POSITIVE HEALTH CHECK EVALUATION TRIAL

Protocol

NCT Number: NCT03292913

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Study Aims

Study Objectives:
We will evaluate the effectiveness of Positive Health Check (PHC), an online tool created by RTI and CDC that delivers tailored evidence based prevention messages to HIV positive patients, on improving clinical outcomes and retention in care of HIV positive patients with unsuppressed viral loads. RTI assessed the feasibility of implementation in diverse clinical settings in a pilot trial in the summer of 2015. In the current evaluation trial, we will also assess the costs and processes of implementation to inform future dissemination. The study will take place in four clinics including Atlanta VA Medical Center (Atlanta, GA), Hillsborough County Health Department (Tampa, FL), Rutgers Infectious Disease Practice (Newark, NJ) and Crescent Care (New Orleans, LA). The objectives of the PHC Evaluation Trial are four-fold:

1. Implement a randomized trial to test the efficacy of the PHC intervention for improving clinical health outcomes, specifically viral load and retention in care. While PHC is designed to improve antiretroviral therapy (ART) initiation, ART adherence and retention in care as well as reduce unprotected sex. The primary outcome on which the trial is powered is viral suppression.
2. Conduct a qualitative feasibility assessment to determine strategies to facilitate implementation and integration of PHC into HIV primary care clinics (Aim 2).
3. Collect and document data on the cost of PHC intervention implementation (Aim 3).
4. Document the standard of care at each participating clinic (Aim 4).

About Positive Health Check:
PHC is an online tool that delivers tailored evidence-based prevention messages to HIV positive patients through a series of brief interactive videos designed to simulate a conversation with an HIV primary care provider. Messages delivered via this intervention are evidence-based and have been validated in prior interventions focusing on support for patients managing HIV.

Eligible patients who use the tool will be given a tablet with privacy screen, a set of headphones, and a unique login ID and will be prompted by the tool to create their own private password that clinic staff will not have access to. RTI will provide Android or iOS tablets with the Positive Health Check app installed. The devices are encrypted and password-locked. The project coordinator will maintain the devices and they will be stored in a locked cabinet in a secure area of the clinic when not in use. Since patient information is not being stored on the device, clinic staff will not need to erase any information between patients. RTI will set the clinics up with either “Find my iPhone” or “Android Device Manager” in order to manage the security of the devices. This allows the devices to be located if lost/stolen and allows them to be erased remotely. Patients can access PHC from their home computer but they would need their username and password they received during their clinic visit in order to log in. Additionally, patients would first need to log in at the clinic before being able to log in at home. Once logged in, the tool takes a patient through guided discussions with a video doctor on topics including adherence, retention in care, sexual risk reduction, pregnancy, and intravenous drug use. Throughout the tool patients answer tailoring questions about themselves and based on their answers, are given tailored messages from their chosen video doctor. PHC is designed to facilitate patient-provider communication. In the tool, patients can track what questions they have for their doctor on the topics covered and what health promoting strategies they want to practice before their next visit. At the end they are given a handout to take to their visit of their questions and tips they chose to practice to help them manage their HIV. The web server that PHC is hosted on is owned by the Centers for Disease Control and Prevention (CDC).

The Components of PHC and How They Were Developed:
PHC was developed in partnership with RTI and CDC and includes: patient tailoring questions, educational videos that are tailored to each patient's answers, a patient handout tailored to each patient's preferences that draw from an evidence based tips library and commonly asked questions from the questions library. At the end of the tool, patients can click a link to the 'Extra Info' web page where they can find CDC-approved links to resources addressing a variety of topics.

- **The patient tailoring questions** included in this tool are based on standard questions used by HIV providers. They have been reviewed and approved by a technical expert panel of providers and patients as well as by HIV prevention experts at the CDC. Patients can choose to skip certain questions that they do not want to answer.

- **The videos for PHC** were filmed by RTI using professional actors. The scripts were written using evidence based health messaging by staff at CDC and RTI, reviewed by the Technical Consultant Panel of patients and clinicians, and approved by HIV prevention experts at the CDC.

- **The patient handout** is auto-populated using user generated selections of tips the patient identifies they would like to practice before their next visit and questions they would like to ask their doctor during their visit that day. The handout will be printed with a dedicated study printer or clinic printer at the clinic in a private location only accessible by clinic staff and given to the patient by a clinic staff person. Patients will have the option to have their handout safely destroyed before leaving the clinic. Patients can also select to have the handout emailed by entering their email address into the tool. The email address entered will not be saved in any way and will only be used to email the handout should they request it. Participants that complete PHC at ancillary services provided by the clinics will also have the option to email the handout by entering their email address into the tool. The exact procedures for handling the printed handouts for participants that complete PHC during these ancillary services will be tailored for each of the clinic sites. The handout will not include the patient's name or any personally identifying information, any reference to HIV, or the name of the intervention. The clinic staff will identify which handout belongs to which patient based on the randomly generated user ID number assigned to the patient by the tool printed on the handout. If the patient has not selected any tips or questions they will not receive a handout. The handout has have been reviewed and approved by the technical expert panel and by staff at CDC.

- **The tips library** will be used to populate the handout. Each tip a patient can potentially select has 2 different supporting messages that could appear with the tip on the handout. This is so that if a patient uses the tool several times and selects the same tip to try, they will not get the exact same supporting message for that tip. CDC originally developed 3 messages per tip, then the TC panel ranked the messages, and the top 2 messages for each tip were selected to keep. The tips library will not include any reference to HIV.

- **The questions library** will also be used to populate the handout. Throughout the tool, patients are asked if they would like to commit to asking their doctor questions related to their HIV meds and potential risk behaviors. If they select yes to any of them, their handout will be populated with frequently asked questions about the topics of interest. The questions library was developed using the most commonly noted FAQs on government HIV prevention websites. The questions library will not include any reference to HIV.

- **The clinic web application** (CWA) was developed for clinic staff to be able to manage the implementation of Positive Health Check. Clinic staff can view a patient's progress through the

tool, reset passwords to the intervention, and send a link to the intervention and an electronic copy of the patient handout to the patient's e-mail address. The email address entered will not be saved in any way and will only be used to email the handout should they request it. Staff will also keep track of handout delivery, tool usage (e.g., average time spent in the intervention), the status of patient intervention use and generate reports from summary data.

- **Extra Info** is a CDC-developed website with links to publicly available CDC developed and approved resources that provide additional information on a variety of topics relevant to people living with HIV, including topics addressed in the tool and those that were not.

Based on pre-review with our IRB the tool also includes these disclaimers: 1) the information shown in the intervention was developed with the input of HIV positive patients and doctors who care for HIV positive patients; and 2) the doctors portrayed in the intervention are actors.

FDA Classification as an Investigational Device:
The project team worked with RTI's compliance office to determine whether a FDA Investigational Device Exemption would need to be obtained for the trial. After reviewing the information available on the *Investigational Device Exemption webpage* we have determined that Positive Health Check does not fit the criteria of a medical device and therefore we will not be submitting a Study Risk Determination Request to FDA.

AIM 1

Aim 1 (RCT): Implement a randomized trial to test the efficacy of the PHC intervention for improving clinical health outcomes, specifically viral load and retention in care. While PHC is designed to improve antiretroviral therapy (ART) initiation, ART adherence and retention in care as well as reduce unprotected sex, the primary outcome on which the trial is powered is viral suppression.

OUTCOME MEASURES *(Originally proposed outcome measures are below. Please see statistical analysis plan and published protocol paper for final operationalization of outcome variables. Changes were needed based on final harmonization of data availability)*

Outcome measures will come from the patients' medical records electronically (i.e., EMR) archived in clinic patient registries. Data for patients' VL, the primary outcome variable, will be obtained from the clinic's EMR database for patients in both intervention and control arms:

- **VL copies/mL:** VL laboratory results (and dates) will be obtained per patient as available. Clinics will inform RTI of the VL assay type, version, and range used. The primary endpoint will be the VL (log10) laboratory results at baseline and all VL values available thereafter until the end of the project. For the purposes of the analysis, we will construct a window for the collection of VL data follow-up period ranging from the start of 10 months to the end of 16 months.

- **Sustained HIV-1 VL Suppression:** The analysis will also examine VL trends from baseline up to 24 months of intervention. Data will be compared from the treatment and control groups only for the subgroup of patients in the study for which these data are available. Using EMR data, we will calculate the number and proportion of study participants in the intervention and standard care conditions who achieve VL suppression (< 200 copies/mL) over two consecutive time points.

Data for secondary outcome variables also will be obtained from the clinic's EMR database for both intervention and control arms:

- **Retention in Care:** We will calculate the number and proportion of study participants who attend one clinic visit within 90 days from the date of randomization to either the intervention condition or the standard care condition.

- **Engaged in Care:** We will calculate the number and proportion of HIV-infected individuals who are engaged in care as measured by two clinic visits at least three months apart within 12 months form the date of randomization.

- **ART Initiation:** Data on persons not prescribed ART (treatment naïve or treatment experienced but not currently prescribed ART) who receive a prescription for ART within 90 days from the date of randomization.

- **Risky Sex Behavior:** Data collected on incident STDs as a proxy for risky sexual behavior.

- **Supplemental Data from the Clinic's EMR Database:** The following additional variables will be obtained from medical records to supplement the analysis, depending on the availability in each clinics EMR. These can only be determined after each clinic's EMR is reviewed:
    - Race/ethnicity
    - CD4 cell counts and dates
    - Month and year first tested HIV positive
    - Month and year of birth
    - HIV risk exposure category
    - Primary insurance

The following variables will be obtained from the intervention patients' data collected by the PHC tool, which we can examine descriptively over time:

- **Treatment Initiation:** Whether patient is currently prescribed antiretroviral medication.

- **ART Adherence:** Among those on ART, patients' self-reported ability to take all of their doses in the past 30 days as prescribed, as measured on a scale of very poor, poor, fair, good, very good, or excellent.

- **Retention in Care:** Evaluates the appointment keeping behavior of participants.

- **Sexual Risk Behavior:** For patients that report sexual activity in the prior 2 months, the following measures will be collected:
    - Number of people with whom they have had anal or vaginal intercourse
    - Of those, number of people with whom they have had *unprotected* anal or vaginal intercourse who (1) are HIV-positive or (2) were not HIV-positive or whose HIV status they did not know.

STUDY DESCRIPTION

Sample Size(s):1,010 Patients (505 per intervention arm, distributed across the 4 clinics)

Special Populations (Check all that apply)

	None
	Minors

	Newborns
	Pregnant
X	HIV infected
	Prisoners
	Alcohol, drug, or mental health program clients
	Incompetent
	Employees (specify)_____
	RTI Employees, their family member or friends (specify)_____
	Other (specify)_____

Sample Selection Procedure(s):

Eligibility criteria:
Eligible patients must be:

1. 18 years of age or older
2. Diagnosed with HIV
3. English-speaking
4. Attending one of the four HIV Primary Care clinics
5. Meet at least one of the following:
    - Most recent viral load lab result of ≥200 copies/mL
    - Attended an initial HIV appointment with a provider at one of the four clinics within the past 12 months
    - Out of care (last attended appointment at the clinic was more than 12 months ago)
6. Patients are not enrolled in any other research studies with confounding interests

Identifying Eligible Patients:
A Project Coordinator at each of the sites will identify eligible patients with upcoming scheduled appointments through the clinic's EMR system. Clinic staff will conduct systematic outreach to patients who meet the study criteria. We may not have a VL for patients that attended an initial HIV appointment with a provider at one of the four clinics within the past 12 months or out of care patients; however, we are expecting they will have an unsuppressed VL and would benefit from PHC. If they are found to have a suppressed VL they will be kept in the study due to intent to treat and to avoid biasing the study. Patients who are successfully reengaged in care will be eligible to participate in the study. Note that all four clinics are part of larger organizations that provide a wide range of health services and study staff will be instructed to use their clinic's more general name when conducting any outreach as not to identify the clinic as an HIV specific (i.e. "The Atlanta VA" instead of The "The Atlanta VA Infectious Diseases Clinic").

This project will include patients under the age of 21 who are living with HIV. The investigative team has considerable experience in conducting behavioral clinic-based research with patients under the age of 21 living with HIV. Consistent with other studies, age-based data analyses will group patients below 25 years of age to ensure that a sufficient number of younger patients can be meaningfully analyzed.

We request a partial waiver of HIPAA authorization, based on the bulleted items below, to access patients' clinical values and contact information to determine patient eligibility to (1) identify and recruit eligible patients for the RCT; (2) refer poorly retained patients to PHC outreach; and (3) conduct PHC

outreach. Clinical values Include VL and CD4 laboratory results, STD diagnoses, clinic attendance, demographic data. We will provide the Crescent Care clinic with the partial HIPAA waiver. The remaining three sites, Atlanta VA Medical Center, Hillsborough County Health Department and Rutgers Infectious Disease Practice, have internal IRBs so they will provide their own waiver of HIPAA authorization. The waiver of HIPAA authorization is appropriate and necessary for the following reasons:

- The use of PHI involves no more than minimal risk to the privacy of patients
- The PHI will not be reused or disclosed to any other person or entity other than the participating project sites
- The project could not practicably be conducted without the waiver or alteration
- The project could not practicably be conducted without access to and use of the PHI

Participant Recruitment Procedures:

Recruitment:
The Project Coordinator will contact eligible patients by telephone prior to their upcoming primary care appointment to notify patients that they are eligible for the study and will be approached at their next appointment. If the patient asks not to be approached, the Project Coordinator will record the decline in the study Access database and will not approach the patient in person. Following the designated script, the Project Coordinator will approach eligible patients who do not decline in the waiting room after they have checked in to their appointment. The discussion of the study and completion of PHC will be done in different locations in each clinic:

- VA: PHC will be introduced in the room next to the waiting room and the patient will complete the tool in the waiting room.
- Hillsborough: PHC will be introduced to the patients and completed in the research room. If that room is occupied, clinic staff will have patients use a clinic exam room.
- Rutgers: PHC will be introduced to the patient in an exam room. If that room is occupied, another private space will be identified within the clinic to introduce the patient to the tool. The patient may use the waiting room or exam room to complete the tool.
- Crescent Care: There are 3 clinic sites – Tulane Tower, Marine and FACES. Starting in December of 2018, Tulane Tower and FACES will merge and be one clinic site call Legion Fields. For Tulane, FACES, and Legion Fields, PHC will be introduced in an exam room or another private space and completed in the waiting room or private space. For Marine, PHC will be introduced in a private check-in cubicle and completed in the waiting room or another private space.

The Project Coordinator will give a brief overview of the study and ask the patient if they would be interested in participating. If the patient agrees, the Project Coordinator will bring the patient into a private space for the informed consent process after which they will be randomized to either the treatment or control arm. If the patient does not agree to participate, the decline will be recorded in the Access database and the patient will not be approached again. While patients will not receive reminders to come in for the study visits, the project coordinator will coordinate with the clinic's reminder systems to communicate that participants should come in 20-30 minutes in advance of their appointment to complete Positive Health Check. The initial visit will take approximately 30 minutes and subsequent visits will take approximately 20 minutes.

As another method of recruitment, the Crescent Care clinic will also use flyers that will either be physically handed to patients by Crescent Care staff or made available within the clinic. Flyers will not be distributed outside Crescent Care clinic sites. The flyer will instruct patients to call one of Crescent

Care's project coordinators to see if they qualify for participation in the study. No additional information will be collected on patients through the distribution of handouts and subsequent telephone conversations. Any information obtained throughout this process will be immediately destroyed afterwards.

Screening:
The Project Coordinator will confirm each patient's eligibility using the clinic EMR. The Project Coordinator will also determine whether the patient is sober and cognitively able to complete the tool. This will be done via their best judgement. If the patient does not meet one or more of the screening criteria, they will be marked as ineligible.

Randomization:
Study ID numbers will be generated in advance and run through a random number generator system (e.g., Sealed Envelope, an online study ID randomization program where you enter a list of study IDs and it randomizes them to either control or intervention arm). These numbers will be preprogrammed into each clinic's Access database and will be blinded to clinic staff. After eligibility is confirmed and patients are informed about the study and agree to participate, the coordinator will click a button in the Access database that will reveal the next unassigned ID and arm. The date of generation will be recorded in the database so that RTI can confirm that IDs were assigned sequentially to the appropriate patient (date of generation should match with the patient's appointment). This approach protects against any bias that a Project Coordinator would put patients into the intervention arm because of perceived needs.

Each clinical site will have their own Access database that RTI will develop and send to them for use in the study. This database will house the link between the EMR ID and the study ID. The participant will not need to remember their study ID. They will be provided this ID by the project coordinator who will onboard them on to the study and the intervention. The access database will include names. In the consent form we will note that only the study site will have access to any information that links their study participation to any other information the clinic has in the EMR.

INFORMED CONSENT.

Informed consent must be obtained. A copy of the informed consent must be attached to this protocol.

Type: Check One

	Written not signed
X	Written and signed
	Verbal not signed
	Verbal and signed
	Both verbal and written

Informed Consent Procedures

To maintain the anonymity of participants, RTI will not collect signed informed consent forms. The version of the form to be used at each clinic will be submitted to each clinic's IRB. These authorizations apply to the transmittal of patients' clinical data, including VL and CD4 laboratory results, STD diagnoses, clinic attendance, and demographic data.

The Project Coordinator will review the written consent form with the participant. The Project Coordinator will answer any questions that the patient has about the study and their involvement in it, and ask the patient if they consent to participate. The participant will sign the consent form and receive a copy for their records. Each clinic will retain the patient consent forms so that RTI and CDC do not receive names of participants. The Project Coordinator will record the date and time at which the participant consented and record it in the clinic's Access database. The key file linking EMR IDs to Study IDs will be stored in the password protected Access database. The Project Coordinator, Data Manager and Outreach Coordinator will have access to the Access database where this key file is stored. The database will be stored on the clinic's servers or device, depending on their security. The clinics will be sending de-identified data to RTI in the form of Excel spreadsheets or some other data management tool that is to be determined. The Access database will not be sent to RTI or CDC and will be destroyed from the server after the study is complete.

The participant will also be asked to sign a HIPAA Authorization Form at the time of consent to authorize the clinic to release their de-identified medical records to RTI. RTI will provide the clinics with an authorization form, or they can choose to use their own. In the event that a clinic decides to use their own HIPAA Authorization Form, we will submit an amendment with the form.

With the COVID-19 pandemic, all clinics participating in the PHC have transitioned to conducting telehealth visits. As such, many patient's data collection windows will have closed without a final blood draw, resulting in our team no longer having access to the patient's data. Due to this change, the we are extending the data collection window discussed in the consent to 24 months, specifically the updated consent and HIPAA authorization state that the project coordinator will access patient's medical records for up to 24 months after they have enrolled in the study. This is done to ensure that patient's VL can be collected over two consecutive time points. To ensure this information is communicated to patients, patients that have enrolled in the study and come back into the clinic once it has re-opened will be asked to re-sign a new consent and HIPAA authorization to ensure their most recent data can be collected.

Patients that do not wish to sign a consent and HIPAA authorization will not have their data collection window extended and it will remain at the previously communicated 18-month window.

Participant Compensation:

☐ None

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Upon enrollment, participants will receive a baseline token of appreciation of $50. They will also receive an additional $50 at the 12-month end point. Patients will be informed of both tokens of appreciation upon enrollment in the study. Clinic staff conducting recruitment and outreach will follow scripts on notifying patients of the tokens of appreciation.

If a participant's final VL is collected but the PHC staff is unable to deliver the second gift card while the patient is in the clinic, the PHC staff member may notify the patient that their PHC gift card is available for pick-up. After confirming the patient's address, the PHC staff may also mail the gift card to the participant if they are unable to pick-up the gift card in-person at the clinic. Not all the contact methods listed above will be used for each patient. Patient contact methods may be tailored based on modes of communication available for each patient or pre-existing patient preferences.

It should be noted here that CrescentCare does not have email at their clinic for patient contact. It has been included above because other clinics (Hillsborough, the VA, or Rutgers) might use this method of

contact if approved by the IRBs that oversee their clinic.

If the PHC staff attempt to notify the patient of their available gift card and are unsuccessful, the gift card may then be classified as undeliverable. An unsuccessful attempt to deliver a patient's gift card is defined as three consecutive attempts to reach the patient with no patient contact. If a mailed gift card is returned to the clinic due it being undeliverable or a change of address, clinic staff will make three contact attempts to reach the patient to re-confirm the address. If the patient is not reachable after those three attempts, the gift card will then be classified as undeliverable. The undelivered gift card along with the reason for non-delivery will be documented in the Access database.

DATA COLLECTION PROCEDURES

Description of Procedures

Three staff members at each of the four clinics, all funded by the project through a subcontract with RTI, will be responsible for the implementation of the intervention and collection of data. The sites will be responsible for hiring these three staff members with the funding from the subcontract with RTI. Additionally, each site has a clinician who also acts as the site principal investigator (PI). Each PI has regulatory responsibility due to having an application to their own IRBs (except for one clinic which will come under the RTI IRB). All study staff will have IRB training and approved access to the clinic's EMR system.

1. **Project Coordinator:** Identify eligible patients from the clinic EMR. The eligibility criteria are very specific so recruitment using the clinics EMR was identified as the best way find eligible patients. Recruit patients and consent eligible patients prior to their appointments. Administer the intervention. Track eligible and enrolled patient appointments for recruitment or delivery of the intervention at subsequent visits. Ensure participants receive the appropriate handouts, taking care of the project equipment (such as tablets and headphones), coordinating data collection with RTI, and acting as the main point of contact between the clinic and RTI staff.

2. **Data Manager:** Manage quality control of data collected by the clinic and extraction of data from the clinic EMRs. Collect appointment attendance data. Responsible for the system collecting and transmitting clinical (e.g., HIV viral load, lab test results, pregnancy test results, STD test results) and intervention implementation cost data to RTI, using our data templates and/or forms and adhering to a specified data delivery schedule.

3. **Outreach Coordinator:** Implement PHC outreach protocol to bring patients who 1) are eligible for the study back into care and 2) are enrolled in the study but do not have a 12-month viral load results.

The PHC intervention will be hosted on a secure server and maintained by CDC for the duration of the study. Participants in the control arm will only consent to have their clinical values be made available via passive data abstraction from the electronic medical record (EMR). Both the control and intervention participants will be asked for the date of diagnosis at the time of enrollment- "When were you diagnosed with HIV? If you cannot remember the exact date, can you estimate the month and year?" During the 24-month implementation period, patients in the intervention arm will be expected to log on and complete the PHC intervention before each regularly scheduled clinic visit. Each patient enrolled in the trial will complete the intervention up to three times in a 12-month period, with anticipated scheduled clinic visits at least 2 months apart. Patients assigned to the intervention arm will log in and use Positive Health Check before seeing their clinician. At their first visits, patients will be assigned a study ID that they will use to log in to the tool and a default password. The participant will not need to remember their study ID. They will be provided this ID by the project coordinator who will onboard them on to the study and the intervention. For visits 2 and 3, patients may be approached at

their HIV primary care visits as well as ancillary services. Examples of ancillary services include case management, pharmacy pick-up, mental health services, sexual health services, well-visits, financial services, social services, OBGYN appointments, dental appointments, and Aids Drug Assistance Programs (ADAP). Appointments will only be counted towards the retention in care outcome if the patient attends an HIV primary care visit with a provider. At the time of consent into the study, the project coordinator will ask participants if they would be willing to be approached to complete subsequent PHC visits during ancillary services they receive at the clinic. Participants response will be indicated in the Access Database. Additionally, during PHC clinic site trainings, RTI will emphasize the confidential nature of PHC. Project coordinators will be instructed to not use HIV or HIV related terms when approaching participants at ancillary services. The procedures for where participants complete PHC if they are approached at ancillary services will be tailored for each of the clinic sites. Participants will continue to view the tool with the privacy screens and headphones. The access database will include names and study IDs of participants. In the consent form we will note that only the study site will have access to any information that links their study participation to any other information the clinic has in the EMR. To protect their privacy, patients are required to generate their own password after logging in with the default password. The password must be at least eight characters long and have at least one uppercase letter, one lowercase letter, a symbol such as the pound sign, and a number. Patients will be asked to remember or write down their password. If they forget their password at subsequent visits, the Project Coordinator can reset the password through the CWA. If a handout is generated by the tool, the Project Coordinator will deliver it to the patient before they are called back to see their clinician. Patients can also complete part of the intervention by receiving a link via email after their clinic visit. If an email address is entered into the intervention database a link is automatically generated and sent to the address. Then the email address is automatically deleted. This email is not saved in any study databases or at CDC after the email link is sent. Thus no identifying information is retained.

Patients randomized to the control arm will not use the intervention. Following signing informed consent, these patients will return to the waiting room and receive the standard of care at their clinic. These patients will only consent to have their de-identified clinical values be made available via passive data collection via the electronic medical record (EMR). We considered an attention control instead of usual care arm, but this is a pragmatic trial and so usual care is an appropriate comparison. This answers the question what is the benefit of the intervention beyond usual care and mirrors what would happen if CDC disseminates the intervention nationally. The table below provides information on potentially eligible patients at each of the four study sites. These numbers reflect only those with a viral load equal to or above 200. The actual numbers will be larger given those who have fallen out of care and those who are new to care will also be eligible.

PHC/CWA Data:
CDC will collect user metrics from the PHC tool that is not linked to participants PII. Data collected includes tips and questions selections, video doctor selection, modules visited, and amount of time spent in each module and in the tool overall. Data captured via the PHC tool will also include participant responses to questions that have been integrated into the tool to provide tailored messages related to ART use, clinic attendance, and behaviors that may increase risk of HIV transmission. Data are linked to the patients through the study ID. CDC will send RTI an Excel file with these data through a secure FTP connection monthly. RTI staff will access the FTP site to download the data and then enter into the master database. These PHC data include patients' answers to tailoring questions on ART, adherence, clinic attendance, sex risk, pregnancy planning, and injection drug use (IDU).

Patients will use their study ID to log in to the tool at all three visits CWA data will only be collected for patients in the intervention arm. Data from the Clinic Web Application data are passively collected by the intervention as patients use PHC. Data do not contain identifiable information (Study ID only) and will be stored in CDC servers and made accessible through the CWA export function and dashboard.

Clinical Data:
For patients in both the intervention and control arm, EMR data will be collected every three months. Depending on each clinic's system, some data may also be collected from other electronic systems. For example, information on patient attendance at primary care visits may not be collected in the clinic EMR. The clinic will gather data regarding patient attendance from their electronic scheduling system and provide this data to RTI. Dates of scheduled clinic appointments are considered identifiable information so we will work with each clinic's Institutional Review Board (IRB) to ensure privacy and other regulatory rules are followed. The data collected from the EMR and/or other electronic systems includes laboratory results, ART prescriptions, appointment attendance, STD test results, and demographic information. The sites will collect historical EMR data for 24 months prior to the date of randomization. The consent form informs participants that we will collect EMR data for the 24 months prior to randomization and up to 24 months after randomization. We will use Python or another program to harmonize data before entering it into the master database. Python will be able to take data that is coded differently (e.g. gender coded as male/female or gender coded as 1/2) and harmonize that information.

Viral Load and Study Retention:
For the purposes of the analysis of the main outcome (VL at 12 months post enrollment), we will construct a window for the collection of VL data follow-up period ranging from the start of 10 months to the end of 16 months. We want to obtain these data regardless of each patient's clinic appointment attendance during the 12 months after enrollment and regardless of each patient's participation in the PHC tool (for the treatment arm). In order to ensure VL data collection by month 12 for each patient enrolled in the study, for those who have not returned to the clinic and have no scheduled upcoming appointments, outreach will start at month 10 following their initial visit. Reaching and engaging these patients back into care and scheduling a clinic appointment could take several months to complete for each patient that needs outreach. Therefore, this project allows for the entire final viral load window (10 months to the end of 16 months) for the clinic to conduct outreach.

In order to measure sustained HIV-1 VL suppression, the analysis will also examine VL trends from baseline up to 24 months of intervention in the treatment group and compare those trends with trends in the control group. This will only be done for the subgroup of patients for which these data are available. This analysis can only be completed for those patients with two consecutive time points available at the end of the study.

During the outreach process, the outreach coordinator will document barriers preventing the patient from returning to care, whether the patient is receiving care at another clinic, number of attempts, date, method, and person being contacted during each attempt, and whether outreach was successful. If outreach is successful, the outreach coordinator will work with clinic staff to have the patient schedule an appointment. The appointment information will be passed along to the Project Coordinator. If an enrolled patient moves out of the area during the study period and they have no further data in the clinic's EMR, we will only use data that is available. Data after the move will be recorded as missing. We will not be contacting other clinics to obtain patient information. If any plans to obtain data from other clinics is proposed by sites we will prepare an amendment.

AIMS 2, 3, AND 4

Description of Aims

- **Aim 2 (Process Evaluation):** Conduct a qualitative feasibility assessment to determine strategies to facilitate implementation and integration of PHC into HIV primary care clinics.

- **Aim 3 (Cost Collection):** Collect and document data on the cost of PHC intervention implementation.

- **Aim 4 (SOC):** Document the standard of care (SOC) at each participating clinic.

Sample Selection Procedure(s):

- **Aim 2 (Process Evaluation):** Three to five staff at each clinic site will be selected to participate in interviews and an online survey. The staff will include PHC implementation staff (such as the Project Coordinator, outreach coordinator, and data manager) and other relevant providers and staff members. The study staff at each site will work with RTI staff to identify participants. Any additional categories of interviewee's will be communicated via an amendment (e.g., other clinicians not directly involved in the implementation of the study).

- **Aim 3 (Costs):** Clinic staff who participate in the PHC intervention will complete the labor cost questionnaire. The Project Coordinator will collect all the required data for the labor questionnaire from other staff members, will submit it to RTI, and will serve as our main contact for the cost study data collection. The Project Coordinator will also be responsible for completing a monthly non-labor cost questionnaire and submitting it to RTI.

- **Aim 4 (SOC):** The medical director at each site will complete a survey to assess their clinic's standard of care.

Participant Recruitment Procedures:

- **Aim 2 (Process Evaluation):** RTI will contact clinic staff by phone or email to ask staff to participate and to schedule individual or small group interviews.

- **Aim 3 (Costs):** Each site will hire a Project Coordinator to implement the study. As part of their responsibilities, they will collect cost data.

- **Aim 4 (SOC):** Site contacts will identify the medical director and RTI will contact the medial director at each site through email or by phone.

INFORMED CONSENT.

Informed consent must be obtained.

Type: Check One

	Written not signed
	Written and signed
X	Verbal not signed
	Verbal and signed
	Both verbal and written

Informed Consent Procedures

- **Aim 2 (Process Evaluation):** At the start of each quantitative online survey, staff will indicate their consent by selecting "I agree to participate" to proceed to the survey and submitting the

survey. At the start of each qualitative interview, RTI will verbally consent the participant to participate in the recorded individual or group interview.

- **Aim 3 (Costs):** We request a waiver of informed consent for Aim 3. We will not be collecting personal or sensitive data for Aim 3. Data will be collected using the clinics' systems and is part of understanding the costs of implementation to the clinics.

- **Aim 4 (SOC):** We request a waiver of informed consent for Aim 4. We will be collecting the clinic's standard of care from the medical director and will not be collecting sensitive or personal data.

Participant Compensation

X	None

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Description of Procedures:

Aim 2 (Process Evaluation):
Three to five key clinic staff involved in PHC implementation will complete a 15-minute online survey at the beginning of the study and then at every 3 months of the 2-year implementation period. The exact persons completing the survey will be determined with the Project Coordinator based on who will provide the best information. The survey will have closed-ended questions asking information such as (1) participant background information (e.g., age, race, gender, education level, years of experience), and (2) Likert-scale ratings for several questions regarding the implementation context (e.g., implementation readiness and implementation climate) and perceived fit of the intervention (e.g., appropriateness, acceptability, compatibility).
Individual or small group interviews will be conducted with the key staff involved in implementing PHC who may also have completed the staff survey. The interviews will last between 40 minutes and will be conducted at the beginning and then at every 3 months during the 2-year implementation in the month following the quantitative survey.

Using the semi-structured interview guide, two RTI staff will conduct each interview, one to lead the interview and one to take notes. All interviews will be digitally recorded. Data collected will include staff feedback on open-ended questions about the implementation of PHC, including their perceptions of the intervention's impact on their patients and staff, how effective they perceive the intervention to be, how supportive they feel clinic leadership is in supporting implementation of the intervention, the implementation climate, readiness at their clinic, and the likelihood of intervention adoption in other clinics. Interview notes will be typed in Microsoft Word and saved directly to the secure project share drives. The interviews will also be audio-recorded on RTI devices, transcribed, and entered into NVivo for analysis. Identifiable study data will not be given to the clinics about study staff or other clinic staff that participate in interviews or surveys as part of Aim 2. In addition, data will not be shared across clinic sites.

Aim 3 (Cost Collection):
Clinic staff who participate in the PHC intervention will complete the non-research labor cost questionnaire and PHC labor cost questionnaire and will submit the data to RTI three times: (1) after the first month of PHC intervention implementation; (2) after the 6th month of PHC intervention implementation; and (3) after the 12th month of PHC intervention implementation. The Project Coordinator will collect all the required data for the labor questionnaire from other staff members, will submit it to RTI, and will serve as our main contact for the cost study data collection. The Project

Coordinator will also be responsible for completing a monthly non-labor cost questionnaire **(**and submitting them to RTI. RTI will distribute the instruments and the accompanying user's guides to the clinics at the beginning of the study. RTI will also conduct a training via a webinar on the use on the instrument and instructions for data reporting and collection. Additional technical assistance will be provided on an as-needed basis during the data collection periods. RTI staff will review the data after each submission and will follow up with respondents if necessary.

Clinics will be asked to report labor and non-labor costs associated with implementing the intervention for each PHC program activity category in addition to indirect and overhead expenditures. The seven program activities categories include: (1) staff training and preparation; (2) patient identification and recruitment; (3) intervention delivery; (4) mobile device management; (5) patient outreach; (6) report generation; and (7) administration/general oversight.

Aim 4 (SOC):
Before PHC is implemented, the Medical Officer/Director at each clinic will complete an online survey about the clinic's standard of care for patients living with HIV. There will be both open-ended and closed-ended questions on the type of care typically provided to patients based on best practices and clinical guidelines. At the midpoint and again at the conclusion of implementation, the previously received survey responses will be returned through email to the Medical Officer who will notify RTI using track changes in Microsoft Word or by telephone of any changes to their answers or if no changes are required. We will also request from the Project Coordinator that if any system changes occur between these time points, RTI should be notified to discuss the impact on project workflow. All data will be received electronically, either downloaded from the survey platform website or sent via email from the sites, unless the Medical Officer/Director chooses to convey changes over the telephone.