An Update on the US HIV Epidemic and Recent Strides in HIV Care

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Overview of Presentation

- Update on the epidemiology of HIV/AIDS in the US.
- Update on the epidemiology of HIV/AIDS in Florida.
- Barriers to poor linkage/entry, engagement, and retention in care.
- Effect of poor linkage/entry, engagement, and retention in care.
- Update on trends in mortality in people living with HIV/AIDS.
- Update on prevention and treatment of HIV/AIDS.
Common abbreviations used in this talk

- HIV – Human Immunodeficiency Virus
- AIDS – Acquired Immunodeficiency Syndrome
- PLWHIV – People Living With HIV
- ART – Anti-Retroviral Treatment
- ARV – Anti-Retroviral Medications
Epidemiology

• What is the current status of the HIV/AIDS epidemic in the US?
• How has it changed over time?
HIV Care Continuum for the United States and Puerto Rico
Persons Living with Diagnosed or Undiagnosed HIV Infection
HIV Care Continuum Outcomes, 2012 — US and Puerto Rico

N = 1,218,400

- Diagnosed: 87.2%
- Received medical care: 39.1%
- Prescribed ART: 36.2%
- Viral Suppression: 30.2%

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 2012. 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 2012, were prescribed ART, or whose most recent VL in the previous year was undetectable or <200 copies/mL—United States and Puerto Rico.
Persons Living with Diagnosed or Undiagnosed HIV Infection
US 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.
Linkage to HIV Medical Care within 1 Month after HIV diagnosis during 2013, among persons aged ≥13 years 27 States and the District of Columbia

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. Linkage to HIV medical care was defined as having CD4 or VL test ≤1 month after HIV diagnosis. Hispanics/Latinos can be of any race.
Linkage to HIV Medical Care within 3 Months after HIV diagnosis during 2013, among persons aged ≥13 years in 27 States and the District of Columbia.

Note: Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. Linkage to HIV medical care was defined as having CD4 or VL test ≤3 months after HIV diagnosis. Hispanics/Latinos can be of any race.
Epidemiology of HIV Infection through 2014
Diagnoses of HIV Infection among Adults and Adolescents, by Sex, 2010-2014: US 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, but not for incomplete reporting.
Diagnoses of HIV Infection among Adults and Adolescents, by Transmission Category, 2014: US and 6 Dependent Areas

N = 44,609

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.

- Male-to-male sexual contact: 67%
- Injection drug use (IDU) – Males: 17%
- IDU – Females: 8%
- Male-to-male sexual contact and IDU: 3%
- Heterosexual contact\(^a\) – Males: 2%
- Heterosexual contact\(^a\) – Females: 4%
- Other\(^b\): <1%

\(a\) 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.
Diagnoses of HIV Infection among Adults and Adolescents, by Race/Ethnicity, 2010–2014: US 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, but not for incomplete reporting.

Hispanics/Latinos can be of any race.
Diagnoses of HIV Infection among Adults and Adolescents, by Age at Diagnosis, 2014: US
N = 43,899

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.
### Deaths of Persons with Diagnosed HIV Infection, by Race/Ethnicity, 2013: US

<table>
<thead>
<tr>
<th>Race/ethnicity</th>
<th>No.</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian/Alaska Native</td>
<td>66</td>
<td>2.8</td>
</tr>
<tr>
<td>Asian(^a)</td>
<td>64</td>
<td>0.4</td>
</tr>
<tr>
<td>Black/African American</td>
<td>7,581</td>
<td>19.4</td>
</tr>
<tr>
<td>Hispanic/Latino(^b)</td>
<td>2,664</td>
<td>4.9</td>
</tr>
<tr>
<td>Native Hawaiian/other Pacific Islander</td>
<td>5</td>
<td>0.9</td>
</tr>
<tr>
<td>White</td>
<td>5,028</td>
<td>2.5</td>
</tr>
<tr>
<td>Multiple races</td>
<td>874</td>
<td>14.1</td>
</tr>
<tr>
<td><strong>Total(^c)</strong></td>
<td><strong>16,281</strong></td>
<td><strong>5.1</strong></td>
</tr>
</tbody>
</table>

**Note.** Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. Deaths of persons with a diagnosed HIV infection may be due to any cause. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting. Rates are per 100,000 population.

\(^a\) Includes Asian/Pacific Islander legacy cases.

\(^b\) Hispanics/Latinos can be of any race.

\(^c\) Because column totals for estimated numbers were calculated independently of the values for the subpopulations, the values in each column may not sum to the column total.
Rates of Adults and Adolescents Living with Diagnosed HIV Infection, Year-end 2013—United States and 6 Dependent Areas

N = 950,811  Total Rate = 355.9

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.
Rates of Adults and Adolescents Living with Diagnosed HIV Infection Ever Classified as Stage 3 (AIDS), Year-end 2013—United States and 6 Dependent Areas

N = 527,170       Total Rate = 197.4

Note. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.
Epidemiology

- What is the current status of the HIV/AIDS epidemic in the state of Florida?
- How has it changed over time?
The Epidemic in Florida

Newly *diagnosed** HIV infections in 2014: 5,897
(1\textsuperscript{st} in the nation in 2013, up 17\% from 2013 in FL)

Newly *diagnosed** AIDS cases in 2014: 2,349
(1\textsuperscript{st} in the nation in 2013, down 21\% from 2013 in FL)

Cumulative pediatric AIDS cases *diagnosed** through 2014: 1,548
(2\textsuperscript{nd} in the nation in 2013)

Persons *diagnosed** and living***
with HIV disease through 2014: 110,000→
(3\textsuperscript{rd} in the nation in 2013)

HIV prevalence estimate through 2014: 126,100
(accounts for 12.8\% national estimated unaware of their status)

* Other = Asian/Pacific Islanders; American Indians/Alaskan Natives; multi-racial.
** Data by year of diagnosis for 2014, data as of 06/30/2015
*** Living (prevalence) data as of 06/30/2015
HIV Infection Case Rates* by County of Residence,** Reported in 2014, Florida

Statewide Data:
N= 6,147
State Rate = 31.4
Rate per 100,000 population

*Population data were provided by Florida CHARTS as of 7/9/2015.
**County totals exclude Department of Corrections cases (N=128). Numbers on counties are cases reported.
AIDS Case Rates* by County of Residence,** Reported in 2014, Florida

Statewide Data:  
N=2,698  
State Rate = 13.8  
Rate per 100,000 Population

*Population data provided by Florida CHARTS as of 7/9/2015.  
**County totals exclude Department of Corrections cases (N=54).  
Numbers on counties are cases reported.
Enhanced laboratory reporting (ELR) laws in 2006 and the expansion of ELR in 2007 led to an artificial peak in newly reported cases of AIDS in 2008. Another surge in the expansion of ELR in 2012 was followed by another increase in newly reported cases of AIDS in 2013.

*Source: Population estimates are provided by Florida CHARTS as of 7/9/2015.
Adult HIV Infection and AIDS Cases Reported in 2014 and Population, by Race/Ethnicity, Florida

2014 Florida*
Population Estimates

Over-Representation

<table>
<thead>
<tr>
<th>Race</th>
<th>HIV Population</th>
<th>AIDS Population</th>
<th>Total FL Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black</td>
<td>41%</td>
<td>52%</td>
<td>14%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>26%</td>
<td>20%</td>
<td>23%</td>
</tr>
<tr>
<td>White</td>
<td>31%</td>
<td>26%</td>
<td>59%</td>
</tr>
</tbody>
</table>

N=16,623,794

N=6,132

N=2,685

*Data from Florida Department of Health

**Other Race/Ethnicity
HIV Tests Conducted in Florida and Seropositivity Rates*, 1985-2014

*Seropositivity rates are defined as the percent of positive over the number of tests conducted each year.
Data validated from HIV CT as of 3/9/2015.
Underlying Factors Affecting HIV/AIDS Disparities

- Amount of HIV already in the community
- Late diagnosis of HIV or AIDS*
- Access to/acceptance of care*
- Stigma, denial*
- Discrimination, homophobia*
- HIV/AIDS complacency*
- Poverty and unemployment

*Factors that HIV/AIDS initiatives can impact.

- CDC calculated lifetime risk of HIV infection:
  - General US population: 1 in 64 people
  - Black: 1 in 20
  - Hispanic: 1 in 48
  - Hawaiian/Pacific Island: 1 in 82
  - American Indian/Alaskan Native: 1 in 129
  - White: 1 in 132
  - Asians: 1 in 174

- CDC calculated lifetime risk of HIV infection
  - MSM General 1 in 6 people
    - Black 1 in 2
    - Hispanic 1 in 4
    - White 1 in 11
  - IVDU
    - Women 1 in 23
    - Men 1 in 36
    - Black Women 1 in 6
    - Black Men 1 in 9
HIV screening is recommended for patients in all health-care settings . . . unless the patient declines (opt-out screening).

Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing.

Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings.
Did CDC’s 2006 revised HIV testing recommendations make a difference?

Opt-Out HIV testing helps engagement and retention in care and VL suppression
How does late entry into care affect outcomes?
Racial/ethnic disparities drive missed clinic visits and HIV viral load

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Odds of VF, Patient Variables Only</th>
<th>Odds of VF, With No-Show Count</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR (95% CI)</td>
<td>OR (95% CI)</td>
</tr>
<tr>
<td>Gender: male vs female</td>
<td>1.05 (0.91, 1.21)</td>
<td>1.07 (0.92, 1.23)</td>
</tr>
<tr>
<td>Ethnicity: Hispanic vs non-Hispanic</td>
<td>0.81 (0.67, 0.98)</td>
<td>0.79 (0.65, 0.96)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black vs White</td>
<td>1.19 (1.01, 1.40)</td>
<td>1.11 (0.94, 1.32)</td>
</tr>
<tr>
<td>Other vs White</td>
<td>1.24 (0.89, 1.73)</td>
<td>1.20 (0.85, 1.68)</td>
</tr>
</tbody>
</table>
Racial/ethnic disparities drive missed clinic visits and HIV viral load

FIGURE 1—Percentage of (a) virological failure by race stratified by frequency of no-show visits and (b) no-show visits by race: Centers for Disease Control and Prevention and Health Resources and Services Administration Retention in Care preintervention, 6 US metropolitan areas, May 2008 to April 2009.

Note. The metropolitan areas surveyed were in Baltimore, MD; Birmingham, AL; Boston, MA; Brooklyn, NY; Houston, TX; and Miami, FL.
Racial/ethnic disparities drive missed clinic visits and HIV viral load

<table>
<thead>
<tr>
<th>Setting</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prenatal care settings</td>
<td>126 (92.6)</td>
</tr>
<tr>
<td>Primary care practices caring for adolescents (aged 13-17 years)</td>
<td>74 (54.4)</td>
</tr>
<tr>
<td>Primary care practices caring for adults (aged 18 years and older)</td>
<td>103 (75.7)</td>
</tr>
<tr>
<td>Emergency departments</td>
<td>109 (80.1)</td>
</tr>
<tr>
<td>Hospital inpatient wards</td>
<td>90 (66.2)</td>
</tr>
<tr>
<td>Sexually transmitted infection clinics</td>
<td>132 (97.1)</td>
</tr>
</tbody>
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Care engagement: Do missed visits matter?

<table>
<thead>
<tr>
<th>Variable</th>
<th>Adjusted hazard ratio (95% CI)</th>
<th>P</th>
</tr>
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<tr>
<td>No. of quarters with visita</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1.94 (1.36–2.76)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>2</td>
<td>1.68 (1.24–2.26)</td>
<td>&lt;.001</td>
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<tr>
<td>3</td>
<td>1.41 (1.10–1.82)</td>
<td>&lt;.01</td>
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<tr>
<td>4</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Baseline CD4+ cell count</td>
<td></td>
<td></td>
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<tr>
<td>≤200 × 10^6 cells/L</td>
<td>2.35 (1.82–3.05)</td>
<td>&lt;.001</td>
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<td>201–350 × 10^6 cells/L</td>
<td>1.36 (0.99–1.87)</td>
<td>.06</td>
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<td>&gt;350 × 10^6 cells/L</td>
<td>1.00</td>
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</tr>
<tr>
<td>Baseline CD4&lt;sup&gt;+&lt;/sup&gt; cell count</td>
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<td>1.00</td>
<td></td>
</tr>
</tbody>
</table>
Took medicines ≥75% of the time

Took medicines <75% of the time

Financial Barriers of Care: Competing Subsistence Needs

• Competing Subsistence Needs
  ▪ Routine basic necessities (food, shelter, clothing, child care, etc) that compete for resources otherwise used on health care.

• Cunningham W, et al. 1999.
  ▪ Prospective interview on social determinants.
  ▪ 2,864 individuals living with HIV interviewed
• >33% of the 2,864 sampled patients in care missed or postponed care because of ≥1 of the 4 reasons.
  ▪ Needed money for food, clothing, housing
  ▪ Lacked transportation
  ▪ Felt too sick
  ▪ Couldn’t get off work

  ▪ Some reported foregoing food, clothing, and/or housing because needed money for medical care.
Financial Barriers of Care: Competing Subsistence Needs

Approximately 1/3 of people with each barrier go to the ED for access to care.

<table>
<thead>
<tr>
<th>Barrier to Care</th>
<th>ED Visit in Past 6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needed money for food, clothing, housing</td>
<td>32.9%</td>
</tr>
<tr>
<td>Lacked Transportation</td>
<td>35.4%</td>
</tr>
<tr>
<td>Felt too sick</td>
<td>39.7%</td>
</tr>
<tr>
<td>Foregoing food, clothing, and/or housing because for medical care</td>
<td>37.5%</td>
</tr>
</tbody>
</table>

Cunningham W Med Care 1999.
Financial Barriers: Survival Impact
HIV/AIDS Mortality

• How has the lifespan changed since pre-HAART (pre-1996) era?
• What are the common causes of mortality nowadays?
  - Question: What is the life-expectancy gap between PLWHIV and HIV uninfected patients?

  - Cohort comparison between 25,768 PLWHIV and 257,600 HIV uninfected patients.
    - Cohort match: age, gender, med center, and year.
    - Retrospective analysis of Kaiser Permanente EMR, CA state death certificate registry, and Social Security Admin databases.

<table>
<thead>
<tr>
<th>Era</th>
<th>HIV +</th>
<th>HIV -</th>
<th>Gap</th>
</tr>
</thead>
<tbody>
<tr>
<td>1996-2006</td>
<td>+36yrs</td>
<td>+62.3yrs</td>
<td>26.3yrs</td>
</tr>
<tr>
<td>2007-2011</td>
<td>+48.5yrs</td>
<td>+62.3yrs</td>
<td>13.8yrs</td>
</tr>
</tbody>
</table>
## Causes of Mortality in People Living with HIV

- Analysis of D:A:D collaborative cohort database.
  - 1999 - 2011
  - n=3,909

<table>
<thead>
<tr>
<th>Cause</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AIDS-relate</strong></td>
<td>29%</td>
</tr>
<tr>
<td>Liver-related</td>
<td></td>
</tr>
<tr>
<td>- <em>Chronic viral hepatitis</em></td>
<td>11%</td>
</tr>
<tr>
<td>- <em>Liver failure</em></td>
<td>2%</td>
</tr>
<tr>
<td>CVD-related</td>
<td>11%</td>
</tr>
<tr>
<td>- <em>MI or other heart disease</em></td>
<td>8%</td>
</tr>
<tr>
<td>- <em>Stroke or other CVD</em></td>
<td>3%</td>
</tr>
<tr>
<td>- <em>DM related complications</em></td>
<td>&lt;0.5%</td>
</tr>
<tr>
<td>Non-AIDS cancers</td>
<td>15%</td>
</tr>
<tr>
<td>Other or unknown</td>
<td></td>
</tr>
<tr>
<td>- <em>Suicide</em></td>
<td>4%</td>
</tr>
<tr>
<td>- <em>Invasive bacterial infection</em></td>
<td>7%</td>
</tr>
</tbody>
</table>
Causes of Mortality in People Living with HIV: Trend in Changes

Entire cohort

AIDS-related
Causes of Mortality in People Living with HIV: Trend in Changes

Cohort only of the virally suppressed
Causes of Mortality in People Living with HIV: Trend in Changes

- Data from the HOPS trial
  n=6945

- Red line is ratio of CV Death to AIDS
Pre-Exposure Prophylaxis (PrEP)

- What is recommended?
- Is it effective?
Daily oral PrEP (combination tenofovir disoproxil fumarate (TDF) 300 mg + emtricitabine (FTC) 200 mg) is recommended as one prevention option:

- Adult MSM (men who have sex with men) at substantial risk of HIV acquisition (IA)
- Adult heterosexually active men and women who are at substantial risk of HIV acquisition. (IA)
- Injection drug users (IDU) at substantial risk of HIV acquisition. (IA)
Pre-Exposure Prophylaxis (PrEP)

- Daily oral PrEP (combination tenofovir disoproxil fumarate (TDF) 300 mg + emtricitabine (FTC) 200 mg) should be discussed:
  - Uninfected heterosexually-active individuals whose partners are HIV infected (HIV-discordant couples) as one option to protect the uninfected partner during conception and pregnancy. (IIB)
- Data is insufficient for the efficacy and safety of PrEP for adolescents. The risks and benefits of PrEP should be weighed carefully in the context of local laws and regulations about autonomy in health care decision-making by minors. (IIIB)

CDC 2014 PreP Guidelines.
Pre-Exposure Prophylaxis (PrEP)

  - Oral NRTI medication given to HIV-1 negative partners of heterosexual serodiscordant couples (one partner + and other partner neg for HIV)
  - Once daily medication – 3 arms (n=4747)
    - Tenofovir (TDF) n=1584
    - Tenofovir-Emtracitabine (TDF/FTC) n=1579
    - Placebo n=1584
Pre-Exposure Prophylaxis (PrEP): TDF-FTC (Truvada)

- TDF alone reduced HIV-1 transmission by 67%.
- TDF/FTC reduced HIV-1 transmission by 75%.
Pre-Exposure Prophylaxis (PrEP)

  - Oral NRTI medication given to HIV-1 negative men or transgender women who have sex with men
  - Once daily NRTI – 2 arms (n=2499)
    - Tenofovir-Emtracitabine (TDF/FTC) n=1579
    - Placebo n=1584
Pre-Exposure Prophylaxis (PrEP)

- TDF/FTC reduced HIV-1 transmission by 44%.

[Graph showing cumulative probability of HIV-1 infection over weeks since randomization, with Placebo and FTC-TDF curves compared.]
Pre-Exposure Prophylaxis (PrEP): Dapivirine Vaginal Ring in Women

• Silicone elastomer vaginal matrix ring containing NNRTI dapivirine 25 mg; ring replaced every 4 wks
  ▪ Randomized, double-blind phase III trials
  ▪ Sexually active HIV uninfected women
  ▪ Primary endpoints: efficacy and safety

Dapivirine 25 mg Vaginal Ring Q4W + HIV Prevention Service Package (ASPIRE\textsuperscript{1,2}: n = 1313; IPM-027\textsuperscript{3}: n = 1300)

Versus

Placebo Vaginal Ring Q4W + HIV Prevention Service Package (ASPIRE\textsuperscript{1,2}: n = 1316; IPM-027\textsuperscript{3}: n = 650)

# Pre-Exposure Prophylaxis (PrEP): Dapivirine Vaginal Ring in Women

<table>
<thead>
<tr>
<th>Outcome</th>
<th>ASPIRE(^{[1,2]}): 15 Sites</th>
<th>ASPIRE(^{[1,2]}): 13 Sites*</th>
<th>IPM-027/Ring Study(^{[3]})</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dapivirine (n = 1308)</td>
<td>Placebo (n = 1306)</td>
<td>Dapivirine (n = 1198)</td>
</tr>
<tr>
<td>HIV infections, n</td>
<td>71</td>
<td>97</td>
<td>54</td>
</tr>
<tr>
<td>HIV incidence (per 100 PYs)</td>
<td>3.3</td>
<td>4.5</td>
<td>2.8</td>
</tr>
<tr>
<td>HIV protection efficacy, %</td>
<td>27 (P = .046)</td>
<td>37 (P = .007)</td>
<td>31 (P = .040)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Among women older than 21 yrs</td>
<td>-</td>
<td>56 (P &lt; .001)</td>
<td>37 (P = .10)</td>
</tr>
</tbody>
</table>

Summary

• The incidence of HIV/AIDS is decreasing, but the population of HIV-1 infected people continues to grow.
• Racial/ethnic minorities over-represent the HIV infected population and remain at risk for health care disparities.
• Late entry into care and poor adherence to care is strongly associated with increased mortality.
• Non-AIDS related causes of mortality, particularly CVD and hepatic disease, are increasing in relationship to AIDS related causes.
• Certain medications have been approved for PreP.
• There is a broad armamentum of effective antiviral medications for successful HIV suppression.
• Genetic sequence manipulation (such as CRISPR) may be the future of curing HIV.
References

References