

**ASSESSMENT OF A COMPREHENSIVE HIV CLINIC-BASED INTERVENTION TO  
IMPROVE PATIENTS' HEALTH AND REDUCE TRANSMISSION RISK**

**OMB No. 0920-NEW**

**SUPPORTING STATEMENT A**

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## **A. JUSTIFICATION**

### **A. 1. Circumstances Making the Collection of Information Necessary**

The National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) of the Centers for Disease Control and Prevention (CDC) is requesting Office of Management and Budget (OMB) approval for data collection as part of a clinic-based research study to promote the health of HIV patients and reduce disease transmission risk. This research is funded by the CDC and the National Institute of Mental Health (NIMH) and performed at six university-affiliated HIV clinics in the United States. A 3-year approval is requested for the proposed data collection. This research is authorized under Section 301 (Sec. 241) of the Public Health Service Act (**Appendix 1**).

Approximately 80% of HIV-infected persons in the United States are aware of their seropositive status.<sup>1</sup> Following diagnosis, sexual risk behavior declines dramatically;<sup>2</sup> however, about half of all new HIV infections in the United States stem from sexual risk behaviors of HIV-diagnosed persons.<sup>3</sup>

Roughly 70% of HIV-diagnosed persons enter medical care within 12 months of being diagnosed.<sup>4</sup> The HIV medical care setting is thus an ideal location for delivering a sustainable intervention to large numbers of HIV-positive persons, with the goal of improving patients' health and reducing the potential for transmission of HIV infection. To reach this goal, a comprehensive intervention is needed that not only addresses sexual risk behaviors directly, but also attempts to improve patients' retention in medical care and their adherence to antiretroviral therapy (ART).

Observational studies indicate that approximately 40-50% of HIV-diagnosed persons who have been seen by HIV medical providers are not stable in care (they miss scheduled appointments or have large gaps between care visits).<sup>5,6</sup> Patients who "feel well" or are not on ART may exhibit a higher level of inconsistent attendance for medical care compared with their counterparts.<sup>7</sup> Other studies have shown that for every 100 cells/mm<sup>3</sup> increase in CD4 count, there was a 20% increase in the probability of discontinuing primary HIV care within the first 6 months of care entry.<sup>8</sup>

Improving the regularity with which HIV patients attend clinic may facilitate adherence to ART which may lead to medical and prevention benefits. Patients on ART who see their medical providers regularly are more likely to have undetectable viral load (VL) than those who see their providers' irregularly.<sup>9</sup> Having an undetectable VL means that the amount of HIV in the blood is so low that it cannot be detected by current laboratory assays, but it does not mean that HIV has been eliminated from an infected person's body. Importantly, people who have an undetectable VL are less infectious and thus less likely to transmit HIV infection through risk behaviors.<sup>10,11</sup> Observational cohort studies indicate that approximately 30-40 percent of HIV patients do not have undetectable virus.<sup>12</sup>

## **A. 2. Purpose and Use of Information Collection**

The purpose of the project is to implement and evaluate an HIV clinic-based intervention, the goals of which are to increase the percentage of patients who have an undetectable viral load, who are adherent to ART, who attend clinic regularly for primary care, and practice safer sexual behaviors. Realizing these goals will promote HIV patients' health and reduce risk of transmitting HIV to others. These are strategic 2015 goals of the National HIV/AIDS strategy ([www.whitehouse.gov/ohap](http://www.whitehouse.gov/ohap)) and of the Division of HIV/AIDS Prevention, Centers for Disease Control and Prevention.

The project will be conducted at six HIV clinics affiliated with the following institutions: (1) Baylor College of Medicine, Houston, (2) Boston Medical Center, (3) University of Alabama, Birmingham, (4) University of California at San Diego, (5) University of Miami Medical School, and (6) University of Washington in the state of Washington.

The intervention will be evaluated using a group-randomized design. Three clinics (Panel A: Baylor College of Medicine, University of Alabama, University of Washington) will begin the intervention in October of 2013 and continue offering the intervention to patients until the end of the project (end of September 2016); the other three clinics (Panel B: Boston Medical Center, University of California at San Diego, University of Miami) will delay onset of all intervention components and most of the data collection activities for 12 months and serve as a concurrent control group during that period. The design enables pre-post comparisons of outcomes within clinics and comparisons between the two panels of clinics at the 12 month mark.

The following intervention components will be used in the project:

- Behavioral screener: Three clinics participating in this study are part of the Center for AIDS Research (CFAR) Network of Integrated Clinical Systems (CNICS) and are already conducting behavioral screening of nearly all patients (86% participation rate; University of Alabama, University of Washington, University of California at San Diego); these clinics will not do additional screening. At the other three clinics participating in the study (Baylor College of Medicine, University of Miami, Boston University), all HIV patients will be asked to complete a brief behavioral screener each time they attend clinic for a primary care exam (approximately every 3 months per patient on average). At these three clinics, patients will do the screener before their medical exam and primary care providers will receive the screener information and use it as a guide for talking with their patients about ART adherence, importance of regular care, and sexual risk reduction as needed.

The intervention components below are directed at patients who have detectable VL. These are patients who have HIV that is detectable in their blood and thus are at risk of developing medical problems and at risk of transmitting HIV to others through risk behaviors.

- Computer-based intervention (CBI): All VL detectable (>200 copies per/mL) patients at the participating clinics are eligible to do the CBI three times spaced approximately 3 months apart. The CBI is audio/visual and administered with a tablet, laptop, or desktop computer. The CBI contains five assessment items for which patients give self-reported responses (on the topics of ART, adherence, clinic attendance, sexual risk behavior). Patients receive tailored messages, information, and strategies to help them improve their health. No personally identifiable information is obtained in the CBI. Responses are identified by a unique study ID.

Among patients who do the CBI, their VL status will be compared across these CBI time periods. If no improvement in VL status is observed, the patient will be offered counseling from a Prevention Specialist (PS) at the clinic (PS position funded by CDC/NIMH).

- One-on-one counseling from a Prevention Specialist: Each VL detectable patient offered counseling will have up to three sessions with the PS focusing on the behaviors that need attention (ART adherence, clinic attendance, sexual risk behavior). All counseling sessions will be conducted at the clinic. Patients will receive a token of appreciation when they come for a counseling session.

The primary outcomes are:

- Patients’ viral load status (obtained from databases maintained at the clinics)
- Patients’ attendance for primary care (obtained from databases maintained at the clinics)

Secondary outcomes include:

- Adherence to ART (obtained from patients’ self-reports on the CBI assessments)
- Safer sex (obtained from patients’ self-reports on the CBI assessments)

### ***Proposed Data Collection***

The proposed data collection is necessary for effectively implementing and evaluating the proposed intervention, which has important utility to the government, the six sites participating in the project as well as administrators and primary care providers at HIV clinics.

The proposed data collection with frequency of administration for both phases of the project will include:

<b>Activity</b>	<b>Appendix number</b>
Data manager electronic transmission of clinical outcome variables routinely collected by clinics and stored in clinic’s archived databases (electronic transmittals once every 3 months; this activity will occur for 3 years in both Panel A and Panel B clinics).	Appendix 3
Patient behavioral screener for all patients (at each primary care visit, approximately quarterly per patient on average; this activity will occur for 3 years in Panel A clinics and 2 years in Panel B clinics).	Appendix 4 (English) Appendix 5 (Spanish) Appendix 6 (Creole)
Patient CBI assessment among VL detectable patients (VL detectable patients will be asked to do the CBI three times spaced approximately 3 months apart; this activity will occur for 3 years in Panel A clinics and 2 years in Panel B clinics). We did not produce a Creole version of the CBI due to cost and the limited number of monolingual Creole speaking patients at the clinics.	Appendix 7 (English) Appendix 8 (Spanish)
Patient “exit” survey after medical exam (once every 3 months with small sample of patients surveyed; this activity will occur for 3 years in Panel A and 2 years in Panel B clinics).	Appendix 9 (English) Appendix 10 (Spanish) Appendix 11 (Creole)
Provider survey (once every 3 months; this activity will occur for 3 years in Panel A and 2 years in Panel B clinics).	Appendix 12 (English Only)

The data collection activities are described in detail below.

Data manager electronic transmission of de-identified clinical outcome variables routinely collected and archived by the clinics: A data manager at each clinic will electronically transmit clinical data in batches to CDC on a quarterly basis. These data elements (see list below) are routinely collected and archived by the clinics. The data files will not include patients' names, social security numbers, email addresses, home addresses, telephone numbers, or medical record numbers. The data manager will use a project computer at the clinic to transmit the clinical data to CDC. This computer will have a functional algorithm application on it (supplied by CDC) to convert a patient's electronic medical record number into a unique study ID code per patient. CDC will only receive the study ID code. CDC will not install the algorithm on any computer or server at CDC, thus preventing CDC from having the ability to back-convert the Study ID to a medical record number.

The following clinical data elements for all HIV patients available in the clinic's archived database will be electronically transmitted to CDC (for a three-year period beginning on the date of OMB approval).

- All viral load laboratory results and dates of VL lab tests
- All CD4 cell count and dates of CD4 lab tests
- Attendance for HIV primary care, dates, and dispositions (cancelled, kept, no-show)

The following demographic variables in the clinics' archived databases will also be transmitted to CDC.

- Month and year of birth
- Biological sex
- Ethnicity (Hispanic or Latino; Not Hispanic or Latino)
- Race (indicating all categories that apply)
- HIV risk exposure category
- Date first tested HIV positive
- Health insurance status and type of insurance (e.g., Medicare, Medicaid, Ryan White, private)

**Appendix 3** displays the clinical and demographic variables (from the clinic's archived database) in greater detail.

Behavioral screener for all patients: The purpose of the screener is to obtain information from patients that will be used by clinicians as a guide for intervening with patients as needed (relevant to our outcome variables). Such screening practices are recommended by CDC and the Health Resources and Services Administration (HRSA) ("Recommendations for Incorporating HIV Prevention into The Medical Care of Persons Living with HIV"; MMWR).<sup>13</sup>

Medical providers will use this information as an interventional tool to guide their prevention messages and brief counseling of the patient as needed. This screener information will be used solely for clinical care and will not be transmitted to CDC or used for research purposes.

Patients at the three clinics that are not already conducting behavioral screening will be asked to complete a screener (English version: **Appendix 4**; Spanish version: **Appendix 5**; Creole version: **Appendix 6**) each time they come to clinic for primary care (approximately every 3 months). Patients

will do the screener in the clinic's waiting room or examine room before seeing the provider that day. No token of appreciation will be offered to patients for completing the screener.

The screener contains the following domains:

- Whether patient is currently taking ART
- For those taking ART, pill-taking adherence
- Desire to talk with provider about HIV medications
- Attitudes about coming to clinic for medical care
- Whether sexually active, number of partners (no questions on specific sexual activities)
- Substance use (alcohol/drugs/injection)
- Mental health

CBI assessment for patients with detectable VL: Patients with detectable VL (>200 copies per/mL) will be asked to do the electronic CBI. Patients will do the CBI while at the clinic. The CBI is housed on a secure CDC server and accessed through the Internet. Patients' responses to the CBI assessment items (English version: **Appendix 7**; Spanish version: **Appendix 8**) trigger tailored messages and information for improving one's health. No token of appreciation will be offered to patients for doing the CBI during a regularly scheduled clinic visit. But if a patient needs to make a special trip to the clinic for purpose of doing the CBI, a token of appreciation will be offered. We did not produce a Creole version of the CBI due to cost and the limited number of monolingual Creole speaking patients at the clinics.

The CBI is a stand-alone tool that is used by the patients; patients' CBI assessment responses are not shared with clinic providers. The CBI assessment items, by necessity, cover some of the same domains that are covered in the brief screener described above, although the items in the CBI are more detailed and used to evaluate whether exposure to the CBI changed patients' self-reported behaviors and VL status. Patients' responses to the CBI assessment items will be transmitted to CDC using only the patient's study ID number as identification.

The CBI contains five assessment items:

- Whether patient is on ART
- ART pill-taking adherence (among those on ART)
- Ease-difficulty of coming to all HIV medical appointments
- Sexual risk behavior (two items)

Patient "exit" survey after medical exam: A sample of patients will be asked after their primary care exams to complete a brief survey to document the types of issues (e.g., adherence, attendance, sexual practices) that providers may have discussed with them that day (English version: **Appendix 9**; Spanish version: **Appendix 10**; Creole version: **Appendix 11**). Participation is voluntary. The first survey will occur prior to the onset of the intervention at the clinic and serve as a baseline; subsequent surveys will be administered quarterly. The same survey items will be used each time. A total of 50 patients (10 per day, Monday through Friday) will be surveyed every 3 months (for 3 years in Panel A clinics and 2 years in Panel B clinics). Patients will be randomly selected after their primary care exams (not urgent care visits). A project coordinator will verbally ask the question and the patient will respond privately using an electronic tablet that accesses the survey from a secure CDC server. The surveys will not include any personally invasive questions, and will not include study ID numbers or any personally

identifying information. Patient surveys will not be linked across time. The surveys will include a code to identify the clinic site. No tokens of appreciation will be given to patients who do the survey.

Provider survey: Primary care providers (physicians, physician assistants, nurse practitioners) at each clinic will be asked to complete surveys asking about topics they may have discussed with their patients. Participation is voluntary. The survey questions (in English only) appear in **Appendix 12**. As with the patient survey, the first survey of providers will occur prior to the onset of the intervention at the clinic (baseline) and then the same survey items will be administered quarterly thereafter (total of 4 times per year for 3 years in Panel A clinics and for 2 years in Panel B clinics).

The provider surveys will not include a study ID or any personal identifiers; it will include a code number to identify the clinic site. The quarterly surveys will not be linked across time. Participation is voluntary. Providers will access the surveys, housed on a secure CDC server, using their workplace computers. Automated reminders will be sent to providers. No tokens of appreciation will be given to providers who do the survey.

### **A. 3. Use of Improved Information Technology and Burden Reduction**

We will be using electronic data collection, electronic data transmittal, and electronic storage of encrypted data using a secure server housed at CDC. Data will be collected and transmitted to CDC using a web-based system (described in more detail below). The information technology used in this project will greatly reduce the burden on participants as well as the project staff conducting the study. Below we describe the information technology that will be used in our data collection and data transmission processes.

Data managers at the clinics will electronically transmit to CDC batches of clinical variables for quarterly time periods. These variables are available from electronic archived databases at the clinics. These clinical data will be stored on a secure server at CDC. The data managers at the clinics will not use paper forms, will not need to search any paper medical files, or conduct any hand abstractions of medical charts.

Patients will access the CBI via the Internet from laptops, desktop computers, or tablets at the clinic or from their home computer. Patients' responses to the CBI assessment items will automatically be transmitted and stored on a secure server at CDC.

The patient "exit" surveys and the provider surveys will be conducted using electronic data collection. Patients will respond using a tablet, and providers will use their workplace computers. All survey data will be automatically transmitted and stored on a secure server at CDC.

The only paper copy form that will be used in this project is the "behavioral screener." Patients will mark their answers on a one-page form.

### **A. 4. Efforts to Identify Duplication and Use of Similar Information**

Several steps have been taken to prevent duplication of effort. CDC personnel have conducted extensive, systematic computerized searches of electronic databases of published articles, abstracts,



book chapters, and dissertations. Those databases include MEDLINE, AIDSLINE, PsycInfo, EMBASE, CINAHL, and SOCIOFILE. Hand-searches of relevant journals have also been conducted. We have attended local, national, and international conferences relevant to the topic, communicated frequently with non-federal colleagues at universities, health departments, and community-based organizations (CBOs) as well as with colleagues within the government. The intervention to be implemented and evaluated in this project, and the supportive data collection needed in the evaluation, have not been conducted before and are not currently being conducted apart from the proposed project.

#### **A. 5. Impact on Small Businesses or Other Small Entities**

No small businesses will be involved in this study. Further, the study will not impact small businesses, including health departments, non-profit organizations, dentist or physicians' offices, or CBOs.

#### **A. 6. Consequences of Collecting the Information Less Frequently**

This is a one-time collection. Collection of less information with a smaller sample would reduce the ability to validly evaluate and understand the impact of the HIV clinic-based intervention on increasing the number of HIV patients who have undetectable VL, who adhere optimally to their prescribed ART regimen, attend clinic as recommended by their medical providers, and practice safer sex.

#### **A. 7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

There are no special circumstances relating to the guidelines of CFR 1320.5.

#### **A. 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

The 60-Day-Notice as required in 5 CFR 1320.8(d) was published in the Federal Register on 2/12/2013, Vol. 78, No. 29, pages 9923-9924 (See **Appendix 2**). There were no comments in response to the 60-day Federal Register notice.

The development of the project, including the interventions and data collection instruments, has been a collaborative effort among investigators at CDC, NIMH, and the six participating HIV clinic sites. The following investigators outside of CDC and NIMH, but affiliated with the current project, have reviewed the data collection instruments for clarity, frequency of administration, and need. All of these investigators are HIV clinicians and have particular expertise in data collection activities involving HIV patients.

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**A. 9. Explanation of Any Payment or Gift to Respondents**

Patients referred to the Prevention Specialist for counseling will need to make special trips to the clinics for that counseling. Clinics will offer counseling recipients a token of appreciation of up to \$10.00 per counseling session (up to three sessions). Regarding the CBI administration, every attempt will be made to coordinate the CBI administration with routine care visits at the clinic and thus no tokens of appreciation will be offered. However, in instances when patients must make a special trip to the clinic to complete a CBI, a token of appreciation of up to \$10.00 will be offered. No tokens of appreciation will be offered for the patient “exit” survey or the provider survey. No other gifts, incentives, or reimbursements will be offered to patients for any data collection activities.

**A. 10. Assurance of Confidentiality Provided to Respondents**

Given that this project is funded through a contract mechanism, the Privacy Act does apply to this data collection. However, no personally identifiable information will be received by CDC. CDC will not collect patient names, social security numbers, medical record numbers, home address or zip codes, email address, or full birthdates (just month and year). In the data sent to CDC, respondents will be identified only by a unique study ID code. This code will be generated at the clinics using a functional algorithm applied to the patients’ medical record number. CDC will not install this algorithm on any computer or server at CDC and thus will not have the ability to back-convert a study ID to a medical record number.

Specifically with respect to assurance of privacy, none of the data received by CDC will be identifiable, and no information will be used for any purpose other than the purpose for which it was intended, namely, as information to be used in analysis of the current intervention project.

Further, CDC employees or their agents will not be intervening or interacting with study participants and will not be obtaining individually identifiable private information. Neither CDC employees nor their agents are engaged in the conduct of this research project at the performance sites.

Data Transmittals and Safeguards

CDC will establish and host a secure web-based system for receiving and storing all project-related data at CDC. Secure socket layer (SSL) technology will encrypt all incoming data during the transmission process. The encrypted data will be stored in a secure CDC server.

The project computers at the clinics will be connected to the clinic's existing network (wired, WiFi) to access the Internet for purpose of transmitting data to CDC.

The following safeguards will be in place:

- All encryption device systems will be FIPS 140-2 compliant (federal standard)
- CDC will not receive patient names, medical record numbers, social security numbers, or personally identifiable information.
- No data collected as part of the study will be stored on any project computer or local server at the clinic. All data are encrypted and saved on secure CDC servers.
- Only authorized and authenticated CDC-based project staff (project officer, project coordinator, data manager at CDC) will have access to the data sent to CDC.
- Data records received by CDC will only be identified by a unique study ID code number.
- A functional algorithm will be placed on project computers at the sites to convert a patient's medical record number to study ID (the algorithm can also back-convert for study management purposes at the performance sites).
- The algorithm will not be installed on any computers/servers at CDC thus preventing CDC from back-converting a study ID into a medical record number.
- There will be no databases of medical record numbers and study IDs on any project computers or servers at the sites.
- All project computers used at the clinics for purpose of conducting the study will be password protected.
- Only authorized and authenticated project staff at the clinics (clinic-based data manager, project coordinator, and health coach) will have access to the project computers).
- Papers and presentations will report aggregated information and will not contain any identifying information that can be traced back to a respondent.

### Institutional Review Board (IRB) Approvals

Each of the six HIV clinics participating in this project has obtained IRB approval from their university-affiliated IRBs. **Appendix 13** contains the IRB approval letters from each site. Regarding the IRB at CDC, this project has been given a non-engagement determination by CDC (i.e., no CDC employee will be directly involved in the conduct of the study at the sites), waiving the necessity of having the protocol reviewed by CDC's IRB. The approved non-engagement determination appears in **Appendix 14**.

### Informed Consent

Behavioral screener: At each site, the behavioral screener is viewed as a "standard of care practice" to improve the clinical care of patients and, thus, written informed consent was not required for the patient self-administered behavioral screener at any of the sites. Patients do, however, have the right to refuse to do the screener or to decline specific questions.

Clinical and demographic variables: Written informed consent was not required at any of the six sites for the collection of de-identified electronic clinical data (viral load lab results, CD4 lab results, clinic attendance) and demographic data (biological sex, month/year of birth, race, ethnicity, HIV risk exposure category, month/year tested HIV positive, insurance) maintained in archived databases at the clinics. This was deemed to be of minimal risk and the data collection could not practicably be conducted with written informed consent. The data transmittals will not have any personal identifiers (patient names, initials, social security numbers, medical record numbers). Patients will be identified in the database only by a unique study code number and CDC will not receive any information that could be used to personally identify any data records.

For the computer-based intervention (CBI) and the counseling, the informed consent requirements varied across the sites.

CBI: Written informed consent for the CBI is required at four sites (Boston Medical, University of Alabama, University of Miami, University of Washington). At the other two sites (Baylor, UC San Diego), written informed consent for the CBI was not required. Patients at all sites, however, retain the right to refuse to participate in the CBI and to decline to answer specific questions.

Counseling from the prevention specialist: At all sites (except Baylor), written informed consent will be obtained from patients referred for one-on-one counseling from the prevention specialist. Baylor has integrated the counseling as programmatic practice within their clinic and thus will not be using written consent for counseling. Patients at all sites retain their right to refuse the counseling referral.

The consent forms for the CBI and the counseling appear in **Appendix 15**. Note that at some sites these two elements (CBI and counseling) are included in a single consent form.

Written informed consent is not required for the quarterly patient exit surveys or the quarterly provider surveys. No personally identifiable information will be collected in these electronic surveys. Patients and providers retain the right to refuse to participate in these surveys; they may also skip questions.

#### **A. 11. Justification for Sensitive Questions**

One objective of the intervention is to increase the number of HIV patients who engage in safer sexual behaviors. Thus, to evaluate the intervention with respect to this objective it is necessary to ask respondents about their recent sexual activities. Questions about substance use are also asked to inform our statistical analysis. Another objective is to increase the percent of patients who adhere to their ART regimen and attend clinic regularly for HIV primary care. Thus, it is necessary to ask responses about their pill-taking behavior and their clinic attendance. All respondents will be fully informed of the voluntary nature of the data collected from them and their right to skip questions that they do not wish to answer.

#### **A. 12. Estimates of Annualized Burden Hours and Costs**

The annualized burden hours and costs take into account that 3 clinics (Panel A) will conduct full data collection in each of 3 years, and the other 3 clinics (Panel B) will conduct partial data collection in the first year and full data collection thereafter, as indicated in the table below.

	Panel A clinics	Panel B clinics
Year 1 (after OMB approval)		
Clinical data from clinic’s archived databases	X	X
Patient behavioral screener	X	
Patient CBI assessment items	X	
Patient “exit” survey	X	
Provider survey	X	
Year 2 (after OMB approval)		
Clinical data from clinic’s archived databases	X	X
Patient behavioral screener	X	X
Patient CBI assessment items	X	X
Patient “exit” survey	X	X
Provider survey	X	X
Year 3 (after OMB approval)		
Clinical data from clinic’s archived databases	X	X
Patient behavioral screener	X	X
Patient CBI assessment items	X	X
Patient “exit” survey	X	X
Provider survey	X	X

The burden table below reflects the total estimated annualized respondent burden hours for the project. The annualized burden estimate for each data collection activity was calculated by averaging the number of respondents across the three years and across the two panels of clinics. Note that in the first year for Panel B clinics, there will be no respondents for four data collection activities.

The annualized number of respondents (6, 315) for the behavioral screener only includes patients at the three clinics that are not part of CNICS. The CNICS clinics are already conducting behavioral screening of patients. This annualized estimate takes into account that no behavioral screening will take place in the first year in Panel B clinics.

The annualized number of respondents (2,069) takes into account the current (i.e., existing) VL detectable patients already at the clinics and new VL patients who enter the clinics in subsequent years.

**12 a. Estimated Annualized Burden Hours**

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (Hours)	Total Burden Hours
	Electronic				

Data manager at clinic	transmittal of clinical variables archived in clinic databases (no form)	6	4	24	576
Patient	Behavioral screener for patients with detectable or undetectable VL (paper form)	6,315	4	5/60	2,105
Patient	CBI assessment items for patients with detectable VL (electronic form)	2,069	3	5/60	517
Patient	Patient "exit" survey (electronic form)	1,200	1	5/60	100
Primary care provider	Provider survey (electronic form)	120	4	10/60	80
<b>Total</b>					<b>3,378</b>

The table below presents the estimated annualized burden costs. It is estimated that 50 percent of the primary care provider respondents will be MD-level physicians with an hourly wage of \$84.97 and the remaining primary care providers will be physician assistants, nurse practitioners or nurses with an hourly wage of \$39.24. Using these figures, the average hourly wage rate for all primary care providers is \$62.11. The data managers at the clinics have an average hourly wage of \$35.32. The majority of the patient respondents will be of lower socioeconomic status. If employed, most will be in service-related jobs with an estimated average hourly wage of \$9.08. All estimates of hourly wage rates are based on Bureau of Labor Statistics, National Occupational Employment and Wage Estimates for the United States (May 2012).

**12 b. Estimated Annualized Burden Costs**

Type of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Data manager at clinic	Electronic transmittal of clinical variables archived in clinic databases (no form)	576	\$35.32	\$20,344
Patient	Behavioral screener for patients with detectable or undetectable VL	2,105	\$9.08	\$19,113

Type of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
	(paper form)			
Patient	CBI assessment items for patients with detectable VL (electronic form)	517	\$9.08	\$4,694
Patient	Patient “exit” survey (electronic form)	100	\$9.08	\$908
Primary care provider	Provider survey (electronic form)	80	\$62.11	\$4,969
Total				\$50,028

**A. 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers**

There are no direct costs to respondents other than their time to participate in the data collection.

Table 13a displays total (not annual) start-up cost for equipment purchase necessary to conduct the project. Each clinic needs to purchase laptop computers for the project coordinator and the prevention specialist. Each clinic needs to purchase multiple laptops to administer the CBI to patients who have detectable VL (enough laptops to accommodate multiple patients simultaneously given the size of each clinic’s population of VL detectable patients). Purchase of disposable earbuds is necessary so patients can listen to the CBI videos privately. Each clinic needs to purchase an electronic tablet to administer the patient “exit” survey.

**13 a. Other Cost Burden**

Total start-up costs for the 6 clinics combined	Amount
20 laptop computers	\$24,000
12 tablets	\$6,000
Bulk purchase of disposable earbuds	\$5,000
TOTAL	\$35,000

**A. 14. Annualized Cost to the Government**

The annual cost to the government is \$1,980,609 (Exhibit A.14).



Exhibit A.14 Annualized Cost to the Government

Title	Federal salary grade	Salary	% effort	Annualized cost
6 research contracts	-			\$1,727,989
Lead trainer/intervention overseer (hired through IPA)	NA	\$99,734	30%	\$29,920
Trainer/intervention overseer (hired through IPA)	NA	\$73,260	30%	\$21,978
CDC Project Officer	GS 14-10	\$131,343	60%	\$78,806
CDC Investigator	GS 14-10	\$131,343	20%	\$26,269
CDC Investigator	GS 14-10	\$131,343	10%	\$13,134
CDC-based Project Coordinator (contractor)	NA	\$74,200	70%	\$51,940
NIMH Investigator	GS 15-7	\$148,510	5%	\$7,426
NIMH Investigator	GS 14-4	\$115,731	15%	\$17,360
NIMH Investigator	GS 14-4	\$115,731	5%	\$5,787
Total annualized cost				\$1,980,609

The costs of the 6 contractors (clinic sites), two trainers (funded through IPAs), and the CDC-based Project Coordinator are split 50-50 between the CDC and NIMH.

**A. 15. Explanation for Program Changes or Adjustments**

This is a new collection of information.

**A. 16. Plans for Tabulation and Publication and Project Time Schedule**

The analysis of the primary outcomes (achieved an undetectable VL status [ $<200$  copies/mL] and did not miss any scheduled primary care appointments as specified below) will be performed using the group-randomized design in which Panel B clinics serve as a concurrent control group during the first 12 months of the intervention in Panel A clinics. These outcomes derive from the clinics' electronic databases.

Patients whose VL is over 200 copies/mL are eligible to enroll in the intervention. These patients (regardless of whether they enroll or not) constitute the primary target population for the analysis. Specifically, the baseline target population is patients in Panel A and Panel B who have a VL laboratory result over 200 copies during the first 6 months of a 12-month intervention period in Panel A. The baseline entry date per patient will be the date of their first VL result over 200 in the first 6 months. This represents their baseline VL prior to their first opportunity to be enrolled in the intervention.

Analysis of viral load outcome: After the intervention has run for 12 months in Panel A, we will calculate the percentage of the baseline target population in each panel that has a VL  $< 200$  copies at the 12-month time point. A 60-day window before and after the 12-month mark will be used for ascertaining VL outcome values. If VL lab results are not available within that window, we will use a

conservative approach and code that patient as not having a VL < 200 copies at 12 months. This will be applied to both Panels A and B. If the intervention is successful, we should find a significantly ( $p < 0.05$ ) larger percentage of patients with VL < 200 copies at 12 months in Panel A than in Panel B. The analysis will be done using a log-binomial model adjusting for the correlation of patient's behavior across time and clustering effects within clinics (i.e., lack of independence of behavior among patients within a clinic).

Analysis of clinic attendance for primary care: The clinic attendance outcome will be conducted among the same analytic baseline sample used in the VL analysis. That is, we will examine future clinic attendance for primary care among patients who were eligible to enroll in the intervention, namely, patients who had a VL lab result over 200 copies during the first 6 months of the 12-month intervention period. Attendance for HIV primary care will be examined in the context of the group-randomized design, comparing outcomes between the two panels. Our main outcome will be the percentage of patients who attend all of their scheduled primary care appointments during a 12-month period following their date of entry into the analytic sample. Appointments cancelled ahead of time will not be included as a scheduled appointment. We will also examine gaps in care (e.g., percentage of patients who have gone longer than 6 months without a primary care visit during a 12-month period following their date of entry into the analytic sample. If the intervention is successful, we should find a significantly ( $p < 0.05$ ) larger percentage of patients who keep all of their primary care appointments and a smaller percentage who have a gap in care in Panel A than in Panel B. The analysis of the clinic attendance outcomes will be done using a log-binomial model adjusting for the correlation of patient's behavior across time and clustering effects within clinics.

Analysis of intervention effects in Panel B clinics and longer-term effects: Panel B clinics do not begin delivering the intervention until 12 months after the intervention begins in Panel A clinics. Thus, there is no concurrent control group for examining intervention effects in Panel B clinics. We will examine changes in VL status and clinic attendance after patients in Panel B are exposed to the intervention and compare the outcomes against their VL status and attendance prior to receiving the intervention. This type of pre-post comparison will also be used to examine longer-term intervention effects (e.g., in the third year). These analyses will use McNemara's test for dependent proportions.

Self-reports of ART adherence and sexual risk behavior: These self-reported variables are collected in the computer-based intervention (CBI) assessments among patients whose VL exceeds 200 copies at entry into the intervention. These outcomes will be analyzed as a pre-post change comparing baseline self-reports obtained on the first CBI assessment (before exposure to the CBI intervention components) with self-reports collected in follow-up CBI assessments. McNemara's test for dependent proportions will be used to analyze the proportion of patients who report that they had "excellent ability to take their ART as prescribed" (on a scale that ranges from excellent, very good, good, fair, poor, very poor) and the proportion of patients who report having engaged in sexual risk behavior (unprotected vaginal or anal sex with a partner who was HIV negative or of unknown HIV status) in the past two months.

Analyses of patient exit survey and provider surveys: Data collected in these surveys will be analyzed descriptively to examine the percentage of patients who report that providers discussed specific topics with them and examine the percentage of providers who report that they discussed specific topics with their patients.

**Time line**

Exhibit A16. Project Time Schedule

<b>Project Time Schedule</b>	
<b>Activity</b>	<b>Time Schedule</b>
Intervention at the 3 Panel A clinics	1-36 months after OMB approval
Intervention at the 3 Panel B clinics	13-36 months after OMB approval
Data transmittals to CDC and data cleaning	3-36 months after OMB approval
Conduct first evaluation of the intervention implemented in Panel A using Panel B as the control group	14-16 months after OMB approval
Conduct longer-term evaluation of intervention in Panel A clinics, and evaluation of intervention in Panel B clinics	36 months after OMB approval
Conduct additional statistical analyses as needed	18-36 months after OMB approval
Presentations of findings	24-36 months after OMB approval
Manuscript preparation	24-36 months after OMB approval

**A. 17. Reason(s) Display of OMB Expiration Date is Inappropriate**

We will display the OMB expiration date.

**A. 18. Exceptions to Certification for Paperwork Reduction Act Submissions**

No exceptions to certification for Paperwork Reduction Act submissions are being requested.

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