Disclosures

- None
Outline

- HIV epidemiology
  - Global
  - U.S.
  - Washington, D.C.
- Goals for treatment and prevention
  - UNAIDS
  - U.S. National AIDS Strategy
- Why do we still have an epidemic
  - HIV care continuum
    - Treatment outcomes
    - Effect on transmission
"Pneumocystis Pneumonia --- Los Angeles

In the period October 1980–May 1981, 5 young men, all active homosexuals, were treated for biopsy–confirmed Pneumocystis carinii pneumonia at 3 different hospitals in Los Angeles, California. Two of the patients died... Case reports of these patients follow.”

MMWR Weekly June 18, 1982 / 31(23);305–7. A Cluster of Kaposi's Sarcoma and Pneumocystis carinii Pneumonia among Homosexual Male Residents of Los Angeles and range Counties, California

MMWR Weekly June 11, 1982 / 31(22);294,300–1.
Epidemiologic Notes and Reports Update on Kaposi's Sarcoma and Opportunistic Infections in Previously Healthy Persons -- United States

June 1, 1981 – May 28, 1982: 355 cases of Kaposi's sarcoma, Pneumocystis carinii pneumonia (PCP), and other opportunistic infections

Profile of affected individuals:
previously healthy persons
Ages 15 and 60 years of age
281 (79%) were homosexual (or bisexual) men
41 (12%) were heterosexual men
20 (6%) were men of unknown sexual orientation
13 (4%) were heterosexual women
“CDC has received reports of four infants (under 2 years of age) with unexplained cellular immunodeficiency and opportunistic infections.”

Clinical features (12 infants):
- failure to thrive (83%)
- oral candidiasis (50%)
- hepatosplenomegaly (92%)
- generalized lymphadenopathy (92%)
- chronic pneumonitis without a demonstrable infection (83%)
Adults and children estimated to be living with HIV | 2015

Total: 36.7 million [34.0 million – 39.8 million]
Children (<15 years) estimated to be living with HIV | 2015

Total: 1.8 million [1.5 million – 2.0 million]
HIV Diagnoses in U.S. and Puerto Rico

Estimated AIDS Diagnoses in the United States and Puerto Rico
Cumulative through 1985  N = 23,271

Estimated AIDS Diagnoses in the United States and Puerto Rico
Cumulative through 1991  N = 259,457

Estimated AIDS Diagnoses in the United States and Puerto Rico
Cumulative through 1995  N = 558,521

Estimated AIDS Diagnoses in the United States and Puerto Rico
Cumulative through 2009  N = 1,141,888

Each Dot Represents 50 Cases

Notes: All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting. Data are cumulative AIDS diagnoses through the end of the year reported to CDC by June 2010.
Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.
HIV Epidemic in the U.S.

- An estimated 1.9 million individuals have been infected with HIV in the United States.
- Approximately 698,219 deaths attributed to HIV since the start of the epidemic.
- ~ 44,073 new infections in 2014.
  - Heterogeneity among subgroups and by region.

http://www.cdc.gov/hiv/statistics/overview/ataglance.html
Trends in Annual Rates of Death due to the 9 Leading Causes among Persons 25–44 Years Old, United States, 1987–2010

Note: For comparison with data for 1999 and later years, data for 1987–1998 were modified to account for ICD-10 rules instead of ICD-9 rules.
National HIV AIDS Strategy

- Overarching goals
  - Decrease new HIV infections
    - Focus on key populations and geographic areas
  - Improve health outcomes among HIV-infected individuals
    - Focus on HIV care continuum; health care coverage; models of care for holistic approach
  - Address HIV-related disparities and health inequities
    - Address structural constraints, stigma, & discrimination
  - Coordinated national response to the HIV epidemic
UNAIDS Target: 90–90–90

- UNAIDS target
  - Target 1: 90% of HIV+ individuals diagnosed
  - Target 2: 90% of diagnosed individuals on ART
  - Target 3: 90% of people with suppressed HIV RNA

*HIV-1 RNA < 1000 copies/mL.

HIV Treatment and Transmission
Treatment as prevention

HPTN 052:
Antiretroviral treatment of discordant couples led to a 96% decrease in HIV transmission

Provision of pre-exposure prophylaxis has been shown to decrease HIV transmission.

Okwundu CI et al. Cochrane Database Syst Rev 2012;7:CD007189
Decline in new HIV infections among children

New HIV infections among children have declined by 50% since 2010.

- 2015 – 150 000 [110 000–190 000] children became newly infected with HIV in 2015
- 2010 – 290 000 [250 000–350 000]


Note: All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.
Health Disparities: Not all get to less than 2% transmission

Rate of Perinatally Acquired HIV Infection, According to Year of Birth and Maternal Race or Ethnic Group, 2008–2012.
Smaller decline in new infections among adults

New HIV infections have fallen by 6% since 2010.

2010 – 2.2 million [2 million–2.5 million]
2015 – 2.1 million [1.8 million–2.4 million]

FACT SHEET 2016, GLOBAL STATISTICS—2015.
As of December 2015
• 17 million people accessing antiretroviral therapy
  • 15.8 million in June 2015
  • 46% [43–50%] of all adults living with HIV
• 7.5 million in 2010
New HIV infections among people aged 15 years and over, by region, 2010–2015

Antiretroviral therapy coverage among people living with HIV, by region, 2010–2015

Source: UNAIDS 2016 estimates.
Global HIV Transmission

New HIV infections among adults (aged 15 years and older), global, 2000–2015

New HIV infections among children (aged 0–14 years), global, 2000–2015

Source: UNAIDS 2016 estimates.
Key Populations
U.S. ~ 44,073 new infections in 2014
19% decline from 2005–2014
Heterogeneity among subgroups and by region

Figure 1. HIV Diagnoses by Transmission Category, 2005-2014

http://www.cdc.gov/hiv/statistics/overview/ataglance.html
Diagnoses of HIV Infection among Adults and Adolescents, by Transmission Category, 2010–2014—United States and 6 Dependent Areas

Note: Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays and missing transmission category, but not for incomplete reporting.

- **Heterosexual contact**: Defined as heterosexual contact with a person known to have, or to be at high risk for, HIV infection.
- **Injection drug use (IDU)**: Defined as injection drug use.
- **Male-to-male sexual contact**: Defined as male-to-male sexual contact.
- **Other**: Includes hemophilia, blood transfusion, perinatal exposure, and risk factor not reported or not identified.
Rates of Diagnoses of HIV Infection among Adults and Adolescents, 2014—United States and 6 Dependent Areas
N = 44,609  Total Rate = 16.6

Note: Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.
Diagnoses of HIV Infection among Adults and Adolescents, by Transmission Category, 2014—United States and 6 Dependent Areas

N = 44,609

- Male-to-male sexual contact
- Injection drug use (IDU) – Males
- IDU – Females
- Male-to-male sexual contact and IDU
- Heterosexual contact\textsuperscript{a} – Males
- Heterosexual contact\textsuperscript{a} – Females
- Other\textsuperscript{b}

\textsuperscript{a}Heterosexual contact with a person known to have, or to be at high risk for, HIV infection.

\textsuperscript{b}Includes hemophilia, blood transfusion, perinatal exposure, and risk factor not reported or not identified.

Note: Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed counts have been statistically adjusted to account for reporting delays and missing transmission category, but not for incomplete reporting.
Diagnoses of HIV Infection among Adults and Adolescents, by Sex and Transmission Category, 2014—United States and 6 Dependent Areas

**Males**
N = 36,138

- Male-to-male sexual contact: 82%
- Injection drug use (IDU): 9%
- Male-to-male sexual contact and IDU: 5%
- Other: 3%
- <1%

**Females**
N = 8,471

- Heterosexual contact: 87%
- 13%
- <1%

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Note: Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays and missing transmission category, but not for incomplete reporting.

a Heterosexual contact with a person known to have, or to be at high risk for, HIV infection.
b Includes hemophilia, blood transfusion, perinatal exposure, and risk factor not reported or not identified.
Note: Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.
DC has the Highest Lifetime Risk of HIV Acquisition in the US

Source: Centers for Disease Control and Prevention

http://www.cdc.gov/nchhstp/newsroom/images/2016/croi_lifetime_risk_state.jpg
African Americans at highest risk of HIV Acquisition
HIV Acquisition risk by transmission category/race:
--Highest among MSM
--Particularly high among African American MSM
HIV Care Continuum
WHAT DOES THE HIV CARE CONTINUUM SHOW?

HIV Care Continuum Shows Where Improvements are Needed

In the US, 1.2 million people are living with HIV. Of those:

- **DIAGNOSED**: 86%
- **ENGAGED IN CARE**: 40%
- **PRESCRIBED ART**: 37%
- **VIRALLY SUPPRESSED**: 30%


**Undiagnosed**: N=156,300 (~13%)

Age 13–24 Undiagnosed: N=25,300 (44% of infected in age group)
HIV in Washington, D.C.
HIV in DC

2014 - new diagnoses: 396

HIV prevalence is increasing
Currently ~2.5%
27% of HIV-positive individuals are women

New diagnoses ➔ decreasing
497 new diagnoses in 2013; 396 cases in 2014
In part due to better surveillance/active testing

Annual Epidemiology and Surveillance report 2015
Late presentation rate is still substantial
Heterogeneity in location of new HIV cases, highest in wards 1, 5, 7 and 8

**Map 1. Number Newly Diagnosed HIV Cases by Census Tract and Ward, District of Columbia 2009 and 2013**

Newly Diagnosed Cases, 2009*, †, N=916

Newly Diagnosed Cases, 2013**, ††, N=553

*134 cases had a missing address or an address that did not geocode and were not included on this map
† Though not included on this map, 40 cases were diagnosed in jail and 9 cases were homeless at the time of diagnosis
**67 cases had a missing address or an address that did not geocode and were not included on this map
†† Though not included on this map, 6 cases were diagnosed in jail and 5 cases were homeless at the time of diagnosis
Higher HIV prevalence among African Americans and older individuals

MSM closely followed by heterosexual are reported as risk factor for acquiring HIV
Estimates of new infections remain stable from 2009–2013, despite the demonstrated decline in newly diagnosed cases.

- Incidence estimate: 123.6/100,000
- Highest % new infections
  - Men – 65.9%
  - African American – 73.2%
  - Age 13–29 – 47.9%
  - MSM – 49.9%
State Progress Toward CDC’s Division of HIV/AIDS Prevention Goals for 2015

- Increase HIV Testing (%): 100.0 National Goal, 77.5 District of Columbia Progress
- Increase HIV Status Awareness (%): 100.0 National Goal, 89.0 District of Columbia Progress
- Increase HIV Viral Suppression (%): 100.0 National Goal, 67.8 District of Columbia Progress
- Increase HIV Linkage to Care (%): 100.0 National Goal, 81.2 District of Columbia Progress
- Increase HIV Retention in Care (%): 100.0 National Goal, 53.3 District of Columbia Progress

- Decrease HIV Late-Stage Diagnosis (%): 56.0 District of Columbia Progress
- Decrease HIV Death Rate (%): 21.7 District of Columbia Progress

National Goal

District of Columbia Progress

http://aidsvu.org/state/district-of-columbia/
Trajectory analyses of virologic outcomes reflecting community-based HIV treatment in Washington DC 1994–2012

Joanne Michelle F. Ocampo, Michael Plankey, Kai Zou, Jeff Collmann, Cuiwei Wang, Mary A. Young, Chenglong Liu, Joshua A. Ripple and Seble Kassaye
Methods

- Inclusion criteria
  - HIV-positive DC WIHS women
  - Contributed at least four semi-annual visits

- Total sample size
  - 329 women
  - Contributed 6633 visits between 1994–2012 (visits 1–37)

- Logistic trajectory analysis was used to identify groups of viral load suppression

- Cumulative viral load suppression–years was used to verify groups found above

- Multinomial regression analysis with generalized estimating equations for repeated measures was used to explore group characteristics
DC WIHS: Cross-sectional analysis demonstrates increasing then stable viral suppression

![Graph showing viremia and non-viremia proportions over visits from 1994 to 2012.]

**Fig. 4** Cross-sectional depiction of the proportion of DC WIHS women with viremia and women without viremia 1994–2012 (N = 266)
DC WIHS Women – Viremia trajectory

A “dose–response” effect was seen in the cumulative years of viremia by viremic state, with the highest cumulative years of viremia amongst sustained viremic and lowest among non-viremic groups.
Mortality associated with sustained viremia trajectory, but not intermittent and low level viremia

**Sustained suppression** – 4.9%

**Intermittent viremia** – 6.9%

**Sustained viremia** – 31.1%

*Fig. 3* Kaplan-Meier survival analysis for participants (N = 329) showed a significant difference between sustained viremia (N = 154) survival trends from intermittent viremia (N = 95) and non-viremia (N = 80) HIV treatment careers using >50 copies/mL HIV RNA or lower at time of assay detection limit with (+) signs indicating censored observations and survival time defined as age at last visit seen alive minus age at first visit.
Factors associated with sustained viremic HIV treatment careers:

- **positively associated**: African American ethnicity, older age, depression, and no therapy;
- **negatively associated**: higher CD4+ T-cell count, higher education, and higher adherence

<table>
<thead>
<tr>
<th>Variables analyzed with detection limit at ≥80 copies/mL</th>
<th>Univariate analysis</th>
<th>Multivariate analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR (CI)</td>
<td>P-value</td>
</tr>
<tr>
<td>Above high school education</td>
<td>0.52 (0.32-0.84)</td>
<td>0.0079</td>
</tr>
<tr>
<td>Adherence (≥95%)</td>
<td>0.33 (0.26-0.41)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Age</td>
<td>1.01 (0.99-1.03)</td>
<td>0.5108</td>
</tr>
<tr>
<td>CD4N/100</td>
<td>0.85 (0.80-0.91)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Depression (CESD2≥16)</td>
<td>1.86 (1.38-2.49)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Drug abuse</td>
<td>1.90 (1.28-2.82)</td>
<td>0.0015</td>
</tr>
<tr>
<td>Ethnicity (African-American)</td>
<td>2.58 (1.42-4.69)</td>
<td>0.0019</td>
</tr>
<tr>
<td>Ethnicity (Hispanic-American)</td>
<td>0.57 (0.22-1.45)</td>
<td>0.2355</td>
</tr>
<tr>
<td>Ethnicity (other)</td>
<td>1.95 (0.50-7.60)</td>
<td>0.3388</td>
</tr>
<tr>
<td>Housing</td>
<td>0.71 (0.50-1.00)</td>
<td>0.0518</td>
</tr>
<tr>
<td>No therapy</td>
<td>4.02 (2.77-5.84)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Therapy (ART)^</td>
<td>1.95 (1.45-2.63)</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>
HIV-positive women’s comments on taking HIV treatment, including for treatment as prevention:

“Takin’ a bunch of medication is no fun, you know. Visiting doctors, copays. It’s at-it’s annoying...**It literally changes your life** and who wants to go through that if you don’t have to”

“if it's not broke, why fix it?”
Transmitted Drug Resistance (TDR) was substantial and varied by drug class

- Treatment naïve N=561
- Overall TDR: 126 (22.5%)
Gender and HIV acquisition risk factor associated with falling into a cluster, but not by race/ethnicity

• 14% fall within a transmission cluster – 32 dyads, 5 triads

• Men were more likely to fall into a cluster than women: 20% vs 6% (p<0.0001)

• MSM more likely to fall in a cluster than those with heterosexual risk: 22% vs 14% (p=0.046)

• Transmitted drug resistance was seen among 6 individuals in cluster

What can we do to decrease HIV transmission
Assessing risk

- MSM, heterosexual (male and female)
  - HIV–positive partner
  - Recent STI
  - High number of sex partners
  - Inconsistent/no condom use
  - Sex work

- Heterosexual women and men
  - In high prevalence area or network

- IDU
  - HIV–positive injecting partner
  - Shared equipment/needles
PrEP: Identification

Numbers of Persons at Risk for HIV Remain High, but Percentages Vary by Population

Estimated percentages and numbers of adults with indications for PrEP, by transmission risk group, United States, 2015

<table>
<thead>
<tr>
<th>Transmission risk group</th>
<th>% with PrEP indication*</th>
<th>Estimated number</th>
<th>(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men who have sex with men, aged 18-59 yrs†</td>
<td>24.7</td>
<td>492,000</td>
<td>(212,000-772,000)</td>
</tr>
<tr>
<td>Adults who inject drugs, aged ≥18yrs‡</td>
<td>18.5</td>
<td>115,000</td>
<td>(45,000-185,000)</td>
</tr>
<tr>
<td>Heterosexually active adults, aged 18-59 yrs††</td>
<td>0.4</td>
<td>624,000</td>
<td>(404,000-846,000)</td>
</tr>
<tr>
<td>Men**</td>
<td>0.2</td>
<td>157,000</td>
<td>(62,000-252,000)</td>
</tr>
<tr>
<td>Women</td>
<td>0.6</td>
<td>468,000</td>
<td>(274,000-662,000)</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>1,232,000</td>
<td>(881,000-1,803,000)</td>
</tr>
</tbody>
</table>

Abbreviation: CI = confidence interval.
* Percentage of all estimated persons in each transmission risk group and demograhic subgroups with PrEP indications.
† Based on 2007–2010 National Health and Nutrition Examination Survey (NHANES) data, weighted as recommended using current population estimates. Risk factors used to define PrEP indications included two or more male sex partners and at least one of the following: any condomless sex or sexually transmitted infection diagnosis in past 12 months.
‡ Based on 2010 National Survey on Drug Use and Health. Risk factors used to define PrEP indications included injection of heroin, methamphetamine, stimulants, or cocaine, and injecting with a needle used by someone else before them.
†† Based on 2011–2013 National Survey of Family Growth and 2007–2010 NHANES data, weighted as recommended using current population estimates. Risk factors used to define PrEP indications included two or more opposite sex partners and at least one of the following: sex with an HIV positive partner; or any condomless sex in the last 6 weeks and sex with a male who injects drugs or bisexual male (males only) in last 12 months.
** The relative standard error for males was 50.0%.

PrEP use has increased, but primarily among men

Approximately 14,000 unique individuals had initiated PrEP based on a sample of 39% of all TRUVADA prescriptions through Q1 2015.

New PrEP Starts by Gender

Total Unique Individuals = 8,512

IMS National Prescription Database accounts for approx. 39% of all TVD prescriptions

HIV-negative women were enthusiastic about PrEP for HIV prevention

“We asked the women why do they want to use PrEP... “To save your life” was the unison response.”

HIV-positive women were concerned about side effects and need for frequent clinic visits, laboratory testing/monitoring, and were concerned that barrier would not be used
The First Citywide Program to Get Black Women on PrEP Is Coming to Washington, D.C.

By Christina Cauterucci
Relative contributions of treatment and PrEP to prevention of new HIV infections

- HIV infections prevented due to expanded testing and treatment
- HIV infections prevented due to PrEP (assumes PrEP use among high-risk populations = 40% MSM; 10% PWID; 10% HET)

**Scenario 1:**
Projected new infections by 2020 at current testing
- Total infections: 265,330

**Scenario 2:**
If PrEP use increases among high-risk populations
- Total infections: 217,109
- Infections prevented through PrEP: 48,221

**Scenario 3:**
If 85% of people diagnosed are linked to care, 60% achieve viral
- Total infections: 144,434
- Infections prevented through PrEP: 31,988

**Scenario 4:**
Achieving NHAS goals – if 85% of people diagnosed are linked to care, 80%
- Total infections: 80,270
- Infections prevented through PrEP: 16,928
- Infections prevented through testing and treatment: 168,132
Outbreak of HIV Infection in Southeastern Indiana.

Scott County, Indiana:
- 181 cases of HIV diagnoses October 1 2014 – Nov 1 2015
- 87.8% reported use of ER oxymorphone
- 92.3% were co-infected with HCV

Maximum-Likelihood Phylogenetic Tree of HIV-1 Polymerase Sequences —
- 98.7% highly related

Where Disease Eruption Is a Threat

A CDC report identified 220 counties where factors such as unemployment rates, overdose deaths and sales of prescription painkillers contribute to a high vulnerability for outbreaks of HIV and hepatitis C among injection drug users.

Counties vulnerable to outbreaks of HIV and hepatitis C

Source: Centers for Disease Control and Prevention

THE WALL STREET JOURNAL.
Thank you
HIV-1/2 antigen/antibody combination immunoassay

(+)

(-)

Negative for HIV-1 and HIV-2 antibodies and p24 Ag

HIV-1/HIV-2 antibody differentiation immunoassay

HIV-1 (+) HIV-1 (-) HIV-1 (+) HIV-1 (-) or indeterminate

HIV-2 (-) HIV-2 (+) HIV-2 (+) HIV-2 (-)

HIV-1 antibodies detected HIV-2 antibodies detected HIV antibodies detected HIV-1 NAT

(+), (-) indicate reactive, nonreactive test results
NAT: nucleic acid test

HIV-1 NAT (+) Acute HIV-1 infection
HIV-1 NAT (-) Negative for HIV-1
Table 2. FDA-approved assays included in evidence synthesis

<table>
<thead>
<tr>
<th>Assay class</th>
<th>Trade name (Manufacturer)</th>
<th>Abbreviation used in evidence tables</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-1/HIV-2 immunoassay “3rd generation”</td>
<td>Advia Centaur HIV 1/0/2 Enhanced (Siemens Healthcare Diagnostics, Malvern, PA)</td>
<td>Advia</td>
</tr>
<tr>
<td></td>
<td>GS HIV-1/HIV-2 PLUS O EIA (Bio-Rad Laboratories, Redmond, WA)</td>
<td>GS Plus O</td>
</tr>
<tr>
<td></td>
<td>Vitros Anti-HIV 1+2 Assay (Ortho Clinical Diagnostics, Rochester, NY)</td>
<td>Vitros</td>
</tr>
<tr>
<td>HIV-1/HIV-2 antigen/antibody combination immunoassay “4th generation”</td>
<td>Architect HIV Ag/Ab Combo (Abbott Laboratories, Abbott Park, IL)</td>
<td>Architect Ag/Ab</td>
</tr>
<tr>
<td></td>
<td>GS HIV Combo Ag/Ab EIA (Bio-Rad Laboratories, Redmond, WA)</td>
<td>GS Ag/Ab</td>
</tr>
<tr>
<td>HIV-1 Western blot</td>
<td>GS HIV-1 Western Blot (Bio-Rad Laboratories, Redmond, WA)</td>
<td>WB</td>
</tr>
<tr>
<td></td>
<td>Cambridge Biotech HIV-1 Serum Western Blot (Maxim Biomedical, Inc. Rockville, MD)</td>
<td>WB</td>
</tr>
<tr>
<td>HIV-1/HIV-2 differentiation assay</td>
<td>Multispot HIV-1/HIV-0 Rapid Test (Bio-Rad Laboratories, Redmond, WA)</td>
<td>Multispot</td>
</tr>
<tr>
<td>HIV-1 nucleic acid amplification test</td>
<td>APTIMA HIV-1 RNA Qualitative Assay (Hologic Gen-Probe Inc., San Diego, CA)</td>
<td>APTIMA</td>
</tr>
<tr>
<td></td>
<td>Procleix Ulitro (Novartis Diagnostics, Cambridge, MA)</td>
<td>Procleix</td>
</tr>
</tbody>
</table>

* The Determine HIV 1-2 Ag/Ab Combo rapid test, approved by the FDA in August 2013, was not included in the evidence synthesis because there were no studies evaluating its performance as part of the algorithm.

** APTIMA, FDA-approved for HIV diagnosis, and Procleix Ulitro, FDA-licensed for screening blood donations, are two brand names for the same qualitative RNA assay.