Small Group Activity

Sociocultural and Other Factors that Impact Research and Stakeholder Engagement Activities

Facilitator Prep: *Select the most appropriate Study Design(s) for your participants. More than one study design may be used across the groups (e.g., if some participants are US-based and some are Africa-based); however, each small group must use the same study. Make one photocopy for each participant.*

Instructions for Small Group:

Imagine that you are part of a team that is considering the possible implications that sociocultural factors in your community may have on a study that is preparing to launch. Based on your experience and knowledge of your community, use the description of the study below to answer the question(s) from the GPP sociocultural landscape tool. Discuss the similarities and differences in your responses with other members of your group.

Study Overview/US-based HPTN 073—BMSM Open-Label PrEP Demonstration Project:
To assess the initiation, acceptability, safety, and feasibility of PrEP for Black men who have sex with men (BMSM) utilizing client-centered care coordination (C4) models (see below). Study questions:

- Is it acceptable for local health care facilities to administer C4 along with PrEP to BMSM?
- How much Truvada® is in the blood of BMSM who become infected with HIV?
- How often does HIV drug resistance occur?

Study Population: HIV-uninfected BMSM at risk for HIV infection in three U.S. cities (75 participants at each of three sites). Enrollment includes those aged 18 and over with efforts at each site to attempt to recruit an equal number of BMSM under age 25 and 25 and over. Participants must be willing to provide comprehensive and current locator information (e.g., a physical address, social media page information, email address, information on a relative or friend who could locate them).

Study Description: The ARV that will be used is once daily oral Truvada®. After enrollment, study participants will remain involved for about one year during which they will meet with members of their local study team about seven times. At each of these visits the study team will offer participants the option to use Truvada®. During those visits a member of the study team will provide the participants who have started PrEP with a physical exam that includes checking the health of their liver and kidneys and a blood test to detect levels of the antiretroviral drug. They will also compile a self-report of PrEP adherence and discuss any concerns or side effects that may be related to the study drug. Though not expected, if there are any serious side effects reported, study participants will be told to stop taking the drug.

Participants do not have to agree to take Truvada® to be in this study. They may decide to start taking or stop taking Truvada® at any time. Regardless of whether or not participants utilize Truvada®, everyone will be offered C4 assistance. The C4 healthcare team will develop an individualized plan of care and support that may include referrals to health care and mental health services or to other organizations that can help participants with other needs they may have, such as services for housing assistance, domestic violence or drug or alcohol use counseling. All participants will receive HIV/sexually transmitted infection (STI) risk reduction counseling and an HIV/STI test at each study visit. All participants will be provided with condoms and will be encouraged to use condoms every time they have sex because, while previous studies have shown that Truvada® can reduce the risk of HIV infection, PrEP is not 100% effective and does not protect against other STIs (such as gonorrhea, syphilis or chlamydia).

> C4=*Care Coordination* (provides individualized prevention counseling, support, and service coordination working closely with service providers); *Client-Centered Approach to Care* (an approach in which each client's realities are taken into consideration with the goal of optimizing retention and adherence); *Provider for Clinical Oversight* (different providers will perform different functions related to care coordination, the client-centered approach to care, and PrEP discussions/administration).

Summarized from: www.HPTN.org

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Imagine that you are part of a team that is considering the possible implications that sociocultural factors in your community may have on a study that is preparing to launch. Based on your experience and knowledge of your community, use the description of the study below to answer the question(s) from the GPP sociocultural landscape tool. Discuss the similarities and differences in your responses with other members of your group.

Study Design/Africa-based HPTN 071—Population Effects of ART to Reduce HIV Transmission (PopART)**:** To determine the impact (and cost-effectiveness) of two community-level combination prevention packages, both of which include universal HIV testing and intensified provision of HIV care and ART, on population-level HIV. Study questions:

- Will universal voluntary HIV counseling and testing, combined with immediate ART for those who test HIV-positive, significantly *reduce HIV incidence* at the population level?
- What is the population level impact on HIV incidence of providing ART *regardless of immune status*, with providing ART at the threshold currently recommended by *national guidelines*?

Study Population: Conducted in 21 communities in the Western Cape of South Africa and in Zambia. The combined population of all 21 clusters is approximately 1.2 million individuals. Study outcomes will be measured in a randomly-selected group drawn from the adult population of the communities.

Study Description: Study communities were randomly assigned to one of three study arms; Arm A: Full PopART HIV combination prevention program, Arm B: PopART program but with HIV treatment only offered to those eligible according to national guidelines, Arm C: Current national guidelines (control).

In every study community, ART will be available for those who are infected with HIV. In Arm A, the option to start ART will be offered to all HIV positive individuals irrespective of CD4 count. Individuals found to have positive results in Arm B communities will be offered ART if and when their CD4 count reaches the threshold for starting treatment according to the national HIV treatment guidelines in their country (CD4 <350cells/mm^3).

In both A and B arms, ART will be provided in combination with a prevention package that includes:

- House-to-house deployment of Community HIV-care Providers (CHiPs) to provide:
  - Universal HIV counseling and testing in the home
  - Active linkage to care for individuals diagnosed as HIV-infected
  - Promotion of male circumcision and prevention of mother-to-child transmission services
  - Provision of condoms
- Strengthening of HIV testing and services at health facilities and other venues
- Strengthening of male circumcision and prevention of mother-to-child transmission of HIV services available in the community
- Treatment of sexually transmitted infections (STIs) and provision of condoms at health units

Social science research will document how HIV is impacting communities as well as attitudes toward different prevention approaches. It will also examine the acceptability of the PopART intervention, identify catalysts and barriers to the PopART intervention, and document the effects of the interventions on sexual behavior, social networks, HIV stigma, treatment seeking and community participation. Studies will explore uptake of two of the key PopART interventions—namely the home-based testing and immediate treatment interventions. Economic evaluations will measure the incremental cost of the intervention packages and will assess the burden on local health centers for implementation. Mathematical models fitted to the trial data will be used to estimate the effectiveness and cost effectiveness of the intervention packages and alternative packages both in the study populations and other populations. *Summarized from: www.HPTN.org*

Facilitator Key for HPTN 073 Sociocultural Issues

Listed below is a sampling of several actual sociocultural issues that CLOs encountered:

- Introducing PrEP in communities that were not familiar with the concept
- Assisting participants who are struggling with how to explain to a partner/family member why Truvada is being taken by someone who is HIV-negative
- Managing concerns over developing resistance to Truvada in the community—reducing the effectiveness of that drug as a therapy option for people who are HIV-positive
- Encouraging community buy-in for PrEP when ART drugs may not be available for people who are positive (in some cases, managing anger issues among community members)
- Dealing with concerns over what will happen to people who are HIV-negative after the study and still at high-risk for HIV infection—will there be access to PrEP?
- Managing clinicians in the community sites and study staff who believe themselves to be capable of providing culturally-competent care for BMSM but who actually cannot (and refuse to accept the cultural competency training being offered)
- Negotiating with community-based organizations (CBOs) who are inundated with requests to solicit participants for studies and frustrated by the lack of study funds available to their organization (the solution in this instance was to figure out how to pay the CBO for their participation; for example, funding half of a salaried position to act as a recruiter or paying the CBO per message to send SMS texts to members in their database to solicit participants)

Facilitator Key for HPTN 071 Sociocultural Issues

Listed below is a sampling of several actual sociocultural issues that CLOs encountered:

- Drawing blood was problematic in some cultures
- Storing the samples and then sending them to the US for testing raised questions
- Ensuring that participants are actually understanding the complexity of the study well enough to provide “informed” consent
- Overcoming a cultural taboo surrounding circumcision—women never speak with men about traditional circumcision—how to overcome that obstacle when discussing medical male circumcision—how does a female CLO engage with a group of men on this topic?
- Managing community resistance to the inclusion of anal sex in educational materials for condoms; some communities felt that it would promote homosexuality
- Respecting an individual’s choice to initiate ART when they wanted (even though they meet the criteria assigned to their study arm—the choice of when to start is an individual one)
- Explaining complex population-level study results to community members (i.e., the concept of incidence—tap that drips into a bathtub—drops represent “incidence” or new cases of disease; all the “infected” drops in the tub represent “prevalence”)
- Introducing PrEP in communities that were not familiar with the concept (e.g., why are seemingly healthy people initiating ART?)
- Encouraging community buy-in for PrEP when ART drugs may not be available for people who are positive (in some cases, managing anger issues among community members)
- Managing resistance encountered for a massive study with a huge budget

Facilitator Prep: *Select and photocopy the most appropriate questions; one question(s) per each small group. Cut along the dotted lines and place the questions into a hat or box.*

AVAC

SECTION 1.4

Sociocultural landscape

Purpose:
To assess local attitudes, beliefs, and practices related to HIV prevention and scientific research; to identify issues that stand to impact recruitment, trial conduct, and public perception of the trial.

Record your answers to the following in the space provided, or elsewhere if you'd prefer.

1) List attitudes, beliefs, or sociobehavioral factors in **the local community**(the population around the trial site) that could interfere with recruitment or trial conduct (e.g., social stigma, religious and traditional beliefs or practices, gender discrimination, misconceptions about research, mistrust of research and researchers).

2) List attitudes, beliefs, or sociobehavioral factors among **the potential trial population** that could interfere with recruitment or trial conduct (see examples above).

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Sociocultural landscape

Purpose:
To assess local attitudes, beliefs, and practices related to HIV prevention and scientific research; to identify issues that stand to impact recruitment, trial conduct, and public perception of the trial.

3) Has HIV prevention research received balanced coverage in the local and national media? Has the coverage been positive or negative? Are there aspects of the media coverage (past or ongoing) that might interfere with recruitment or trial conduct (e.g., adherence once the trial is in process)?

SECTION 1.4
Sociocultural landscape

Purpose:
To assess local attitudes, beliefs, and practices related to HIV prevention and scientific research; to identify issues that stand to impact recruitment, trial conduct, and public perception of the trial.

4) List local organizations (e.g., CBOs, advocacy groups) that might have a stake in or influence—whether positive or negative—over the proposed trial. Are they likely to support the research? Might they oppose it and present obstacles? How significant an impact might they have?

SECTION 1.5

Legislation, guidelines, standards, and structural issues

Purpose:
To assess local, national, and international rules, regulations, and standards that will have to be upheld in planning and conducting the proposed trial

2) List any legislative, regulatory, and political issues that could impact recruitment, trial conduct, or other aspects of the research (e.g., legislative issues, such as criminalization of homosexuality; political stances, such as opposition to the proposed research from influential leaders).

SECTION 1.5

Legislation, guidelines, standards, and structural issues

Purpose:
To assess local, national, and international rules, regulations, and standards that will have to be upheld in planning and conducting the proposed trial

3) List any economic or structural issues (e.g., poverty, lack of education, unemployment) that may interfere with recruitment, adherence, or other aspects of the trial.

Source for Questions: *GPP Blueprint for Stakeholder Engagement*, Sociocultural Landscape (section 1.4) and Legislation, Guidelines and Standards and Structural Issues (Section 1.5). AVAC, 2014.