Community Engagement and Research with Vulnerable Populations of Youth

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Goals of Community Engagement in Research

• Improve feasibility of research
  – Recruitment and retention

• Improve acceptability of research
  – Ethically congruent with community standards
  – History of experimentation on vulnerable populations raises questions within communities regarding trust and motivation

• Improve effectiveness research
  – Technology transfer
  – Broader uptake
    • Lessons learned from HBV and HPV vaccines
Vulnerable Populations and HIV Risk

- Youth aged 13 to 24 accounted for an estimated 26% of all new HIV infections in the United States in 2010.
- Most new HIV infections among youth occur among gay and bisexual males.
- Among 15-19 year olds, highest percentages of new infection among minority youth are:
  - African American 56%
  - Latino 21%
  - Pacific Islander 15%
Unawareness of HIV Infection: Missed Opportunity for Prevention and Care

Cascade of Care in HIV-Infected Youth in the United States

Adapted from: Zanoni and Mayer: *AIDS Pt Care and STDs*, 2014
Poor Engagement in HIV Care Leads to Mortality

**Take home message:**
Missed visits are clinically relevant & actionable events with prognostic value beyond core indicators of retention in care

Mugavero M, et al. Beyond Core Indicators of Retention in HIV Care. CROI 2014 (Abst # 983)
ATN Community Consultation, 2001

- Clear interest in having their youth participate in adolescent HIV trials
- Vaccines must be part of a larger community-level prevention activity that involves the community
- Communities must be educated about vaccines
- There must be a means for monitoring the impact of trials on communities
- Community participation must precede vaccine trials
ATN Community Engagement Strategies

- Community-Based Participatory Research
  - Connect to Protect®
- Community Education
  - PROTECT Toolkit
- Community Protection
  - Community Impact Monitoring Plan (CIMP)
Connect to Protect®

- Initiative of the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN)
  - Funded by NICHD, NIDA, NIMH
  - Conducted in 15 high risk urban communities over 12 years

- Objectives
  - To determine whether community mobilization can lead to structural change
  - To determine whether structural change can lead to decreased risk for transmission
C2P Definition of Structural Change

• New or modified programs, policies, or practices
  – Logically linkable to HIV acquisition and transmission
  – Can be sustained over time, even when key actors are no longer involved
  – Changes may directly or indirectly impact individuals
C2P Definition of Community Mobilization

• Collaborative problem solving that leads to reduced health or other social problems
  – Sustained efforts over time are essential to effectiveness of mobilization
  – Increased sharing of leadership, on-going feedback, and continued growth in capacity are essential elements of sustained effort
Phases of C2P

• Phase I ATN 016a (2002-2004)
  – Identification of target community and population
  – Selection of community partners
• Phase II ATN 016b (2004-2006)
  – Venue-based needs assessment of target youth
  – Establishing community coalition
• Phase III ATN 040/040b (2006-2011)
  – Community mobilization
  – Annual cross-sectional surveys of target youth
• Phase IV ATN 095/105 (2011-2016)
  – Emphasizes Root Cause Analysis and greater strategic thinking
  – Baseline and follow-up survey(s)
C2P Process of Community Mobilization

- Strategic planning process
  - Vision statement
  - Mission statement (actionable)
  - Objectives (what structural changes, when, and by whom)
  - Strategies
  - Action Plan

- Action plan implementation

- Continuous evaluation and feedback
HIV Testing SCO

- Louisiana Juvenile Justice System will implement HIV/STD screening of youth upon intake into New Orleans JJ facilities
- Shelby County Health Dept. (Memphis) will change policy to allow alternate forms of ID from individuals seeking HIV test results
- All Montefiore Community Health Centers (Bronx) will modify policy to offer routine HIV testing to patients over 13 years old
- DC Dept. of Health will require all grantees that are HIV testing/treatment sites to adhere to youth competency protocol
- FL Dept. of Health will register Our Kids of Miami-Dade and Monroe as HIV testing sites for youth in foster care
Linkage to Care SCOs

- Hillsborough County Health & Human Services Ryan White Administration will amend guidelines to exempt minors with HIV from providing income eligibility documentation.

- Detroit Receiving Hospital ER will have new policy to refer youth into care when they test preliminary positive.

- New Orleans Regional Transit Authority will provide free bus tokens to HIV+ youth referred for medical care.

- Fenway Medical Division (Boston) will modify existing appointment policy for HIV+ youth to ensure 100% of all youth will receive a scheduled follow-up appointment at end of all medical visits.

- Denver’s school-based health centers will adopt a LTC policy for students identified as HIV+.
ATN Community Education Plan (CEP)

- Each protocol chair, in consultation with their protocol team, makes a determination of need for CEP
- Encouraged for biomedical studies of agents used for HIV prevention (e.g., PreP).
- Utilize PROTECT: A Community Preparedness Toolkit
  - Module 1: Research Ethics
  - Module 2: Clinical Research
  - Modules 3-5: Vaccines, Microbicides, PreP
What is Clinical Research?

• Research is an investigation to find an answer to a problem
• Research tries to find better ways to prevent, diagnose, treat, and understand illness
• Clinical trials can test new medications and vaccines
• Clinical trials depend on the people who volunteer to participate in the research
What are some types of Clinical Trials?

<table>
<thead>
<tr>
<th>Type of Trial</th>
<th>Goal</th>
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</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>To test new medications or procedures that could help to treat an illness</td>
</tr>
<tr>
<td>Prevention</td>
<td>To look for better ways to prevent an illness in people who have never had the illness. Better ways to prevent an illness may include medicines, vaccines, and/or lifestyle changes</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>To find better tests or procedures for identifying a particular illness or condition</td>
</tr>
<tr>
<td>Screening</td>
<td>To test the best way to detect certain illnesses or health conditions</td>
</tr>
<tr>
<td>Quality of Life</td>
<td>To explore ways to improve the comfort and quality of life of people with a long-term illness</td>
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Clinical Research is Important for Everyone

- Illnesses do not effect everyone in the same way
  - For example, some people may get sicker than others
- Medicine does not always work the same in everyone
- Clinical research helps us understand what these differences are and why they happen
Community Impact Monitoring Plan (CI MP)

• Goal:
  – “…[to] combine ongoing assessments from the community, particularly from those members most affected by the research, with assessments from the research group and established community advisors to provide a comprehensive view of the impact the research is having on the community.”
Phases of CI MP

• Phase I
  – Determination of need
  – If required, identification of community-related consequences, predictable and unintended

• Phase II
  – Develop a plan for information collection necessary to monitor community impact.

• Phase III
  – Annual report to CI MP Oversight Committee and Ethics Advisory Committee
NIH Leadership

- Audrey Rogers
- Bill Kapogiannis
- Sonia Lee
- Lynne Mofenson
- Rohan Hazra
- George Siberry
- ATN Ethics Advisory Panel