Overview of cohorts of HIV-infected women and girls

WRI March 17-20, 2011

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HIV pandemic (adults & children) by end-2009

TOTAL 33.3 (31.4-35.3) million

- North America: 1.5 million
- Caribbean: 240,000
- Central & South America: 1.4 million
- Western & Central Europe: 820,000
- North Africa & Middle East: 460,000
- Sub-Saharan Africa: 22.5 million
- Eastern Europe & Central Asia: 1.4 million
- East Asia: 770,000
- South & Southeast Asia: 4.1 million
- Australia/Oceania: 57,000

~51% of cases now in females

UNAIDS 2010
AIDS Diagnoses among Adult and Adolescent Females, 1985–2008—United States and Dependent Areas

Note. All displayed data have been estimated. Estimated numbers resulted from statistical adjustment that accounted for reporting delays, but not for incomplete reporting.
### Diagnosis of HIV infection in Adults and Adolescents by Race/ Ethnicity CDC 2008 (cases/100,000 population)

<table>
<thead>
<tr>
<th>Race</th>
<th>Female (11.5)</th>
<th>All Male (35.9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black/ African-American</td>
<td>56.0</td>
<td>131.9</td>
</tr>
<tr>
<td>Hispanic/ Latino</td>
<td>13.3</td>
<td>52.3</td>
</tr>
<tr>
<td>White</td>
<td>2.9</td>
<td>16.6</td>
</tr>
<tr>
<td>American-Indian / Alaskan Native</td>
<td>6.9</td>
<td>23.4</td>
</tr>
<tr>
<td>Asian</td>
<td>3.0</td>
<td>15.8</td>
</tr>
<tr>
<td>Native Hawaiian/ Other Pacific Islander</td>
<td>10.6</td>
<td>48.2</td>
</tr>
<tr>
<td>Multiple races</td>
<td>11.9</td>
<td>33.6</td>
</tr>
</tbody>
</table>
## Diagnoses of HIV Infection among Adult and Adolescent Females, by Transmission Category and Age at Diagnosis, 2008—37 States and 5 U.S. Dependent Areas

<table>
<thead>
<tr>
<th>Transmission category</th>
<th>13–19</th>
<th>20–24</th>
<th>25–34</th>
<th>35–44</th>
<th>≥45</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection drug use</td>
<td>9.5</td>
<td>10.4</td>
<td>13.1</td>
<td>15.7</td>
<td>18.9</td>
</tr>
<tr>
<td>Heterosexual contact&lt;sup&gt;a&lt;/sup&gt;</td>
<td>90.5</td>
<td>89.5</td>
<td>86.7</td>
<td>83.9</td>
<td>79.3</td>
</tr>
<tr>
<td>Other&lt;sup&gt;b&lt;/sup&gt;</td>
<td>&lt;0.1</td>
<td>0.1</td>
<td>0.2</td>
<td>0.4</td>
<td>1.8</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

**Note.** Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. Data from 37 states and 5 U.S. dependent areas with confidential name-based HIV infection reporting since at least January 2005. All displayed data have been estimated. Estimated numbers resulted from statistical adjustment that accounted for reporting delays and missing risk-factor information, but not for incomplete reporting.  
<sup>a</sup>Heterosexual contact with a person known to have, or to be at high risk for, HIV infection.  
<sup>b</sup>Includes blood transfusion, perinatal exposure, and risk factor not reported or not identified.
Massive impact in women

- **Women and health: today's evidence tomorrow's agenda** released by the World Health Organization (WHO) on November 9, 2009

- “Globally, the leading cause of death and disease among women of reproductive age (between the ages of 15 and 44) is HIV/AIDS. . . “

November 9, 2009;
Daunting task. So many cohorts

- NIH-funded cohorts
  - International Epidemiologic Databases to Evaluate AIDS (IeDEA)
  - Center for AIDS Research (CFAR) Network of Integrated Clinical Systems (CNICS)
  - Women’s Interagency HIV Study (WIHS)
  - Pediatric HIV/AIDS Cohort Study (PHACS)
  - NICHD International Site Development Initiative (NISDI)
  - Women’s HIV Interdisciplinary Network (WHIN)
  - Multicenter AIDS Cohort Study (MACS)

- NIH-funded clinical trials with cohorts
  - Microbicide Trials Network (MTN)
  - International Maternal-Pediatric-Adolescent AIDS Clinical Trials (IMPAACT) Group
  - Adult AIDS Clinical Trial Group: ALLRT cohort
  - Adolescent Medicine Trials Network (ATN) for HIV/AIDS Interventions
  - HIV Prevention Trials Network cohorts

- Everything else
  - Europe
  - Canada
  - Australia
  - Latin America
  - Africa
  - India

- CDC
  - HERS
  - SUN
• 12 regions defined (7 funded), one data center funded per region

• Regional IeDEAs
  – Identify and pursue relevant regional research
  – Adults and children
  – Serve as a resource for region
    • Data collection, standards and harmonization of data
    • Data management, storage, analysis

• Global coordination between IeDEA regions
  – Pursue “continental questions”
  – Work towards harmonization globally
  – Chair (from PIs) serves for 2 yrs
12 regions defined; 7 funded (active)
# Global IeDEA Regions

<table>
<thead>
<tr>
<th>Region</th>
<th>PI</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>North America (NA-ACCORD)</td>
<td>Richard Moore</td>
<td>Johns Hopkins University</td>
</tr>
<tr>
<td>Caribbean Central and South America (CCASA-net)</td>
<td>Daniel Masys</td>
<td>Vanderbilt University</td>
</tr>
<tr>
<td>Australia/Asia/China (APHOD/, TApHOD)</td>
<td>David Cooper</td>
<td>AMFAR</td>
</tr>
<tr>
<td>West Africa (WADA)</td>
<td>François Dabis</td>
<td>Victor Segalen University, Bordeaux France</td>
</tr>
<tr>
<td>Central Africa</td>
<td>Ty Hartwell</td>
<td>Research Triangle Institute</td>
</tr>
<tr>
<td>East Africa (REACT)</td>
<td>Constantin Yiannoutsos</td>
<td>Indiana University</td>
</tr>
<tr>
<td>South Africa (OASIS)</td>
<td>Matthias Egger</td>
<td>University of Bern, Switzerland</td>
</tr>
</tbody>
</table>
# (%) of women/girls by site (moving target)

Totals: $N=708,956$ (377,392; 53% female)

- **Region 1: North America (NA ACCORD)**
  - Canada
  - United States
  - $N=37,348$
  - Female 61% (22,730)

- **Region 2: Latin America & Caribbean (CCASAnet)**
  - Argentina
  - Brazil
  - Chile
  - Haiti
  - Honduras
  - Mexico
  - Peru
  - $N=12,957$
  - Female 40% (5182)

- **Region 8: West Africa (WADA)**
  - Benin
  - Burkina Faso
  - Cote d'Ivoire
  - Gambia
  - $N=37,348$
  - Female 61% (22,730)

- **Region 9: Central Africa (OASIS)**
  - Burundi
  - Cameroon
  - Congo, Dem. Rep. of
  - Rwanda
  - $N=17,722$
  - Female 67% (11,811)

- **Region 10: East Africa (REACT)**
  - Kenya
  - Tanzania
  - Uganda
  - $N=199,114$
  - Female 62% (122,716)

- **Region 11: Southern Africa (OASIS)**
  - Botswana
  - Malawi
  - Mozambique
  - South Africa
  - Zambia
  - Zimbabwe
  - $N=314,600$
  - Female 61% (192,564)

- **Region 5: Australia, India, Pakistan, Asia (APHOD)**
  - Australia
  - Cambodia
  - China
  - India
  - Indonesia
  - Japan
  - Malaysia
  - Philippines
  - Singapore
  - South Korea
  - Taiwan
  - Thailand
  - $N=13,215$
  - Female 29% (3889)

- **Region 3: Europe (VESDA)**
  - $N=114,000$ (Adults only)
  - Women 16% (18,400)

- **Region 7: Africa (OASIS)**
  - $N=199,114$
  - Female 62% (122,716)
ART-LINC (now ended)

- Antiretroviral therapy in low income countries (Office of AIDS Research, NIAID, and ANRS)
- 46% (2976) treatment naïve women; 5% (31) treatment-experienced women
CNICS
CFAR NETWORK OF INTEGRATED CLINICAL SYSTEMS
Overview of CNICS

- Links data and specimens from specific Center for AIDS Research (CFARs) US sites via electronic health records into a single research database.

- Established in 2002 (has grown from 4 to 8 sites since 2006)
  - First national CFAR seed funding, now supported by NIH R24

- CNICS data and specimens are available to any investigator who desires to use the platform
  - Emphasis on mentoring of junior investigators
  - Biostatistical support

- Establishment of a high quality clinical database
  - Patient reported outcomes, labs including resistance
  - Specimen repository, including cells
CNICS Sites

- University of Alabama at Birmingham (UAB)
  - National PI: Michael Saag/Site PI: Michael Mugavero
- University of California at San Francisco (UCSF)
  - Site PI: James Kahn
- University of Washington (UW)
  - Site PI: Mari Kitahata
- Case Western Reserve University (CWRU)
  - Site Leader: Benigno Rodriguez
- Brown University CFAR (Fenway)
  - Site Leader: Steve Boswell
- University of California, San Diego (UCSD)
  - Site Leader: Chris Mathews
- University of North Carolina at Chapel Hill (UNC)
  - Site Leader: Joseph Eron
- Johns Hopkins University (JHU)
  - Site Leader: Richard Moore
# CNICS Cohort as of Dec 2010

<table>
<thead>
<tr>
<th>Total</th>
<th>22317</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male</strong></td>
<td>18028</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td>4289</td>
</tr>
<tr>
<td><em>White</em></td>
<td>10191</td>
</tr>
<tr>
<td><em>Black</em></td>
<td>8661</td>
</tr>
<tr>
<td><em>Hispanic</em></td>
<td>2386</td>
</tr>
<tr>
<td><em>Other</em></td>
<td>927</td>
</tr>
<tr>
<td><strong>HIV Transmission Risk</strong></td>
<td></td>
</tr>
<tr>
<td><em>MSM</em></td>
<td>10575</td>
</tr>
<tr>
<td><em>Injection drugs</em></td>
<td>2975</td>
</tr>
<tr>
<td><em>Heterosexual</em></td>
<td>5150</td>
</tr>
<tr>
<td><em>Other</em></td>
<td>2093</td>
</tr>
<tr>
<td><strong>Region</strong></td>
<td></td>
</tr>
<tr>
<td><em>East</em></td>
<td>6341</td>
</tr>
<tr>
<td><em>South</em></td>
<td>4293</td>
</tr>
<tr>
<td><em>Central</em></td>
<td>1665</td>
</tr>
<tr>
<td><em>West</em></td>
<td>10018</td>
</tr>
</tbody>
</table>
Women’s Interagency HIV Study (WIHS)
History of WIHS

- Initiated August 1993 to study natural history, laboratory, clinical, behavioral impact of HIV among U.S. women
- Largest cohort of dedicated cohort of HIV-infected women worldwide (+risk-matched HIV-negative controls)
  - As of March 2010, 3766 participants
  - 2791 (74%) HIV-positive; 975 (26%) HIV-negative
- Re-enrollment 2001-2002
- Currently discussing “replenishing”
- Sponsored by NIAID, NIDA, NICHD, NCI, NIDA, NCRR
- Semi-annual visit (interview-administered questionnaires, physical exam, specimen collection)
Areas of Focused Scientific Research in the WIHS

- Behavior & Substance Use
- Cancer
- Cardiovascular Disease
- Epidemiology
- Genetics
- Hepatitis / Liver Disease
- Human Papillomavirus

- Menopause & Aging
- Metabolics & Renal Disease
- Neurocognition
- Pathogenesis
- Pharmacokinetics & Antiretroviral Exposure
Pediatric HIV/AIDS Cohort Study

&

NISDI: NICHD International Site Development Initiative
Two cohorts

- **SMARTT: Surveillance Monitoring for ART Toxicities Study in HIV-uninfected Children Born to HIV-infected Women**
  - From WITS (longitudinal 1990-2006 -public dataset, limited specimens)
  - HIV & ART-exposed, but uninfected children (~half female)
  - Estimate incidence of conditions and diagnoses related to *in utero* exposure or within 1st 2 months of life to ART
  - **Static** (closed, 1240 participants <12 years) & **Dynamic** Surveillance Cohorts: Total ~2300 HIV-exposed/uninfected infants & children w/ 200-300 new infants enrolled/yr (Caregivers also enrolled, mostly HIV-infected women)

- **AMP: Adolescent Master Protocol**
  - ~450 children (~half female) born to HIV-infected mothers
  - Comparison -227 perinatally exposed, HIV-infected children
  - Define impact of HIV & ART on pre-adolescents and adolescents with perinatal HIV
NISDI: NICHD International Site Development Initiative

- Similar to PHACS, with 2 protocols
- Prospective, observational study of HIV-exposed & HIV-infected children at clinical sites in Latin American and Caribbean countries (~half female)
  - LILAC/Perinatal - 500 HIV-exposed/uninfected infants & children
  - PLACES/Pediatric - 500 perinatally HIV-infected infants & children (and database of ~1000 perinatally HIV-infected & ~800 exposed/uninfected)
Cohorts in clinical trial networks

• NIH-funded cohorts
  – International Epidemiologic Databases to Evaluate AIDS (IeDEA)
  – Center for AIDS Research (CFAR) Network of Integrated Clinical Systems (CNICS)
  – Women’s Interagency HIV Study (WIHS)
  – Pediatric HIV/AIDS Cohort Study (PHACS)
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• Everything else
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  – Africa
  – India
• Microbicide trials network
  • MTN-015: *Observational Cohort of Women following HIV-1 Seroconversion in Microbicide Trials*
    - Observational study of HIV progression and treatment response in HIV+ women formerly enrolled in an MTN trial who had been using a topical microbicide or oral ARVs (as PrEP) when infected
  • MTN-016: *HIV Prevention Agent Pregnancy Exposure Registry*
    - Prospective observational cohort of prevention agent (microbicide) and control group exposures in pregnancy
• ALLRT: *AIDS Clinical Trials Group Longitudinal Linked Randomized Trials*
  • Participants in randomized trials of ART in ACTG followed beyond end of study
  • As of June 2010, ~17% (728) women (1.8-6.8 years)
- **IMPAACT P0174**: *A prospective surveillance study of long term outcomes in HIV-infected females, infants, children and adolescents*
  - Follow up protocol to PACTG 219/219C. Annual chart abstraction. 900 enrolled to date (~half female) with current target ~2000 (no new specimens, visits, not enrolled in PHACS AMP)
  - Identify possible long-term adverse outcomes of HIV & complications of ART and experimental interventions in HIV-infected infants, children and adolescents at IMPAACT sites in the U.S.
  - P1074 linked with other databases to detect signals of adverse events (and enable focused sub-studies)

*Cohorts in clinical trial networks*
Cohorts in multiple other locations

• NIH-funded cohorts
  – International Epidemiologic Databases to Evaluate AIDS (IeDEA)
  – Center for AIDS Research (CFAR) Network of Integrated Clinical Systems (CNICS)
  – Women’s Interagency HIV Study (WIHS)
  – Pediatric HIV/AIDS Cohort Study (PHACS)
  – NICHD International Site Development Initiative (NISDI)
  – Women’s HIV Interdisciplinary Network (WHIN)
  – Multicenter AIDS Cohort Study (MACS)

• NIH-funded clinical trials with cohorts
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• Everything else
  – Europe
  – Canada
  – Australia
  – Latin America
  – Africa
  – India
European collaborative cohorts

- **COHERE**
- **SWISS**
- **HIV**
- **COHORT STUDY**
- **ART**
- **Cohort Collaboration**
- **D:A:D STUDY**
- **CASCADE**
- **Concerted Action on Seroconversion to AIDS and Death in Europe**
- **EuroSIDA**
- **anRS**
- **ATHENA**
- **Collaborative HIV Paediatric Study**
## European/ Australian/Canadian/ other cohorts

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Description</th>
<th>(% and n female)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANRS: French Hospital Database on HIV</td>
<td>HIV-infected pts in 62 French teaching hospitals</td>
<td>118,147 (32%; 37,807 women)</td>
</tr>
<tr>
<td>ART-CC: ART Cohort Collaboration</td>
<td>19 cohort studies from Europe and North America of patients on ART</td>
<td>74,048 (26%; 18,924 women)</td>
</tr>
<tr>
<td>D:A:D: Data Collection on Adverse Events of Anti-HIV Drugs</td>
<td>Multinational cohort collaboration (Europe, USA, Australia)</td>
<td>35,441 (24%; 8,506 women)</td>
</tr>
<tr>
<td>Swiss HIV Cohort Study</td>
<td>Observational study of HIV-infected patients in Switzerland</td>
<td>12,500 (29%; 3,625 women)</td>
</tr>
<tr>
<td>EuroSIDA</td>
<td>Prospective cohort, 80 clinics in 30 European countries and Argentina</td>
<td>11,243 (22.9%, 2,575 women)</td>
</tr>
<tr>
<td>I.Co.N.A: Italian Cohort Naïve from ARVs</td>
<td>Prospective cohort in Italy of HIV-positive patients naive to ARVs</td>
<td>5,869 (30.3%; 1,778 women)</td>
</tr>
<tr>
<td>CASCADE: Concerted Action on Seroconversion to AIDS &amp; Death in Europe</td>
<td>Pooled data, 22 cohorts of HIV pts w/ known seroconversion Dates, Europe, Australia, Canada</td>
<td>8332 (19%; 1,583 women)</td>
</tr>
<tr>
<td>Royal Free Cohort</td>
<td>All HIV-positive patients in Royal Free Clinic, London, UK</td>
<td>3,661 (21.1%; 772 women)</td>
</tr>
<tr>
<td>CHIPS (Collaborative HIV Paediatric Study Cohort)</td>
<td>Children presenting with HIV and infants born to HIV-infected mothers in UK and Ireland</td>
<td>627 (50%; 312 girls)</td>
</tr>
</tbody>
</table>
### Examples from Latin America

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Caribbean Central and South America</strong></td>
<td>(CCASA-net), region 2 IeDEA</td>
<td>n= 12,957 (40% female)</td>
</tr>
<tr>
<td><strong>NICHD International Site Development</strong></td>
<td>Initiative (NISDI)</td>
<td>n= 2,800 (50% girls)</td>
</tr>
<tr>
<td><strong>Chilean AIDS Cohort</strong></td>
<td>(P. Vasquez)</td>
<td>n = 5,120 (16% women)</td>
</tr>
<tr>
<td><strong>Rapid II study group</strong></td>
<td>7 Latin American countries; Pts enrolled to study metabolic and CVD.</td>
<td>n= 4010 (26% women)</td>
</tr>
<tr>
<td><strong>LATINA cohort</strong></td>
<td>Retrospective cohort – Brazil (1); Mexico (1); Peru (1); Argentina (5)</td>
<td>n= 6007 (30% female)</td>
</tr>
</tbody>
</table>
RWISA

Rwandan Women’s Inter-association and Assessment: Originally funded by NIH supplement ’04; building research capacity and informing clinical care. 936 women (76% HIV+)

STIAL

South African Test, Identify and Link: Prospective cohort from 2 sites in KwaZulu-Natal (one Durban, McCord Hospital); 2777 pts (49% women)

FACES

Family AIDS Care and Education Services (Kenya): PEPFAR-funded HIV care and treatment program with cohort for research (88,000; 65% women).

Examples from Africa
Examples from India

Tamil Nadu Family Continuum of Care (TNFCC)
Sex specific findings from cohorts:
Outcome trends improving in women

1987

- Differential use of ARVs
- Unknown infection date
- Differential access to care
- Differential provider treatment
- Social factors
- Higher rates of IVDU

Worse outcomes in women

Rothenberg 1987; Reeves 1988
Friedland 1991; Lemp 1992; Melnick 1994

2009

Higher uptake of ARVs (IVDU Spain)
?Lower viral load & higher CD4
?Higher drug levels
Higher baseline life expectancies
?Better cardiovascular outcomes
?Less viral resistance

Better outcomes in women

Cozzi Lepri 1994; Chaisson. 1995
Brettle 1996; Prins 1999
Pezzotti 1999; Junghans 1999
Sterling 2001; Lewden 2001; Gebo 2003; Porter 2003; Moore A 2003;
Perez-Hoyos 2007

Moore A. 2002; Perez-Hoyos. 2003
Nicastrri 2007; Collazos 2007
CASCADE cohort:
AIDS and death rates lower in women in HAART era

Pre-1997, men
Pre-1997, women
1997-onwards, men
1997-onwards, women

Jarrin. Am. J of Epidemiol-08
Reasons for mortality differ by sex in the U.S.

- Comparison study of causes of mortality in Multicenter AIDS Cohort Study (MACS) and Women’s Interagency HIV Study (WIHS)\(^1\)

- Higher rates accident or injury-related mortality in women vs men (2.96 vs. 0.79/1000; OR 1.88 (1.13-3.16), \(p\) 0.016)

- Risk factors for death varied by gender

<table>
<thead>
<tr>
<th>WOMEN</th>
<th>MEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decreased CD4 ((p) 0.047)</td>
<td>Higher education ((p) 0.009)</td>
</tr>
<tr>
<td>Unemployment ((p) 0.023)</td>
<td>Depression ((p) 0.001)</td>
</tr>
<tr>
<td>Higher etoh use ((p) 0.002)</td>
<td>Higher # sex partners ((p) 0.036)</td>
</tr>
<tr>
<td>IVDU ((p) &lt; 0.001)</td>
<td></td>
</tr>
</tbody>
</table>

\(^1\)Hessol N. Am J Med 2002
Cohorts (and clinical trials – GRACE⁸, CASTLE⁶) – show more treatment discontinuation in women

- UK Collaborative HIV Cohort (CHIC)⁹
- I.Co.N.A.
- Swiss Cohort Study
- Royal Free Clinic
- CASCADE

Other cohorts in the workshop’s “cohort session”

LISA
Longitudinal Investigation into Supportive & Ancillary Health Services

CANOC

ISIS
a women’s study

Chilean AIDS Cohort Study
STOP AIDS. Make the Promise.

Each of us can help stop the spread of HIV and reduce the impact of AIDS. You don’t have to be a top scientist working on a cure to make a difference. Protecting yourself and others from HIV infection, welcoming someone living with HIV into your life or even just talking about HIV and AIDS can help. Are you taking action?

Make your promise now at www.worldaidscampaign.org
Acknowledgements

- **NICHD**: Lynne Mofenson, Rohan Hazra, Heather Watts
- **NIAID**: Carlie Williams, Gerald Sharp, Rosemary McKaig, Robin Huebner, Lori Zimand
- **Treat Asia**: Annette Sohn
- **WIHS**: Stephen Gange
- **European Cohorts**: Caroline Sabin
- **ACTG**: Judith Currier
- **IeDEA PIs**
- **African cohorts**: Kathy Anastos, Ingrid Bassett, Elizabeth Bukusi

*Manuscript in preparation: Sanjiv Baxi, Caroline Sabin, Gerald Sharp, Gina Brown, Monica Gandhi.*