

Community Engagement and Research with Vulnerable Populations of Youth

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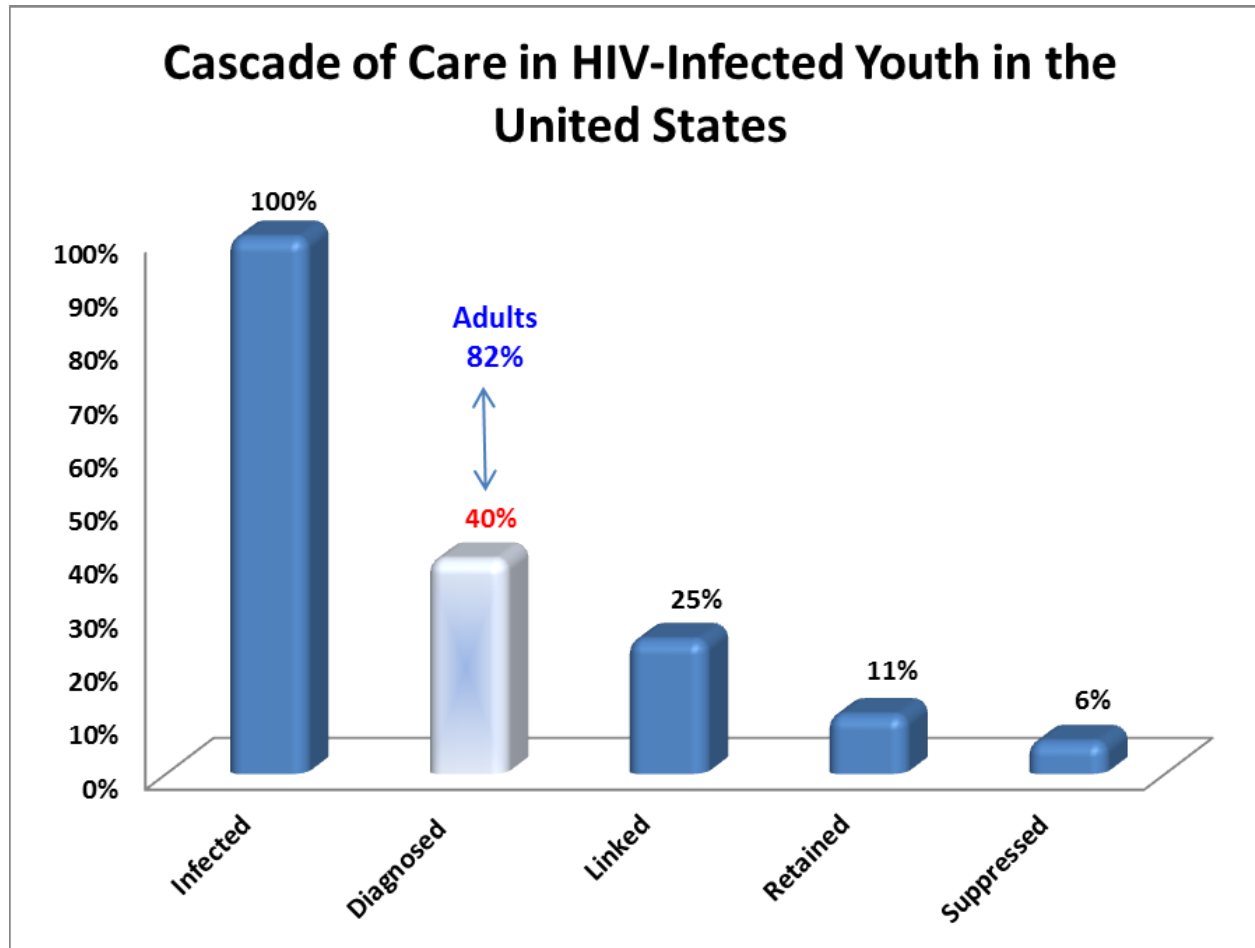
Goals of Community Engagement in Research

- 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

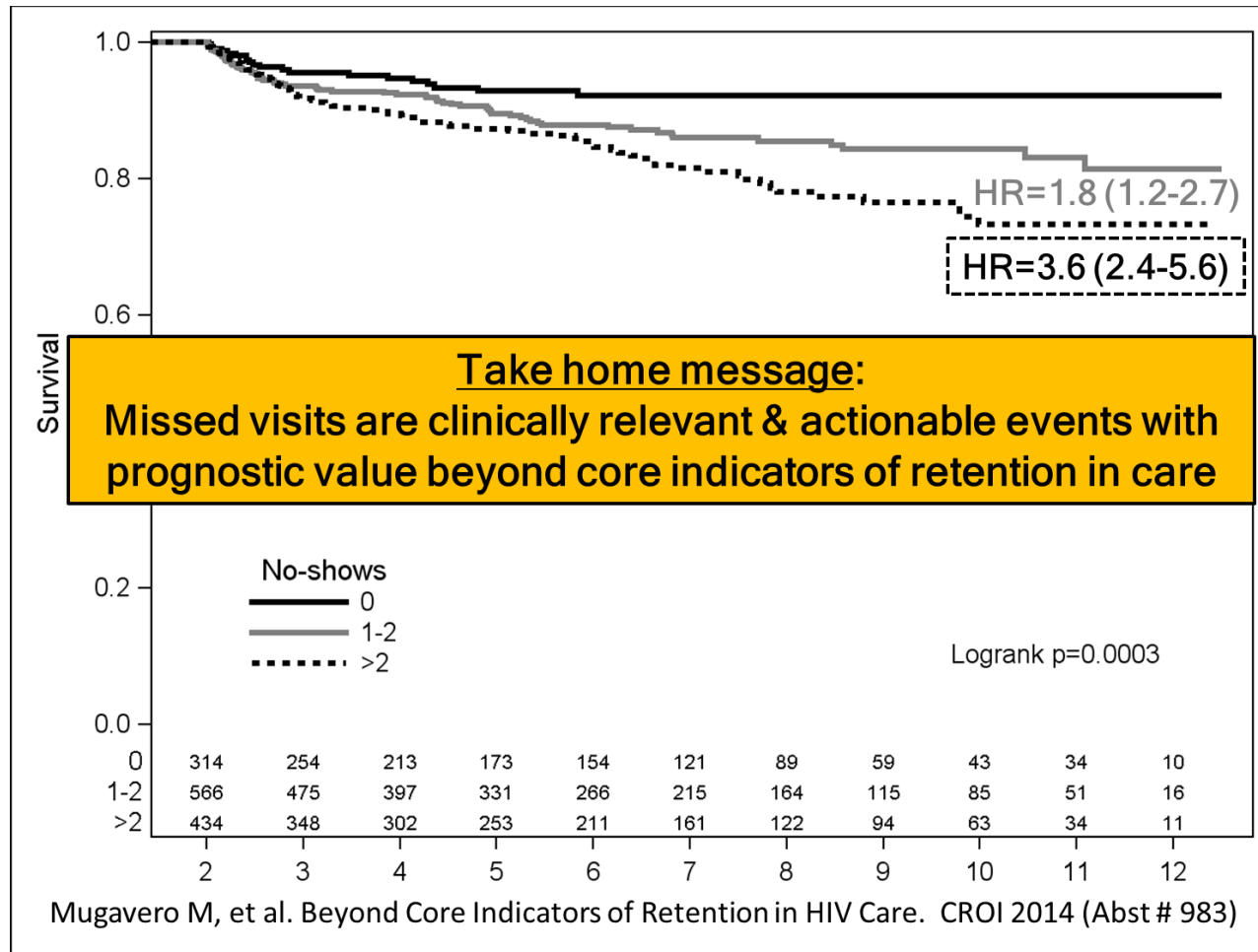
Vulnerable Populations and HIV Risk

- 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



Poor Engagement in HIV Care Leads to Mortality



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
 - **V**ision statement
 - **M**ission statement (actionable)
 - **O**bjectives (what structural changes, when, and by whom)
 - **S**trategies
 - **A**ction Plan
- Action plan implementation
- Continuous evaluation and feedback

HIV Testing SCO's

- 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?

Type of Trial	Goal
Treatment	To test new medications or procedures that could help to treat an illness
Prevention	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
Diagnosis	To find better tests or procedures for identifying a particular illness or condition
Screening	To test the best way to detect certain illnesses or health conditions
Quality of Life	To explore ways to improve the comfort and quality of life of people with a long-term illness

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 (CIMP)

- 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 CIMP

- 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 CIMP Oversight Committee and Ethics Advisory Committee

NIH Leadership

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