Stakeholder Engagement in HIV Cure Research

HIV Cure Research Training Curriculum

Stakeholder Engagement Module presented by:

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The HIV CURE research training curriculum is a collaborative project aimed at making HIV cure research science accessible to the community and the HIV research field.
Session Objectives

Describe:

- Lessons learned from HIV prevention research
- What is stakeholder engagement
- Why engagement is important for HIV cure research
How Can We Define Stakeholders?
How Can We Define Stakeholders?

- Global Stakeholders
- National Stakeholders
- Broader stakeholders
- Community Stakeholders
- Trial Participants/Potential Participants
Global Stakeholders

- International NGOs
- Trial sponsors
- WHO/UNAIDS
- International Foundations
- Funders

Exam
National Stakeholders

National NGOs, Ministries of Health, Regulatory Bodies, Ethical Review Committees
Broader Stakeholders

NGOs, Local Policymakers, Local Media, Medical Professionals
Community Stakeholders

CBOs, participant family, friends, schools, peers, trial site staff, local health service providers, community advisory boards, traditional leaders
Global Stakeholders

National Stakeholders

Broader Stakeholders

Community Stakeholders

Examples

Trial Participant/Potential User

- national NGOs
- parliamentarians
- trial sponsors and networks

- NGOs
- local policymakers
- local media
- medical professionals

- local religious institutions
- traditional leaders
- community advisory boards
- local health-service providers

- CBQs
- participant's family
- friends
- schools
- colleagues
- peers
- trial site staff

- WHO/UNAIDS
- international organisations
- international foundations
- funders
How Can We Define Community?
How Can We Define Community?

● “A group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographical locations or settings.” (MacQueen, 2001)

● “who is included and who is excluded from membership” (Institute of Medicine, 1995)
Where Does Engagement Fit?

- Good Clinical Practice
- WHO CIOMS UNAIDS
- Human Rights Considerations
- Stakeholder Engagement
GCP is NOT GPP

Research Investigator

Research teams (and trial sponsors and funders)

GCP

Trial Participants

GPP

Stakeholders
Why Do We Engage Beyond the Participant?

- PrEP Research trial controversy
- 2004 - Cambodia trials were not initiated
- 2005 - Cameroon and Nigeria trials discontinued
What Principles Make Good Engagement?
How Do We Engage?

Stakeholder Advisory Mechanisms

Informal

- Stakeholder meetings
- Local events
- Ongoing dialogue with CBOs
- Focus group discussions
- Call in radio shows

Formal

- CABs
- NGO advisory groups
- Participant groups
- Groups already established in the area

Examples of Mechanisms

Research Team

- Ongoing dialogue with CBOs
- NGO advisory group
- Focus group discussions
- Local meetings or events
- CABs

Stakeholders
Why is Engagement Important?
Landscape of Engagement

- Racial Stigma
- Food security
- Personal Health
- Treatment Access
- Housing security
- HIV-positive Diagnosis
- Stigma
- Gender Based Violence
- Discrimination
- Criminalization
- Homophobia
- Poverty
- Job security

Adopted from Joe Amon
Research in the Age of Fast Media

- Headlines aren’t always accurate
- Potential to spread rumors
- Potential to erode trust

“Cure for HIV possible within three years as scientists snip virus from cells”
- Telegraph, 2016
Research in the Age of Fast Media - Lesson from Prevention

- In December 2009 MDP 301 announced flat trial results

- A Zambian blogger based in the UK published false information about the trial that was picked up by local Zambian media

- Years after this incidence researchers had challenges securing approval for microbicide research
HIV Cure Research Has New Language
Sample Protocol

Study Week

VRC01 (n=18)

Randomized 3:1

Placebo (n=6)

Enrollment

Volunteers from Health Center

- 20-50 years old
- Started on ART during AHI (Fl-FIII)
- Prescribed ART for ≥24 mo
- HIV-1 RNA <50 copies/mL
- CD4 >400 cells/mm³

*4-week PI substitution for subjects prescribed NNRTI

Primary Endpoint:

- Virologic control (RNA <50 copies/mL)

Secondary Endpoints:

- HIV Reservoirs
- Inflammatory markers
- CD4 count

Optional:

- LP
- Gut biopsy
- Lymph node biopsy

Analytic Treatment Interruption

= HIV RNA Assessment

Any positive HIV RNA prompts repeat quantitative testing every 3 days until negative or ART resumed

From Crowell, TA (2015)
Engagement in HIV Cure Research
Formative Research Activities

Allows the research team to:
- gain informed understanding of local populations
- socio cultural norms
- local power dynamics
- local perceptions
- channels of communication
- site selection
SearcHIV

- Conducting research in Cape Town, Guangzhou and Chapel Hill
- Develop a theoretical framework about HIV cure research and early implementation
- Determine HIV cure stakeholder perspectives on cure research

APSEC

- Assessing motivations and barriers that influence willingness to participate in HIV cure clinical trials
- Explore factors associated with perceived tolerance and acceptability of various HIV cure clinical trial designs
Stakeholder Engagement Plan

- **Communication component**
  - Policies and strategies to increase broad awareness of the trial and facilitate accurate dissemination of research

- **Education component**
  - Key to building research literacy and empowering community stakeholders as decision-making agents
Informed Consent Process

- Comprehension should be assessed throughout the research process
- Forms, materials and techniques to assess understanding should be locally appropriate
- Strategies to pilot tools of consent

**Partner consent process**

- Participant first hears about the research
- Participant talks to physician about study
- Participant first sees informed consent documents
- Participant talks to partner, friends, family
- Participant signs documents. Enrolls in trial
- Participant receives 1st comprehension exam
Access to HIV Care

- HIV care includes all psychosocial, psychological and clinical components of HIV care
  - Alternative regimens
  - Counseling – e.g. partner disclosure

- HIV care and treatment guidelines vary by country and should be considered
  - Long term logistics planning should be considered
  - Access guidelines should be updated with national guidelines
Policies on Trial Related Harm

How research teams will treat and compensate trial participants

- **Physical harms** - include any negative physical event

- **Social harms** - non medical consequences such as
  - Social isolation
  - Stigma or discrimination
  - Employment or housing loss
  - Difficulties in personal relationships
Why is Stakeholder Engagement Important?
Research is Happening
Engagement in HIV Cure Research

- **Education and transparency** are key goals that stakeholder advisory mechanisms must strive to incorporate.

- Critical that all stakeholders, **including health care providers**, understand how early phase cure related research can benefit future populations.

- Developing comprehensive engagement plans that reflect sociocultural norms and stakeholder needs are crucial to advancing research aims.
Questions

For additional information visit: www.avac.org/CUREiculum
Acknowledgements