“Nothing About Us Without Us!”
Community Engagement in HIV Research

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Engaging Patients, Families and Communities in all Phases of Translational Research to Improve Health
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Outline: Focus on Three Aspects

• Treatment/Research Advocacy
• Engagement in Clinical Trials
• Translation/Implementation
## Global HIV Epidemic

### Global summary of the AIDS epidemic | 2012

#### Number of people living with HIV

<table>
<thead>
<tr>
<th>Category</th>
<th>Total</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>32.1 million</td>
<td>[29.1 million – 35.3 million]</td>
</tr>
<tr>
<td>Women</td>
<td>17.7 million</td>
<td>[16.4 million – 19.3 million]</td>
</tr>
<tr>
<td>Children (&lt;15 years)</td>
<td>3.3 million</td>
<td>[3.0 million – 3.7 million]</td>
</tr>
</tbody>
</table>

#### People newly infected with HIV in 2012

<table>
<thead>
<tr>
<th>Category</th>
<th>Total</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>2.0 million</td>
<td>[1.7 million – 2.4 million]</td>
</tr>
<tr>
<td>Children (&lt;15 years)</td>
<td>260,000</td>
<td>[230,000 – 320,000]</td>
</tr>
</tbody>
</table>

#### AIDS deaths in 2012

<table>
<thead>
<tr>
<th>Category</th>
<th>Total</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>1.4 million</td>
<td>[1.2 million – 1.7 million]</td>
</tr>
<tr>
<td>Children (&lt;15 years)</td>
<td>210,000</td>
<td>[190,000 – 250,000]</td>
</tr>
</tbody>
</table>

*World Health Organization*  
*UNAIDS*
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.
*Standard: age distribution of 2000 US population
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.
Hardest Hit Communities: Gay Men & PWID

Fighting for our Lives

An AIDS Candlelight March
A personal expression to honor the dead and support the living.

San Francisco
7:30 P.M.
From Castro & Market
To G.N. Plaza Civic Center
Bring Candle
Info: AIDS C.E.O. Foundation
(415) 984-4336

New York
8:00 P.M.
From Sheridan Square
To Federal Building
Bring Candle
Bring Arm Band
With Black Arm Band
Info: GMHC Hotline
(212) 455-3902

Monday, May 2, 1983

San Francisco AIDS cases and deaths

* New cases reported
* New deaths reported
Cases through November: 868
Deaths through November: 402

Source: San Francisco Department of Public Health

Historical Reconstruction of HIV-1 Seroprevalence among Active Intravenous Drug Users in Manhattan, New York City

% Positive

75  76  77  78  79  80  81  82  83  84  85  86  87

Year

*This reconstruction is based on seroprevalence data for 1978-84, and 1986-87, with AIDS case data used to estimate seroprevalence for the other years. The curve has been smoothed for 1984-1987.
San Francisco Gay Men’s Chorus, 1993
Advocacy

Our government continues to ignore the lives, deaths and suffering of people with HIV infection because they are gay, black, Hispanic or poor. By July 4, 1989 over 55 thousand will be dead. Take direct action now. Fight back. Fight AIDS.

Women don’t get AIDS. They just die from it.

Ignorance = Fear

Silence = Death

Fight AIDS

Act Up

Clean needles save lives

The government has blood on its hands

AIDS death every half hour

You don’t get AIDS from kissing

Can you get AIDS from mosquitoes?
Community Advocacy

Education

Protest

Memorialization
Research Advocacy
Research Advocacy: ACT UP, TAG, GMHC
Creation of the NIH Office of AIDS Research
Total NIH HIV/AIDS Research Funding (1982-2012)

Source: NIH Office of AIDS Research
**Overhauling AIDS Research: Views From the Community**

A massive review of the National Institutes of Health’s (NIH) AIDS research portfolio, now nearing its final stretch, has been anticipated for some time. The report is a result of recent NIH Office of the Director recommendations, which sought to bring together more than 300 leading researchers from across the United States and Canada to create a comprehensive plan to better understand and combat AIDS. The report, titled “Overhauling AIDS Research: Achieving the Promise,” was released in 2000 and has been widely hailed as a landmark in the history of AIDS research. It provides a blueprint for future research, outlining key areas for investment and potential breakthroughs in the fight against AIDS.

### Panel Members

**Chair:**
- Stephen Paley, Ph.D.
- Paula S. Greenwell, M.D.
- James M. Anderson, M.D.
- Robert M. Fine, Ph.D.
- Mark H. Dybul, M.D.
- Jonathan D. Mann, M.D.

**Staff:**
- Lisa A. Hyslop, Ph.D.
- Mark A. Pluznick, Ph.D.
- Marcia A. Michel, Ph.D.
- Elizabeth A. Smith, M.D.
- Jennifer P. Friesen, M.D.

### Key Findings

1. **Low Fruit’s Call to Action:**
   - "We need a new strategy that focuses on the promise of new drugs and vaccines that can be launched quickly and on a broad scale to target the most urgent needs." — Dr. William P. Nvidia

2. **Budget Allocation:**
   - The report recommends a doubling of the NIH AIDS budget to $10 billion, with a focus on accelerating the development of new treatments and vaccines.

3. **Transdisciplinary Research:**
   - The panel emphasized the importance of transdisciplinary research, noting that advances in one field can inform and benefit research in another.

4. **Clinical Trials:**
   - The panel called for a doubling of the number of clinical trials and a focus on accelerating the progress of promising candidates to the clinic.

5. **Research Prioritization:**
   - The panel recommended prioritizing research on key areas such as virus transmission, vaccine development, and treatment of HIV-related diseases.

### Recommendations

- **Accelerate Drug Development:**
  - Invest additional resources to support the development of new drugs and therapies.

- **Enhance Vaccine Research:**
  - Increase funding for vaccine research, including both prophylactic and therapeutic vaccines.

- **Expand Clinical Trials:**
  - Double the number of clinical trials and ensure that they are conducted in a timely and efficient manner.

- ** Foster Transdisciplinary Research:**
  - Support research that crosses traditional disciplinary boundaries.

This comprehensive report provides a roadmap for the future of AIDS research and sets the stage for significant advancements in the fight against this disease.
Antiretroviral Therapy:
1996      2014

1 pill; once a day
18-24 pills; divided 3-4x/d
Evolution of Combination Therapy

http://depts.washington.edu/hivaids/arvrx/case2/discussion.html
HIV Treatment 2014

• 28 approved drugs
• 7 preferred first-line regimens
• 3 approved one-pill once-daily regimens
  • 4th at the FDA, 5th in phase 3 clinical trials
• Virologic response rates
  • >85% with HIV RNA suppression
• Life expectancy close to that of the general population
HIV Survival and Life Expectancy

“This is a life expectancy that approaches that of a 20-year old in the general population today.”

Community Engagement in Clinical Trials
Proposal to Mandate Condom Distribution in Prisons Would Reduce Correctional Facility Costs for Inmate Health Care in California

Question: What is the potential impact of the proposed bill (AB989, Levine) mandating the California Department of Corrections and Rehabilitation to make condoms available to inmates in its 33 California prisons?

Background: In response to a newly released report on the pilot program that evaluated condoms distribution in one of the four Solano State Prison facilities (Lucas, 2013), California Assembly Member Rob Bonta recently proposed AB989, which would require the California Department of Corrections and Rehabilitation (CDOR) to develop a five-year plan for making condoms available in all California prisons. AB989 would instruct CDOR to use funds from its budget to provide condoms and condom dispensing machines at all California prisons by December 2018. It would encourage facilities to consider also allowing prisoners to request condoms privately from prison medical and mental health care providers and would require a condom program planning and implementation to be included in inmate peer educators and advisory council, medical, public health, and custody staff.

There are currently over 124,000 individuals housed in California prisons on any given day, of whom over 95% are male. The mean length of stay is 23 months and close to 60% return within two years of release (CODR, 2011). Here currently have access to condoms – a public health HIV/STD prevention tool that the World Health Organization and the United Nations Program on HIV/AIDS recommend be made available in custody settings.

Methods: Review of findings from evaluations of condom distribution programs in California correctional institutions and brief analysis of potential HIV infections averted in CA prison by AB989.

Findings: Solano Prison Pilot Program

The California Correctional Health Care Services (CCHCS), Public Health Unit (PU), in collaboration with the California Department of Public Health, Office of AIDS (OD), and Sexually Transmitted Diseases (STD) Control Branch, evaluated the risk, feasibility, and cost of a condom program implemented to provide condoms to inmates at Solano State Prison Facility II (Lucas, 2013). Based on reports of the number of condoms dispensed each week, the cost of distribution, a comparison of the rule violation reports for the pre- and post-pilot period, and surveys of inmates (+25 pre and 25 post) and staff (+25 pre and 25 post), the authors concluded:

1) An average of 35 condoms were distributed per week in a facility with an average daily population of 330.
2) There was no evidence that providing condoms posed an increased risk to safety and security or resulted in injuries to staff or inmates.
3) Serious condom related safety or management issues were rare.
4) Dispensing machines provide a feasible and relatively low cost method of condom distribution.
5) Providing condoms would likely reduce the transmission of HIV, STDS, and hepatitis in CDOR prisons, thereby reducing medical costs in both CDOR and the community.
6) The first year start-up cost including dispensers, condoms, and staff time was estimated at about $3,735/inmate and the program’s annual cost at $575/inmate. This
Institutionalizing Community Engagement

- Denver Principles: 1983
- Greater Involvement of People Living with AIDS (GIPA): 1994
- Good Participatory Practices (GPP): 2007

**The Denver Principles (1983)**

Statement from the People with AIDS advisory committee

We condemn attempts to label us as "victims," a term which implies defeat, and we are only occasionally "patients," a term which implies passivity, helplessness, and dependence upon the care of others. We are "People With AIDS."
Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials

- Response to pre-exposure prophylaxis (PrEP) trial controversies in Cambodia and Cameroon in 2004/2005
- Leadership from AVAC and UNAIDS
- First edition (2007) developed by international, multidisciplinary working group with input from stakeholders around the globe
- The second edition (2011) incorporates feedback gathered through global consultations and piloting

Source: Kate MacQueen, AIDS 2014
Who is “the community”?

21st Century global research includes:

- Multi-site trials
- Public-private partnerships
- Profit/non-profit sponsors/implementers
- Government/foundation/corporate funders
- Advocates: population, disease, social causes
- Policy: local, national, global
GPP Examples of Stakeholders

- Trial Participant
- Community Stakeholders
- Broader Stakeholders
- National Stakeholders
- Global Stakeholders

Examples:
- Trial sponsor and networks
- WHO/UNAIDS
- International organisations
- International NGOs
- Trial sponsors and networks
- Ministries of Health
- Media
- Regulatory bodies
- Ethical review committees
- Funders
- Sponsors

Other examples:
- NGOs
- Local policymakers
- Local media
- Medical professionals
- Local health service providers
- Community advisory boards
- Community leaders
- Traditional leaders
- Participants’ family
- Friends
- Schools
- Colleagues
- Peers
- Trial site staff
- Religious leaders
Printed copies of the Stakeholder Engagement Toolkit for HIV Prevention Trials are available by request.

Email publications@fhi360.org

Includes a CD with the 2014 Toolkit Quick Guide and additional resources.

Objectives of the SE Toolkit

- **Provide step-by-step guidance** to help HIV researchers engage stakeholders efficiently and transparently

- **Provide tools** to help staff document their plans and experiences as they implement a SE strategy

- Make it easier for research teams in different settings to **compare methods and identify best practices**
GPP-TB: extending the model

- Critical Path to TB Drug Regimens (CPTR) initiative
- Stakeholder & Community Engagement Workgroup (SCE-WG)
- 2011 mapping exercise by WG confirmed need for guidance
- In 2012 WG partnered with AVAC to adapt GPP-HIV to TB context
Community Engagement Post-Trial?

Source: Pedro Goicochea, AIDS 2014
The Ethics

• First PrEP trial to provide post-trial access of a successful intervention to study participants
• Facilitated resources to inform and educate communities and generate discussion with stakeholders at local level and national level
• FTC/TDF for tx is approved in all countries where the iPrEx study took place but one, Peru (an application is in process)
• However:
  – How can investigators deliver access to a product over which they have limited control?¹

¹Haire B, Jordens C. Mind the gap: An empirical study of post-trial access in HIV biomedical prevention trials. Developing world bioethics 2013

Source: Pedro Goicochea, AIDS 2014
Using Point of Care HIV Testing Technologies to More Rapidly Detect HIV Infection and Link Clients to Primary Care

Steve Gibbons, MSW; Judy Auerbach, PhD; Ernest Hopkins; Rob Rydick, BA, MA; M. Wu; Courtney Mathews-Pearson, MPH; Chris Hall, MD

OBJECTIVES:
Utilize advances in HIV testing technologies and improve the ability to point of care testing sites to detect HIV infection, including rapid testing and link patients to care.

METHODOLOGY:
Working in collaboration with the San Francisco Department of Public Health, the Center for Disease Control and Prevention, and private organizations, Magenta—a program of SFAP—has implemented a number of new and emerging HIV testing technologies into a community-based sexual health center for gay men to reach new audiences of HIV infections and to improve linkage to care.

Magenta provides rapid and robust testing at one Quick Advance to more than 6,000 clients annually. Magenta and SFAP have implemented a Rapid Test Algorithm to provide same-day confirmation for persons with a preliminary positive diagnosis and to link persons immediately to care. More patients with recent and elevated behavioral risk are offered an HIV-10K test with specimens collection at one site and processed at the SFAPH Laboratory. Magenta also offers a rapid test algorithm to confirm same-day confirmatory diagnosis for persons with a preliminary positive diagnosis and to link persons immediately to care. More patients with recent and elevated behavioral risk are offered an HIV-10K test with specimens collection at one site and processed at the SFAPH Laboratory.

“Screening for HIV infection using the test of choice for many clinical laboratories to diagnose infection and link clients to care. Advances in HIV testing technologies increase the speed in testing and can more rapidly diagnose persons with HIV than can conventional delayed-based testing.”

saf.org Working to radically reduce new HIV infections and ensure access to care for all who need it
OVERALL: Of the 1.1 million Americans living with HIV, only 25 percent are virally suppressed.
Conclusion
Acknowledgements

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