

2. DESIGN

The pilot study is designed as an implementation of an anonymous, cross-sectional survey of HIV-related behaviors and prevention experiences, using ACASI software. The pilot will be conducted in a consistent fashion in four different MSA. This design will afford the opportunity to compare and contrast the performance of the sampling plan, the recruitment strategy, interviewer training, and questionnaire administration across the four locations. The experience of the pilot will help in the development of methods and instruments for a larger scale surveillance effort among transgender persons. The pilot data will also be useful locally for understanding the spread of current HIV prevention efforts among the transgender participants.

Stakeholder Participation

Stakeholders in THBS cover a wide gamut of health professionals, program administrators, social service providers, health risk behavior researchers, and individuals living in transgender communities, and will be found at the national, state and local levels. Local stakeholders in THBS include: the state or local health department, community-based organizations that provide HIV prevention services to transgender persons, the HIV community planning group, transgender service organizations, and the transgender populations.

Opportunities for stakeholder participation have been built into all stages of the THBS pilot study - development, implementation, and dissemination. During the development stages, CDC held a meeting of researchers who had conducted similar behavioral surveys among transgender populations. At this meeting, strategies for asking about sexual behaviors, gender identity, and sampling of transgender persons were discussed. Recommendations from this meeting were considered while creating the protocol and questionnaire for this pilot. In addition to this meeting, CDC also consulted with researchers who were unable to attend the meeting. Prior to implementation, CDC will conduct cognitive interviews and focus groups among minority male-to-female transgender persons to get their input on the questionnaire. In addition, in order to apply for funding to conduct THBS, the four project areas will need to seek input on implementing the survey from their local transgender communities. During implementation, the THBS staff will collect information from transgender participants. Given that the interview will be conducted in ACASI format, a series of questions at the conclusion of the interview will provide respondent feedback on the instrument. These findings, along with others, will be summarized in a final report about THBS at the conclusion of data collection.

Dissemination of THBS findings will engage a broad audience as well. Each project area is expected to share local THBS findings with their local stakeholders. The data should be shared with local stakeholders in a forum that allows feedback on the project. CDC will be responsible for overseeing reporting of multi-site data to its stakeholders and to the general public.

The input received during each stage: development, implementation, and dissemination will be used to refine future protocols and questionnaires used to collect HIV-related behavioral data from transgender populations. In addition, findings and lessons learned from conducting the THBS pilot will be incorporated as appropriate into similar behavioral surveys conducted by CDC.

Survey time line

Implementation of the activities described in this protocol is planned for the Fall of 2008. Prior to implementation, project sites will submit protocols to their local IRB. Data collection will not be performed until local IRB has been approved. Initial THBS results are expected in the Spring of 2009.

Potential Risks and Anticipated Benefits

Participation in THBS presents no more risks to respondents than that which might occur outside of the context of surveillance. These non-surveillance contexts include participation in individual or group HIV prevention activities, and interactions with HIV prevention and health-care providers in public or clinical settings. Similar to these contexts, participating in THBS might cause discomfort to those participants whose risks for HIV/STD infection are not fully recognized. Although privacy will be protected to the greatest extent possible, some acquaintances may recognize respondents who enter field site location and choose to participate.

Participants may benefit from participating in the THBS survey by better recognizing their own risks for HIV infection, speaking to trained staff about how to reduce those risks, learning more about local HIV prevention efforts, and obtaining prevention materials and referrals for health care, drug treatment, or HIV/STD testing and prevention services. Participating in THBS also benefits communities by helping prevention planners to better direct state and local HIV prevention efforts.

Voluntary Participation

Participation in THBS is completely voluntary. Participants can refuse to participate in the THBS survey. Once participants have started the survey, they can refuse to answer any question or end the survey at any time without penalty.

Anonymity and Privacy Protections

As a component of HIV/AIDS surveillance, THBS data at CDC are protected by the Assurance of Confidentiality (Section 308(d) of the Public Health Service Act, 42 U.S.C. 242 m(d)). This assurance prohibits the disclosure of any information that could be used to directly or indirectly identify individuals. A copy of the Assurance of Confidentiality for HIV/AIDS Surveillance Data is provided in Appendix A.

In accordance with the Assurance of Confidentiality requirements, each project area will adhere to the existing standards of its pertinent State or local health department for protecting the security and confidentiality of HIV/AIDS surveillance data to THBS data, because these are approved by the Overall Responsible Party (ORP) at the health department. They may need to write a data security policy based upon these local guidelines for the THBS staff to follow. For guidance on developing data security policies for HIV surveillance data, they will consult the *Technical Guidance for HIV/AIDS Surveillance Programs, Volume III: Security and Confidentiality Guidelines* (available online at <http://www.cdc.gov/hiv/topics/surveillance/resources/guidelines/guidance/>). This document establishes the minimum data security standards for protecting HIV/AIDS surveillance data.

The written policy developed by the THBS project area should describe:

- Standard operating procedures and policies for maintaining the security of THBS data,
- Data release policy describing the provisions for protecting against access to raw data or data tables containing small-denominator populations that could be indirectly identifying, and
- Evaluation of the data security measures outlined in the document.

Anonymity protections

Participation in THBS is anonymous. Participants will not be required to provide their names or other personal identifiers as a condition for participation. Instead, potential participants will be assigned an anonymous survey number which can be used to link recruitment and survey data. No personal identifiers will be on any survey forms. The CDC protocol does not require participants to sign consent forms. If a local IRB requires consent forms to be signed, the forms will not have a Survey ID number that could be linked to survey responses. If participants voluntarily disclose their names or personal identifiers, these will not be maintained by THBS project staff nor linked with any survey data.

Privacy protections

THBS staff will always conduct surveillance activities using procedures to protect the privacy of participants. All federal, state, and local staff will adhere to the ethical principles and standards by respecting and protecting, to the maximum extent possible, the privacy, confidentiality, and autonomy of participants.

Paper copies of THBS consent forms or other forms will be stored in locked filing cabinets that are maintained in secure office environments with limited and controlled access. Laptop computers used to administer the CDC-developed interview program will be password protected. Computers and networks where data will be downloaded and stored will also be password protected. Only authorized project staff will have access to completed survey data and study files. All project staff who will have access to the THBS data must undergo local security and confidentiality training and must sign a statement of confidentiality.

Institutional Review Board Approval

This protocol is submitted for review by CDC's Institutional Review Board (IRB). RTI and local project areas will also follow their procedures for obtaining IRB approval.

Waiver of Documentation of Informed Consent

For this protocol, a waiver of documentation of informed consent is requested from the CDC IRB. The only record linking the subject and the research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality. This protocol presents no more than minimal risk of harm to subjects. Participation involves the completion of an anonymous self-administered risk behavior questionnaire. The interviewer will document consent by recording in the laptop computer used for conducting interviews that consent was obtained for the survey. If local IRB review is required, then local project areas should request a waiver of documentation of informed consent and allow the use of oral consent (see Appendix B).

Waiver of Parental Permission for Participants Aged 15 to 17

For this protocol, a waiver of parental permission for participants aged 15 to 17 years is requested from the CDC IRB. Federal Regulations Title 46, Section 408, Requirements for permission by parents or guardians and for assent by children, paragraph (c) specifies that “for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects, it may waive the consent requirements ... provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided that the waiver is not inconsistent with Federal, state, and local law.”

Requiring transgender youth to obtain parental consent to participate in this survey requires them to be forthcoming with their parents about their gender. Asking transgender youth to reveal their gender variance to their parents or guardians may needlessly jeopardize their security, domestic stability, and welfare. Youth in this age group often are dependent on their parents and guardians for care, shelter, financial support, and other needs. However, parents of transgender youth may have difficulty accepting their child’s gender variance (Brown & Rounsley, 1996; Ettner, 1996). As a result, these youth may experience psychological and physical harm and abandonment if their parents learn about their public expression of their preferred gender. This may explain why transgender youth face a dilemma between seeking family support and risking rejection (Kruks, 1991).

In addition, most state and local laws allow persons as young as 15 years to consent to HIV testing services without parental permission. Routine counseling with HIV testing involves reviewing risk behaviors like the ones on the THBS survey. Therefore, participating in the THBS survey will pose no more of a risk than participating in HIV testing services. However, to protect young participants in THBS, it is recommended that each local project area identify a person who is not affiliated with the survey to serve as a child advocate; participants younger than 18 years in age should be offered the option of conferring with this person prior to providing their consent. The local IRB will also determine whether waiving of parental permission and mechanisms for protecting young participants is allowable given local law and policies regarding including minors in research.

Staffing Roles and Responsibilities

The following staff are recommended for the THBS pilot. Strong leadership abilities, good communication skills, and a marked enthusiasm for the project are essential attributes for THBS pilot staff. Participating THBS project areas are encouraged to tailor these recommendations to meet their local staffing situation.

Principal Investigator

The principal investigator is expected to provide scientific and administrative oversight to the local THBS team. This person would be responsible for hiring local THBS staff.

Project Coordinator

A successful Project Coordinator must have considerable knowledge of the local transgender community, broad knowledge of HIV/AIDS, excellent leadership skills and experience, and attention to detail. S/he performs all managerial and administrative aspects of THBS. S/he is responsible for

maintaining all necessary administrative records which will require knowledge of computer programs such as word processing, spreadsheets, and file management. S/he will be responsible for using and teaching others to use Coupon Manager, RDS Analysis Software (RDSAT) and Questionnaire Development System (QDS). The Project Coordinator will develop the local Institutional Review Board (IRB) application, participate in CDC site visits, train and supervise THBS staff, serve as the community's contact person, and coordinate with local stakeholders.

Interviewers

Interviewers will be responsible for screening recruits for eligibility and conducting the interviews. These individuals should be highly motivated and able and willing to work outside the office and outside normal business hours, which may include evening and weekend hours. Interviews will be conducted using ACASI technology; interviewers must be very competent in this regard. Interviewers will be knowledgeable about HIV/AIDS, familiar with transgender issues, willing to work with transgender persons, and culturally competent in terms of gender and race/ethnicity. To the extent possible, interviewers should be representative of the racial and ethnic minority populations in the MSA. If local transgender communities are small, interviewers from outside the immediate transgender community will be sought to help ensure that the anonymity of participants is maintained.