HIV Outpatient Study (HOPS)

OMB No. 0920-1080

Supporting Statement B

December 15, 2020

Contact: Kate Buchacz
National Center for HIV, Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Rd, NE, MS E-45
Atlanta, Georgia 30333
Phone: (404) 639-5167
Fax: (404) 639-6127
E-mail: acu7@cdc.gov

Table of Contents

B. Statistical Methods

1. Respondent Universe and Sampling Methods

The HIV Outpatient Study (HOPS) is a longitudinal observational study of HIV-infected adults. Participation is voluntary. The respondent universe is a convenience sample of patients who receive medical care at any of 8 CDC-funded outpatient HIV clinics in 6 cities (Denver, CO; Chicago, IL; Philadelphia, PA; Washington, DC; Stony Brook, NY; and Tampa, FL). The HOPS 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. The study aims to enroll approximately 450 new patients (average of 50-60 per site) per year. Study staff approach patients at the participating clinics for enrollment as their funded human resource capacity and time allow. Each year a portion of patients also cease to participate for a variety of reasons (e.g., the patient relocated to another city; the patient transferred to a non-HOPS clinic or is no longer eligible for HIV treatment in an outpatient setting; the patient died; or the patient is lost to follow-up).

Participating 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, but the HOPS study strives to ensure that patients enrolled from each HOPS site broadly reflect characteristics of 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(ART)combined with 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.

The convenience sample approach is appropriate given the goals and the longitudinal observational nature of the HOPS.

Medical Chart abstraction

All patients enrolled in the HOPS give voluntary consent (**Attachment 4**) for information to be abstracted from their medical charts. Medical records are the principal source of information for the HOPS.

Telephone/web based behavioral survey

The annual behavioral patient survey is an optional component of the HOPS(**Attachment 3a, 3b and 5**). This component of the HOPS data collection activity is a convenience sample of patients enrolled in the HOPS at each study site. 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 in a given calendar year. The spreadsheets are periodically returned and their data aggregated by the HOPS data management contractor. Because of the optional nature of the survey, and constraints of site staff availability, the levels of survey offer have varied over time and by site. Importantly, however, approximately 60-70% of active HOPS patients have completed the survey at least once. This permits the HOPS to gather additional covariate information (e.g., tobacco use, sexual and substance use history, ART adherence) that can be combined with data from medical records collected at a similar point in time, for focused in-depth analyses for a subset of patients.

2. Procedures for the Collection of Information

Four hundred–fifty new HOPS study participants are to be recruited annually into the HOPS from a pool of adult individuals currently in HIV-care at the eight aforementioned clinics. Patients are approached by HOPS project clinic staff during one of their routine clinic visits and invited to participate in the HOPS. 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, aggregated and analyzed by the CDC's Contractor (CERNER Corporation), and reported without any personal identifiers to the CDC. (**Attachment 4**). The HOPS protocol states that all patients are to be approached once per year by HOPS project clinic staff and offered the behavioral survey (**Attachment 3a, 3b and 5)**. Therefore, the maximum number is 2,700 patient participants in an annual voluntary behavioral survey.

HOPS is a convenience sample of patients in care at the participating HIV clinic sites. 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 clinic patients, with a minimum participation of 75 active practice patients. Due to human resource constraints at some large HIV clinic sites, which have 300 or more patients actively participating, enrollment is focused on those patients who are more recently diagnosed with HIV or newly entering HIV care at the participating HOPS clinics.

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 8 study sites. Patients sign informed consents(**Attachement 4**) to have information collected from their physician visits and aggregated, analyzed, and anonymously reported by the local clinician, Cerner Corporation, and CDC. 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. See **Attachment 6**.

Telephone/web based behavioral survey

Additional patient health risk behavior data are collected via telephone audio computer assisted self-interview or a web-based computer assisted self-interview (ACASI) surveys (**Attachment 3a,3b and 5**). HOPS patients accessing the telephone version (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 employs industry standard https protocol for data transmission encryption and no patient identifiable information is collected or stored.

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. Data are abstracted from regular HIV patient care encounters, including any diagnoses or treatments as these are charted by clinicians. 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 asked to participate in the behavioral survey. The optional 7-minute behavioral survey is offered in two formats for participants' convenience: by telephone and web-based administration.Participants may elect to 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 are trained by the Cerner Corporation Contractor in correct and complete abstractions. Contractor implements 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

Over the years of HOPS conduct, several consultations were conducted with various scientists and public health practitioners outside the agency. In the last 3 years, the consultants have included the following persons.

Consultant	**Organization**	**email**
Rick Novak, MD Medical doctor	University of Illinois College of Medicine at Chicago, 808 S Wood St, Chicago, IL 60612	rmnovak@uic.edu
Frank Palella, MD Medical doctor	Northwestern University School of Medicine, 645 N. Michigan Ave, Suite 900; Chicago, IL 60611	f-palella@northwestern.edu
Jonathan Mahnken, PhD Statistician	The University of Kansas Alzheimer's Disease Center, 3901 Rainbow Blvd. Kansas City, KS 66160	jmahnken@kumc.edu
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
Jeff Naughton MBA, Market General Manager	CERNER corporation 2800 Rockcreek PKWY; Kansas City, MO 64117-2521.	Jeff.Naughton@Cerner.com

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 published and are 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. A list of publications is provided in **Attachment 8**. The publications address multiple domains in HIV infection and treatment relating to the goals of the National HIV/AIDS Strategy.

Data collection and analysis are conducted by CERNER corporation 2800 Rockcreek PKWY; Kansas City, MO 64117-2521.

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

CDC Project Officers		
Kate Buchacz	acu7@cdc.gov	404-639-5167
Marcus Durham	mvd8@cdc.gov	404-639-5193
Jun Li	ffa2@cdc.gov	770-488-3030