The Brave New World of HIV Prevention: Human Rights, Human Risks

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Center on Halstead
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“O brave new world that has such people in it...”
To know where we’re going, we have to know where we’ve been
HIV/AIDS in the United States - Current CDC Estimates

- 988,376 cumulative AIDS diagnoses through 2005.
- 550,394 cumulative AIDS deaths through 2005.
- Approx. 1.1 million U.S. residents living with HIV infection.
- 40,000 new infections annually, unchanged in >10 years.

Proportions of AIDS Cases and Population by Race/Ethnicity, Reported in 2005—50 States and DC

AIDS cases
N = 40,733*

- White, not Hispanic: 30%
- Black, not Hispanic: 50%
- Hispanic: 18%
- <1%

U.S. population
N = 296,410,404

- White, not Hispanic: 68%
- Black, not Hispanic: 13%
- Hispanic: 14%
- Asian/Pacific Islander: 5%
- American Indian/Alaska Native: <1%

* Includes 283 persons of unknown race or multiple races.
AIDS Cases among Male Adolescents and Young Adults, by Transmission Category 2001–2005—United States and Dependent Areas

<table>
<thead>
<tr>
<th>Transmission category</th>
<th>13–19 years</th>
<th></th>
<th>20–24 years</th>
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<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Male-to-male sexual contact</td>
<td>706</td>
<td>60</td>
<td>3,800</td>
<td>70</td>
</tr>
<tr>
<td>Injection drug use (IDU)</td>
<td>110</td>
<td>9</td>
<td>530</td>
<td>10</td>
</tr>
<tr>
<td>Male-to-male sexual contact and IDU</td>
<td>39</td>
<td>3</td>
<td>327</td>
<td>6</td>
</tr>
<tr>
<td>High-risk heterosexual contact*</td>
<td>146</td>
<td>12</td>
<td>751</td>
<td>14</td>
</tr>
<tr>
<td>Other/not identified†</td>
<td>183</td>
<td>16</td>
<td>55</td>
<td>&lt;1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>1,184</td>
<td>100</td>
<td>5,462</td>
<td>100</td>
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</tbody>
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Note. Data have been adjusted for reporting delays and cases without risk factor information were proportionally redistributed.

* Heterosexual contact with a person known to have, or to be at high risk for, HIV infection.
† Includes hemophilia, blood transfusion, perinatal exposure, and risk factor not reported or not identified.
### AIDS Cases among Female Adolescents and Young Adults, by Transmission Category 2001–2005—United States and Dependent Areas

<table>
<thead>
<tr>
<th>Transmission Category</th>
<th>13–19 years</th>
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<th>20–24 years</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Injection drug use</td>
<td>122</td>
<td>13</td>
<td>473</td>
<td>17</td>
</tr>
<tr>
<td>High-risk heterosexual contact*</td>
<td>580</td>
<td>63</td>
<td>2,237</td>
<td>81</td>
</tr>
<tr>
<td>Other/not Identified†</td>
<td>225</td>
<td>24</td>
<td>55</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>926</td>
<td>100</td>
<td>2,766</td>
<td>100</td>
</tr>
</tbody>
</table>

Note. Data have been adjusted for reporting delays and cases without risk factor information were proportionally redistributed.

* Heterosexual contact with a person known to have, or at high risk for, HIV infection.

† Includes hemophilia, blood transfusion, perinatal exposure, and risk factor not reported or not identified.
AIDS Rates for Adults and Adolescents, by Population of Area of Residence and Region, Reported in 2004 50 States and D.C.

Note: Data based on residence at time of AIDS diagnosis.
* Includes persons whose population of area of residence is unknown.
Adimora et al., 2006: Risk factors associated with heterosexually contracted HIV infection among African Americans in North Carolina.

The “usual suspects” for those reporting high risk behaviors:
- less than HS education
- higher number of partners
- crack use or partner’s crack/IDU

For those reporting low risk:
- less than HS education
- food insecurity
- non-monogamous sex partner

Examination of sexual networks and concurrency

Respondents described:

- Pervasive economic and racial oppression
- Lack of community recreation, boredom, resultant substance abuse
- Shortage of black men (higher mortality and incarceration rates)
- Widespread concurrency among unmarried people

Heterosexual HIV & African Americans

Major Proximal Causes:

- High prevalence of STDs
- Sexual network patterns: concurrency and mixing among different subpopulations

Distal determinants help shape behavior and risk associated with behavior

- Poverty, inequality, discrimination

Future Shock (and Awe?):
The Brave New World of HIV Prevention
Male Circumcision

Two meta-analyses of observational studies found the risk of HIV among circumcised men was about half that of uncircumcised men.

Data from RCTs:
- South Africa: (N = 3,000), 70% protective effect
- Kenya: (N=2,784); 53% protective effect
- Uganda: (N=4,996); 48% protective effect

Sources: Weiss, et al. 2000; Siegfried, et al. 2004; Auvert, et al. 2005; Bailey et al., manuscript in preparation; Gray et al., manuscript in preparation
Cervical Barrier Methods

- The cervix may be particularly vulnerable to HIV and STI transmission.
- Observational studies indicate diaphragm used with spermicide may protect against some STIs and associated sequelae.
- Seven clinical trials underway to examine effectiveness of diaphragm in preventing STIs including HIV.
Microbicides

- Lactobacillus
- HIV
- Physical barrier lubrication
- Vaginal epithelium
- Maintenance of normal microflora
- Viral disruption/inactivation
- Prevention of other STDs

www.amfar.org
Pre-Exposure Prophylaxis (PrEP)

WHAT IF A PILL A DAY COULD PREVENT HIV?

WHAT'S THE TIE?

a study for men who have sex with men.
So what do we know?

• Great deal of evidence for efficacy/effectiveness of a number of HIV prevention interventions.

• Risk reduction and declining HIV incidence can be achieved through behavioral, biomedical, and social strategies, especially in combination.

• No intervention will be 100% effective.

• We must not confuse lack of implementation with lack of effectiveness.
Estimates of Access to Effective Interventions for At-risk Populations, 2005

- 9% of MSM received prevention services
- <20% of IDUs received prevention services
  - <10% in Eastern Europe & Central Asia
- 9% of pregnant women were provided PMTCT services

Sources: UNAIDS 2006.
Other factors that must be considered in HIV prevention

- Psychological, social, economic, and cultural dynamics of gender and sexuality
- New and changing context for both sexual and substance use behavior
- Differences in the perceived consequences of HIV infection
- Social, structural, environmental factors and contexts that contribute to the HIV/AIDS epidemic
- “Garden variety” denial of the epidemic
Syringe Exchange Programs

- Syringe exchange programs have been shown to reduce the risk of HIV transmission among IDUs without increasing drug use.

- In NYC, HIV incidence among IDU declined by over 40% between 1991 and 1996, in great part due to access to clean needles.

The War on Drugs

• Intended to curb supply and diminish demand for certain psychoactive substances.

• The term was coined in 1971 by Richard Nixon to describe a new set of initiatives designed to enhance drug prohibition.

But…
Prohibition has increased the prevalence of drug use in all categories.
NEP/SEP domestically

- NEP/SEP can be supported by state and local funds (depending on existing laws) or through private sources.

- Many states are changing laws re: possession, distribution, and sale of syringes to reflect public health priorities.

- Forty-seven states continue to classify syringes as drug paraphernalia, making them illegal to buy or own without a prescription.

- There are currently over 185 needle exchange programs operating in 36 states as well as Washington D.C., Puerto Rico, and Native American lands… but only 10% of IDU have access to NEPs.
The US & NEP/SEP globally

- US federal policies do not permit direct support of NEP/SEP programs.
- The USG has required that organizations receiving support adopt certain ideologies as a condition of funding.
- The USG has:
  - Blocked resolutions at the UN level that recognize the human rights of IDU
  - Obstructed the work of UNAIDS and UNODC in promoting harm reduction and NEP
  - Encouraged governments to adopt criminal law approaches to drug use rather than approaches focusing on addiction or public health
Mathematica report found that ab-only-until-marriage programs had **no** impact on:

- remaining abstinent
- condom use
- age at first intercourse
- number of sex partners
WRONG!

Democratic House leadership allocated $141 million (an increase of $27.8 million) for abstinence only programs.
Limited Resources for HIV Prevention Research

NIH Funding for HIV-Related Research FY 2006 (P.B.)

- **Therapeutics**: $712M (24.3%)
- **Vaccines**: $607M (20.7%)
- **Etiology and Pathogenesis**: $703M (24.0%)
- **Natural History and Epidemiology**: $313M (10.7%)
- **Behavioral and Social Science**: $412M (14.0%)
- **Training, Infrastructure, and Information Dissemination**: $186M (6.3%)

Total: $2.93 Billion
$33 Billion in Cumulative Funding (through FY 2006)
Community Engagement in Research

- Essential to ensuring ethical design and conduct of clinical trials
- As key stakeholders, community members should be involved at the earliest stages of trial planning— not after the trial is designed
- Community input vital to assure acceptable study design and realistic implementation logistics
Community Engagement: PrEP Example

Cambodian PrEP trial was stopped before it even started due to community opposition and unaddressed concerns.
Interpreting Research
Results: Partial Efficacy

- Intervention provides some degree of - but not complete (100%) - protection against HIV

- Expectation for “successful” HIV vaccine candidate is about 35% efficacy

- Efficacy of male circumcision as a prevention strategy is between 48-70%
Risk Compensation

• Adjusting one’s behavior in response to perceived change in risk
  – Example: engaging in risky behavior because you think you are protected

• Also called “behavioral disinhibition”

• Raises concerns by prevention advocates about abandonment of hard fought prevention battles
Partial Efficacy & Risk Compensation: PrEP Example

• Cost-effectiveness: low efficacy means more money per infection prevented
  – More expensive PrEP drugs (TDF/FTC) must have higher efficacy to be as cost effective as cheaper drugs (TDF or 3TC)

• If efficacy is low, increased risk taking can actually increase numbers of HIV infections
Behavior Change Alters Net Protective Effect

Especially at Lower Efficacy Levels

(SlideCourtesy of Robert Grant)
Issues of Access to New Prevention Strategies

• Communities participating in trials should receive intervention first, if successful
• Planning for intervention roll-out should begin during trial design phase
  – Includes monitoring infrastructure - labs, clinical care as well as drug costs
  – Little support available for translational work
  – Patents, regulatory approvals, other legal issues (e.g., intellectual property) can slow process
Rolling Out New Interventions: PrEP Example

- No clear plan yet for access to TDF or TDF/FTC following trials, if effective
- Gilead pressed to provide TDF or TDF/FTC to at-risk populations free or at cost
- Lab monitoring needs determined by efficacy, safety, and resistance profiles
  - Is there infrastructure and who will pay?
- Long term monitoring of PrEP implementation will be needed: no plans yet
Where does this leave us in 2007?
Fighting HIV: the Big Picture Approach

- General socioeconomic, cultural and environmental conditions
- Living and working conditions
- Social and community influences
- Individual lifestyle factors
- Age, sex & hereditary factors
Thank you!

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