settings Adults and Adolescents

- Intended for all health care settings
  - Inpatient services, EDs, urgent care clinics, STD clinics, TB clinics, public health clinics, community clinics, substance abuse treatment centers, correctional health facilities, primary care settings
- Communicate test results in same manner as other diagnostic/screening tests
- Provide clinical HIV care or establish reliable referral to qualified providers

CDC 2006 HIV testing in Health-Care Settings Pregnant Women

- Universal opt-out HIV screening
  - Include HIV in routine panel of prenatal screening tests
  - Consent for prenatal care includes HIV testing
  - Notification and option to decline
- Second test in 3rd trimester for pregnant women:
  - Known to be at risk for HIV
  - In jurisdictions with elevated HIV incidence
  - In high HIV prevalence health care facilities

Annals of Internal Medicine | CLINICAL GUIDELINE

Screening for HIV: U.S. Preventive Services Task Force Recommendation Statement

Virginia A. Moyer, MD, MPH, on behalf of the U.S. Preventive Services Task Force*

Recommendation: The USPSTF recommends that clinicians screen adolescents and adults aged 15 to 65 years for HIV infection. Younger adolescents and older adults who are at increased risk should also be screened. (Grade A recommendation)

Recommendation: Screen all pregnant women for HIV, including those who present in labor who are untested and whose HIV status is unknown. (Grade A recommendation)

http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/human-immunodeficiency-virus-hiv-infection-screening

-April 30, 2013

Why USPSTF Grades Matter

- Health Care Reform:

SEC. 2713. COVERAGE OF PREVENTIVE HEALTH SERVICES.

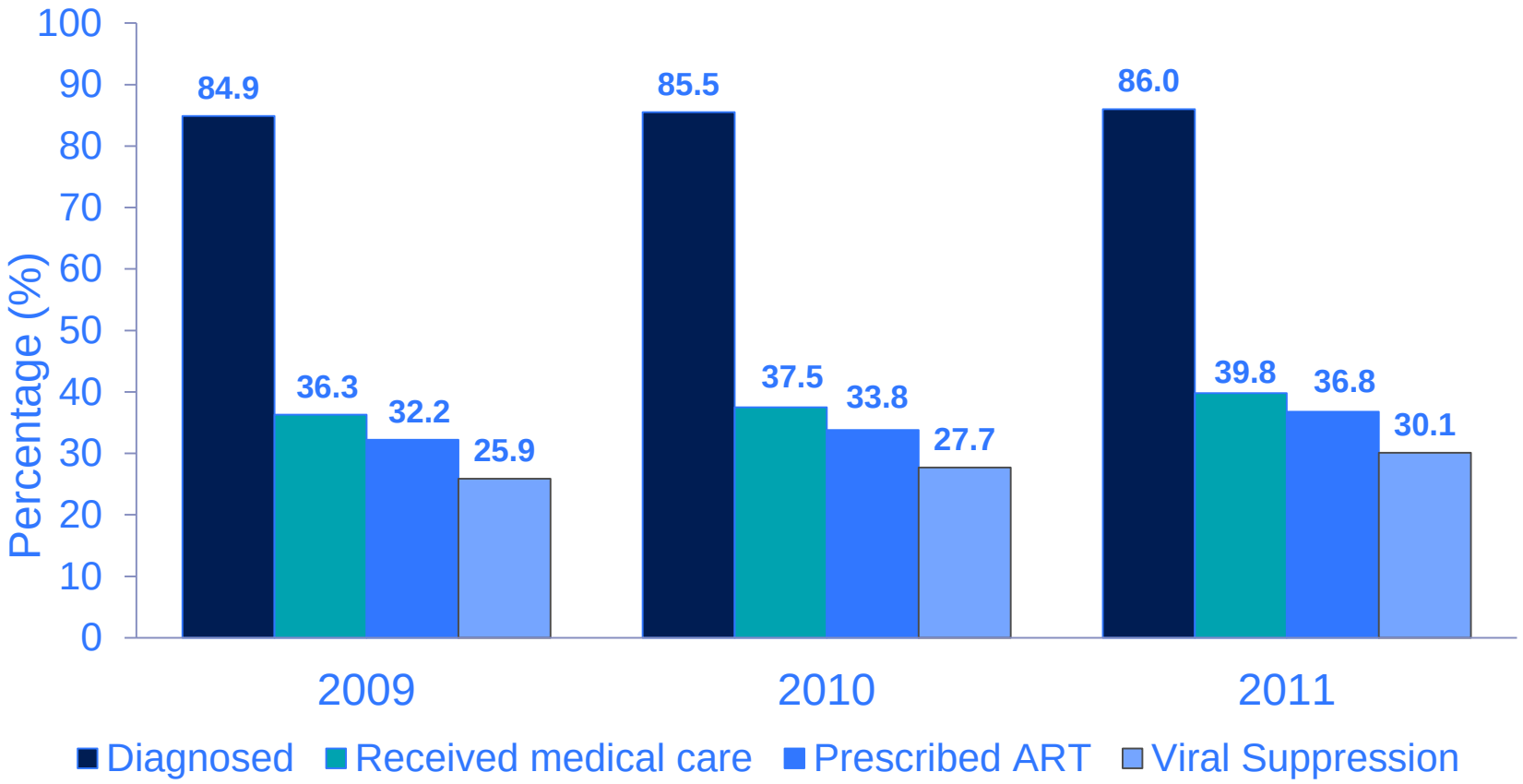
(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum, provide coverage for and shall not impose any cost sharing requirements for—

(1) evidence-based items or services that have in effect a rating of ‘A’ or ‘B’ in the current recommendations of the United States Preventive Services Task Force;

Comparison between CDC and UPSTF

- Ages for routine testing
  - CDC 2006- screen all Americans age 13-64
  - UPSTF 2013- screen 15 to 65 years for HIV infection
- UPSTF
  - Elaborated on possible definitions of risk and screening intervals
    - Very high risk - at least annually
    - Increased risk - every 3-5 years

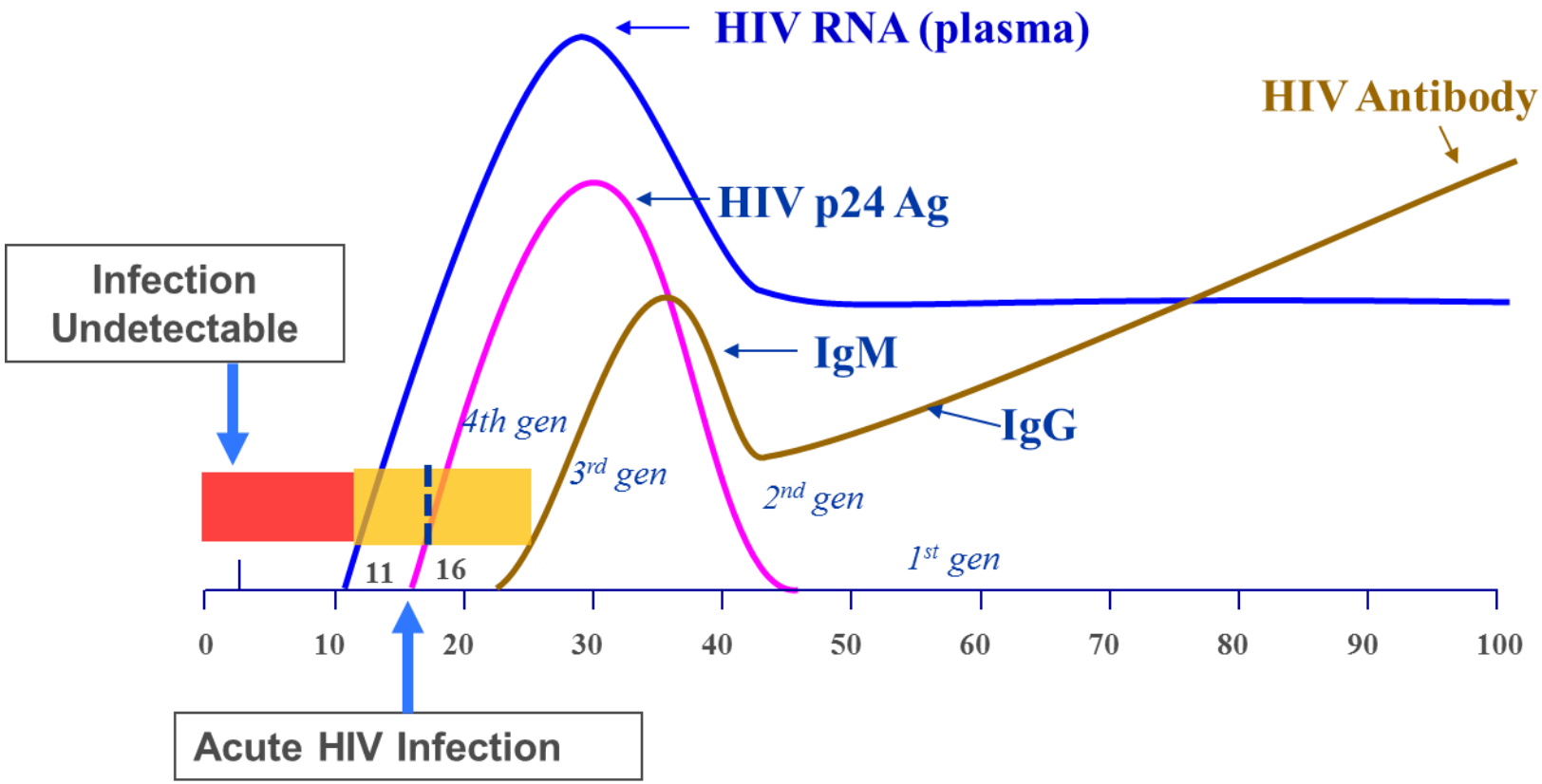
Persons Living with Diagnosed or Undiagnosed HIV Infection
HIV Care Continuum Outcomes, 2009, 2010 and 2011
United States and Puerto Rico



National HIV Surveillance System,: Estimated number of persons aged ≥13 years living with diagnosed or undiagnosed HIV infection (prevalence) in the United States at the end of the specified year . The estimated number of persons with diagnosed HIV infection was calculated as part of the overall prevalence estimate.

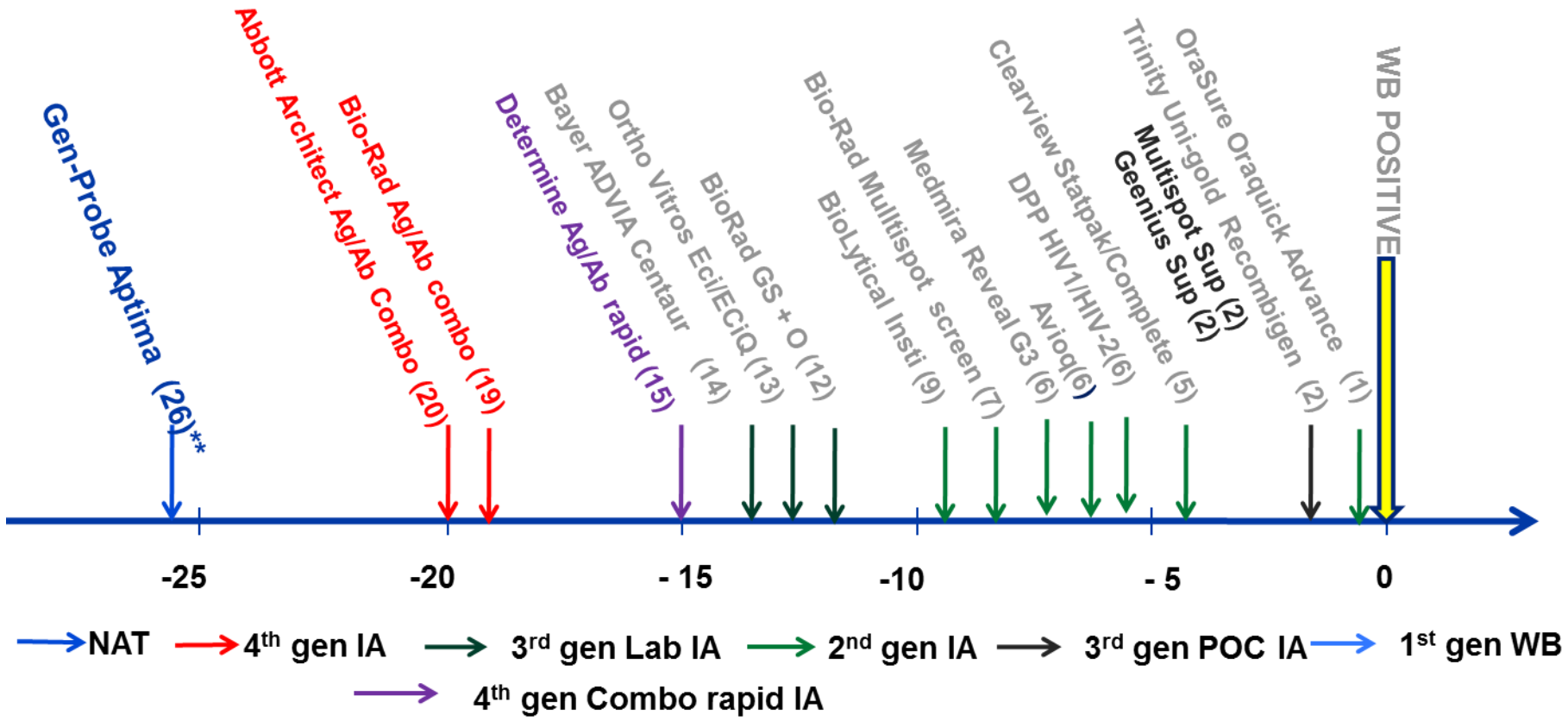
Medical Monitoring Project: Estimated number of persons aged ≥18 years who received HIV medical care during January to April of the specified year, were prescribed ART, or whose most recent VL in the previous year was undetectable or <200 copies/mL—United States and Puerto Rico.

HIV Infection and Laboratory Markers



Modified after Busch et al. Am J Med. 1997

Sequence of HIV Assay Reactivity During Early HIV Infection relative to Western Blot*



***Assay sensitivity above is based on frozen plasma only. Whole-blood and oral fluid has not been characterized for early infection.**

****Current data suggests that the Gen-Probe Aptima can detect HIV-1 RNA ~9-11 days after infection.**

Adapted from Owen et al J Clin Micro 2008 and Masciotra et al J Clin Virol 2011

Early Diagnosis Benefits

- **Public Health- Decrease Transmission**
  - Behavioral
    - Transmission rate ~3.5 times higher in the unaware group compared to the people aware of status[1]
    - Persons with acute HIV named 2.5 times as many partners and twice as many partners with undiagnosed HIV, compared with people with longstanding inection[2]
    - Modeling data from US MSM suggests epidemic would be larger without behavior change[3]
  - Biologic- **Greater infectiousness?**
    - Higher rates of transmission (10-26X) from individuals in acute/early stages of infection.[4,5]
    - SIV: plasma from acute infection 750 times more infectious per virion than plasma from chronic infection[6]
    - Treatment as prevention works![7]
    - Treatment as Prevention works [3]
      - Decrease in VL prevents transmission

[1]*Marks et al AIDS 2006*, [2]*Moore et al JAIDS 2009*, [3] *Khanna et al. AIDS Behav 2014*, [4]Wawer et al JID 2005, [5] *Hollingsworth et al JID, 2008* , [6]*Ma et al J Virol 2009* [7] *Cohen et al N Engl J Med 2011*

Early Diagnosis Benefits

- **Individual Benefit**
  - Multiple studies with indirect or antidotal evidence
  - Strategic Timing of Anti-Retroviral Treatment (START) study
    - First large-scale randomized clinical trial to establish that earlier antiretroviral treatment benefits all HIV-infected individuals
      - “The DSMB’s interim analysis found risk of developing serious illness or death was reduced by 53 percent among those in the early treatment group, compared to those in the deferred group”
      - http://www.niaid.nih.gov/news/newsreleases/2015/Pages/START.aspx

HIV-2 Infection

- **Remains uncommon in U.S., but**
  - Does not respond to NNRTIs, some PIs (first line therapy)
  - Undetectable by HIV-1 viral load tests

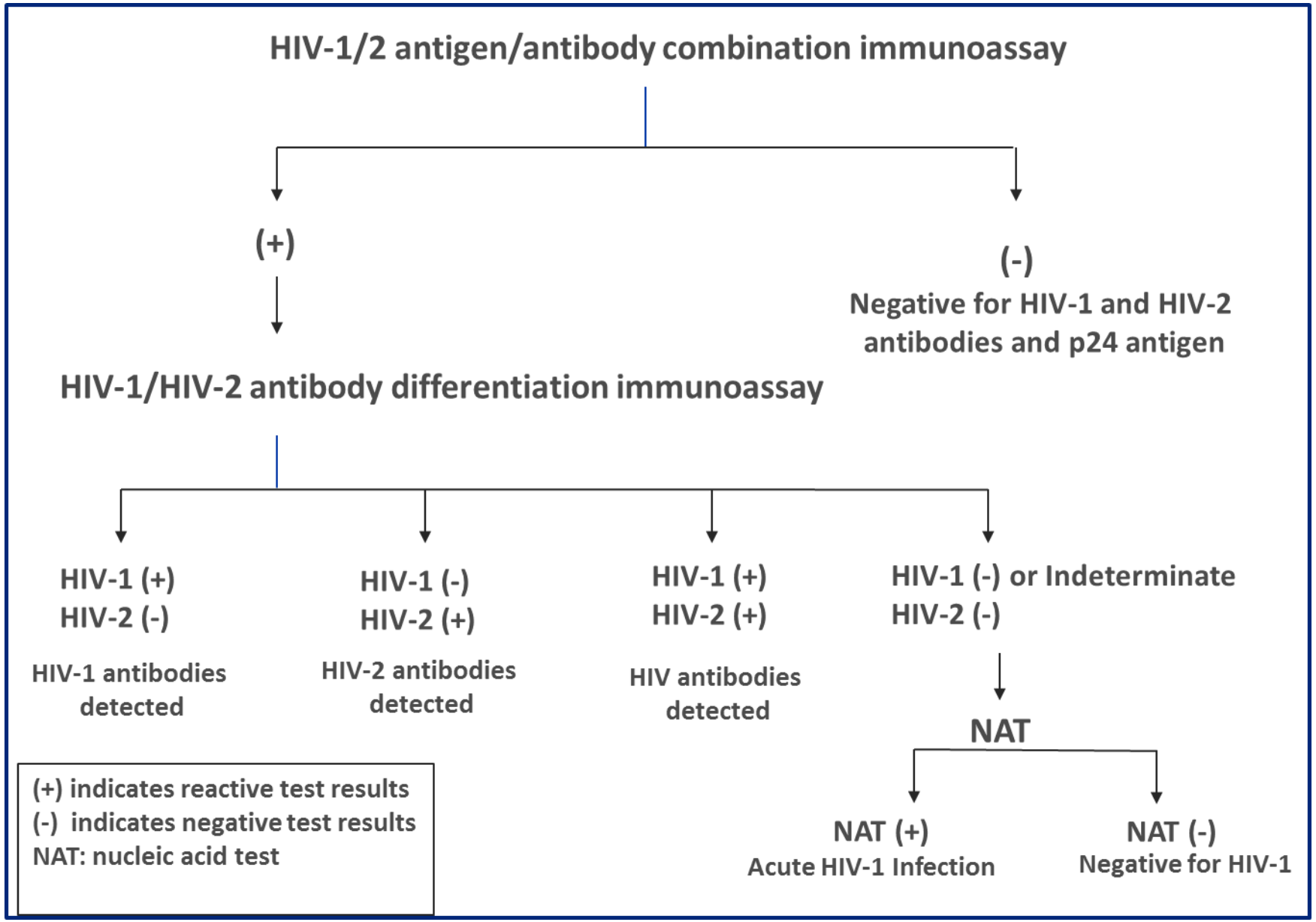
- **Misclassification by HIV-1 Western blot:**
  - 54/58 (93%) HIV-2 patients tested had positive HIV-1 WB (NYC)*
  - 97/163 (60%) HIV-2 cases reported had positive HIV -1 WB (CDC)**

- **HIV-2 often diagnosed after immunologic deterioration in patient with negative viral load**

**Torian et al, Clinical Infectious Disease 2010*
***MMWR July 2011*

Objectives of Recommended Lab Algorithm

- Improve diagnosis of acute/early HIV infection
- Accurate diagnosis of HIV-2
- Decrease turn-around time for results
- No substantial change in cost for testing



http://www.cdc.gov/hiv/testing/lab/guidelines/

Considerations for HIV POC Testing

- **Locations/populations that lab testing is difficult or not feasible**
  - Better to use POC than no test
- **POC assays continue to improve and have good sensitivity and specificity for established infections but…**
  - Be aware of assay limitations
    - Provide informed counseling messages
  - Oral Fluid assays will miss acute infections and some early infections [1,2]

[1] *Stekler et al, JCV 2013,* [2] *Luo et al JCV 2013*

Indiana Outbreak

- Rural community with extremely low prevalence
- Limited health care in area
- "Close community"

Indiana Outbreak

- Investigation winding down, but
  - >170 infections identified
  - Some indication of spread to neighboring KY areas
  - Once intensive screening was initiated, acute infections were identified

Risk Factors in Outbreak Preliminary Analysis

- Epidemiological data indicates multiple modes of transmission
  - Injection drug use
  - Sexual transmission
    - CSW
    - MSM
    - Heterosexual

Outbreak Demonstrates Value of Testing

- Both surveillance and lab noticed "a few" more cases than usual for the rural community
- CDC was contacted for assistance
- Once epidemiologists were on the ground, the extent of the "outbreak" was realized
- Infection found in males and females, including pregnant females
- Molecular testing and recency testing indicate most infections are recent and highly linked
- Some infections would have been missed with POC tests

Final Remarks

- Routine testing should reduce stigma associated with testing
- Substantial evidence of behavior change related to testing
- Early identification of infection has positive public health and individual benefits
- Laboratory testing offers the best potential for early diagnosis

Acknowledgement
Dr. Bernie Branson

Questions?

Michele Owen

mowen@cdc.gov

404 639-1046

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.