HIV Outpatient Study (HOPS)

Supporting Statement B

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B. Statistical Methods

1. Respondent Universe and Sampling Methods

The respondent universe is a convenience sample of HIV-infected adults receiving medical care at 9 CDC funded outpatient HIV clinics in 6 cities (Denver, CO; Chicago, IL; Philadelphia, PA; Washington, DC; Stony Brook, NY; and Tampa, FL). The HOPS study uses a convenience sample approach, which means that study staff approach patients at the participating clinics for enrollment in the HOPS medical chart abstraction as their funded human resource capacity and time allows. Therefore, the “universe population” as a whole are all adult patients at the 9 CDC HOPS clinics, and these clinics vary widely by size. Therefore, a relatively small (~25%) percentage of patients are HOPS-enrolled at some large university-based clinics and there is nearly universal HOPS enrollment at the smaller private HIV clinics. No specific sampling strata are used or proposed in the HOPS. This convenience sample approach is appropriate given the goals and the longitudinal observational nature of the HOPS.

Medical Chart abstraction

The HOPS study employs a **convenience sample** but strives to ensure that patients enrolled from each HIV Outpatient Study (HOPS) site reflect in their characteristics the whole patient population seen at that site. Historically, since 1993, HOPS clinicians at the participating sites have been asked to attempt to enroll and maintain in the HOPS at least 80% of their HIV clinic patients,

with a minimum participation of 75 active practice patients. However, the increasing longevity of HIV-infected patients treated with modern HIV antiretroviral therapies combined steady rates of new HIV infections in the US, has led to swelling of patient rolls at some of our sites, and this goal of 80% enrollment is no longer achievable for some sites. Due to CDC-funding and human resource constraints at some large HIV clinic sites, these sites today prioritize enrolling patients who are more recently HIV diagnosed or newly entering HIV care to supplement their existing cohorts of HOPS participants, many of whom have been diagnosed in 1990s but continue to live long and healthy lives with the help of HIV antiretroviral therapy. Thus HOPS is a convenience sample of patients in care at the participating HIV clinic sites.

Telephone/web based behavioral survey

This annual patient survey is an optional component of the HOPS. This component of the HOPS data collection activity is a convenience sample of patients enrolled in the HOPS at each study site. All patients are systematically approached by the study staff and offered the participation in a brief behavioral survey, which on average takes 7 minutes to complete. In order to systematically offer this survey to all HOPS enrollees, the clinic staff employ site-specific strategies, including maintaining a spreadsheet roster of all active HOPS patients and their upcoming visits, and tracking if the patient has been offered or not offered the survey at these visits and in a given calendar year. The spreadsheets are periodically returned and their data aggregated by the HOPS data management contractor. Historically, the participation rate among active HOPS patients across all nine HIV clinics has been 60-70%.

2. Procedures for the Collection of Information

Participation in the HOPS project is voluntary. Respondents may refuse to participate in all or in part. As described in #1, there is no formal statistical sampling scheme for the HOPS study medical abstraction. The cohort has a robust size of approximately 2,700 patients across the participating HOPS clinics, which allows for estimation of rates of most outcomes with adequate statistical precision.

Medical Chart abstraction

HOPS clinic data are collected through medical chart abstraction/review by trained data collectors and entered into a secure proprietary web-based data collection system at each of the above mentioned 9 study sites. Information in five general categories is abstracted from each patient visit and electronically entered in a common data collection system that spans the time of observation; the data are reviewed and corrected by Cerner staff. The five areas are demographics and risk behaviors for HIV infection; symptoms; diagnosed conditions (definitive and presumptive); medications prescribed (including dose, duration, and reasons for stopping); all laboratory values, including CD4+ T-lymphocyte (CD4+) cell counts, plasma HIV-RNA determinations, and genotype, phenotype, and trophile results. Data on visit frequency, AIDS, and death are acquired from the clinic chart. Although only data from the clinic chart are abstracted, serious AIDS opportunistic infections and other key diagnoses made in hospital stays are recorded in problem lists and hospital discharge summaries placed in clinic charts. These data are abstracted and entered into the HOPS database. Complete medical information is obtained from the entire period since HIV diagnosis, if available, or from the first study visit to their most recent visit to a HOPS clinic, including beginning and end dates for all prescribed therapies and dates of onset for all charted symptoms and medical conditions. To ensure that the sample of patients from each site is representative of that site, practitioners are asked to attempt to enroll at least 80% of HIV clinic patients, with a minimum participation of 75 active practice patients. Patients, who have been actively recruited throughout the study period for this ongoing project, sign informed consents to have information collected from their physician visits and aggregated, analyzed, and anonymously reported by the local clinician, Cerner Corporation, and CDC.

Telephone/web based behavioral survey

Additional patient health risk behavior data is collected via telephone audio computer assisted self-interview or a web-based computer assisted self-interview. HOPS patients accessing the T-ACASI are assigned unique 4-digit numbers, and asked to complete the anonymous survey by dialing a 1-800 number from a private

location in the clinic or from home. Those patients completing the web based ACASI are given a unique code and asked to complete the anonymous survey located on a secure encrypted web-site from a private location in the clinic or from home. The ACASI will employ industry standard https protocol for data transmission encryption and no patient identifiable information is collected or stored. The entire survey takes an average of 7 minutes to complete.

3. Methods to Maximize Response Rates and Deal with Nonresponses

The chart abstraction component of the HOPS study does not require patient interaction nor do the patients provide any responses. Therefore, no adoption of methodologies to maximize response rates or deal with nonresponses is necessary for this portion of the HOPS data collection activity.

The behavioral survey relies on a convenience sample of HOPS patients. The HOPS protocol states that all patients are to be approached once per year and offered behavioral survey. The optional 7-minute behavioral survey is offered in two formats for participants' convenience: by telephone and web-based, and participants can complete the survey in a private location at the clinic or from home. All responses are voluntary and participants can elect to not participate and or decline to answer specific survey items. These items are coded as such and included in the data analysis as "declined to answer".

4. Test of Procedures or Methods to be Undertaken

The information collected by the optional patient survey is consistent with the routine medical care of HIV-infected persons and includes age, sex at birth, use of alcohol and drugs, cigarette smoking, adherence to antiretroviral medications, types of sexual intercourse, condom use, and disclosure of HIV status to partners. These questions have been used and proven to be clear and acceptable in a previous CDC-funded study, the "Study to Understand the Natural History of HIV and AIDS in the Era of Effective Therapy (SUN)" thus no further testing of these questions was needed. The SUN study, which has since ceased data collection activity, held a clinical exemption and therefore was not subject to OMB review. The HOPS data abstraction from medical

charts focuses on clearly defined subset of variables in the areas of laboratory tests, diagnoses, treatments, hospitalization events and deaths when they occur. All the medical chart abstractors will be trained by the Contractor in correct and complete abstractions. Contractor will implement further automated data quality checks and data reconciliations in the HOPS databases.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Several consultations were conducted with various scientists and public health practitioners outside the agency.

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Ellen Tedaldi, MD Medical doctor	Temple University, 1316 W, Ontario Street; Jones Hall, Suite 808; Philadelphia, PA 19140	ellen.tedaldi@tuhs.temple.edu
Alan Greenberg, MD Medical epidemiologist	George Washington University School of Public Health, 950 New Hampshire Ave, NW 7th Floor Washington, DC 20052	aeg1@gwu.edu
Harlen Hayes, MPH, Statistician	Quantitative Research and Biostatistics. CERNER Corporation, 1953 Gallows Rd, Suite 500; Vienna, VA 22180	harlen.hays@cerner.com

In preparation for this new data collection activity, monthly consultation calls were held with HOPS data analysts and a statistical consultant to discuss analytic and data collection considerations in the HOPS project. Bimonthly calls were also held with medical doctors specializing in the treatment of HIV associated with the project to discuss which data to gather for HIV-infected patients, including which diagnoses, laboratory measurements and treatments, so to best inform epidemiologic analyses of patient management and care. HOPS data have been routinely presented at international HIV conferences (including Conference on Retroviruses and Opportunistic Infections and International AIDS Society Meeting) where the project benefits from scientific peer review and consultations for continuous quality improvement.

Data collection and analysis were conducted by CERNER corporation 1953 Gallows Rd, Suite 500; Vienna, VA 22180. The current contract is set to expire September 30 2015 and the new contract has yet to be awarded. Therefore the entity in charge of data collection and analysis beginning October 1, 2015 is yet to be determined.

Data sent to the Centers for Disease Control (CDC) is received by CDC Project Officers.

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