Development of a Community-based HCV Treatment Completion Intervention Among HCV Positive Homeless Adults

NCT04513899

Protocol Summary

July 16, 2018

Section 4 - Protocol Synopsis

4.1. Brief Summary

The RCT will test the efficacy of a Community Health Worker/Registered Nurse (CHW-RN) HCV intervention for homeless individuals, many who are also drug users. The intervention will be designed during Phase I of the proposal (see Research Strategy) using an iterative process between a Community Advisory Board (CAB) and focus groups. The CHW/RN intervention will occur over a 2 month (8 week) period. Homeless adults assigned to the CHW/RN HCV treatment group will receive culturally-sensitive education, case management, and daily DOT delivery of Mavyret™ (pibrentasvir/glecaprevir) by a RN-guided CHW. The CHW will run a brief (20 min) weekly 1:1 education and 20 min case management session over the 8 weeks and will deliver all components of the program (which will be developed and refined during Phase I). The CHW-RN HCV intervention will be compared to a clinic-based standard of care group (cbSOC). Primary outcomes are completion of the DAA treatment (month 2) and SVR12 Cure (month 5). Secondary outcomes are improved mental health status, decrease in substance use, and improved access to health care, and shelter stability at month 5.

4.2.a. Narrative Study Description

Our study is a mixed-methods, individually randomized group-treatment trial (IRGT). As detailed in the Research Strategy, Phase 1 will implement a novel, community-based approach, which will use a Community Advisory Board (CAB) and focus groups, drawn from the community, to help develop and refine an HCV intervention for homeless adults. The results of Phase 1 will inform the design of Phase 2, our pilot IRGT, described below.

After potential participants are identified, screening procedures are completed, and eligibility is confirmed (see Research Strategy and Recruitment & Retention (question 4.4. on Study record: PHS Human Subjects and Clinical Trials Information form) sections), informed consent will be obtained for interested participants (see question **3.1. Protections of Human Subjects section and 2.5 Recruitment & Retention Section**). Then, participants will be randomized, using computer randomization, into CHW/RN (treatment) group or standard care cbSOC MD/RN (control) group, with 54 participants in each group. While about 65%% of the HCV cases are male[98], we will still ensure that a sufficient number of women (n=43) are enrolled to evaluate gender differences in intervention effect. To enable comparisons, group assignment will be stratified by gender and residence (shelter vs. street). Next, trained staff (see below for full details of training and fidelity assurance) will administer a 60-minute questionnaire, with periods of breaks and nourishing snacks. The health care providers at the research site (MDs or NPs [under standardized protocols supervised by the clinic MD]) will provide the DAA doses which will then be delivered by either the nurse-guided CHW in the community or in the clinic setting (in one month supply) by the cbSOC MD/RN. The MDs will provide back-up to the RNs.

Cultural Sensitivity of the Intervention is a Strength. The CAB will discuss how best to communicate results of being HCV positive with homeless persons, how to encourage adherence to HCV medication, discuss strategies to enhance support offered by the nurse and CHW, and in getting the homeless adults to accept referrals for housing, substance use, mental health issues and job skills. In addition, we have now added how we can sensitively use technologies to assist in locating our homeless participants for DAA administration. These discussions will be integrated into the CHW/RN TBI program and its implementation. Further, by conducting focus groups with homeless adults with a history of being diagnosed with HCV and either completing or not completing treatment, a "theater testing approach"[88] will be conducted by our study CHW to demonstrate the culturally sensitive program just refined. As presented in the text, this will demonstrate initial encounter, treatment discussion phase, delivery of medication, dealing with emotional, physical and life crises, role of nurse-CHW, etc. Rating of acceptability and feasibility will provide further evidence that the program is culturally sensitive.

Specific strategies employed by our successful Latina Project Director to deal with common issues faced when providing care to low-income Latino community, include:

1. Begin with an understanding of the barriers to healthcare usually experienced by low-income/homeless minority groups via focus group discussions
2. Language barriers, addressed by ensuring bilingual staff and proper interpretation services
3. Low health-literacy levels addressed by providing linguistically-appropriate literature on TBI, and TB disease prevention; answering all questions in the appropriate language and using vocabulary appropriate to the person's literacy level.
4. Behavioral Norm differences, addressed by culturally-appropriate education and establishing trust between the study team and the participant.
5. Historic mistrust of healthcare entities within minority communities, addressed by normalizing visits to clinics and communication between provider and participant; actively addressing common patient misconceptions about the healthcare system and providers.
6. Specify to participants that the services provided are free of charge; and facilitate needed clinic visits through interpretation and transportation.

Description of the CHW/RN Intervention. A team of two CHW and a research RN will compose the CHW/RN team. In the CHW/RN group, each participant will be assigned to one of two CHW, who will deliver all components of the program and assess HCV side effects under the guidance of their RN. Recruitment will be staggered: each CHW may be assigned 7-8 participants or 15-16 (total study enrollment) every 2 months until target sample size (n=54 for intervention group) is achieved. After the first dose of DAA (see below for rationale of choosing DAA), the CHW will run a brief (20 min) weekly 1:1 education and 20 min case management session over the 8 weeks (see details of weekly elements below). The CHW will also be involved in facilitating medical, mental health, substance use, social service and

legal appointments for participants, as well as housing referrals, and accompany the participants to the appointments as requested. The CHW will rigorously track participants who have missed a dose, and promote the building of effective coping skills, personal assertiveness, self-management, communication, and self-esteem, as well as providing knowledge about HCV and prevention of HBV, and HIV. The directly observed treatment (DOT) (on a daily basis) of the DAA and the sessions will be delivered in a safe area in the community, mutually agreed upon by the CHW/RN and participant. A detailed community resource directory will also be provided. The RN will oversee all components of the program, including assessing HCV side effects, referrals, and supporting the CHW in counseling with complex health-related issues. Even though DAA has been found to have few adverse effects, we will conduct monthly liver function tests.

Weekly sessions will likely include the following elements described below, although modified according to results of Phase I CAB and focus group recommendations:

In week 1, detailed information about the program will be provided; personal values and goals will be delineated. Information will be shared about HCV, its transmission, and risk reduction. Stigma associated with having HCV will be discussed. Culturally-sensitive discussions will be provided throughout about potential barriers to completing treatment, seeking health care access, etc. CHW will work early on with their contacts in the community to facilitate securing stable housing.

In weeks 2-3. The impact of drug and alcohol use and its role as a risk factor for HCV, HBV and HIV will be discussed, as well as gender-specific reasons why people use drugs. CHW will actively work with participants to facilitate their attending outpatient drug and or alcohol substance use programs, if actively using, and to continue their work in securing stable housing, job skills, and other goals, with support of the RN.

In weeks 4-6, CHW will continue facilitating stable housing opportunities, reducing drug and alcohol use, and seeking health care access, etc. Basic problem solving in relation to reducing risk will include: a) identifying triggers that could increase use of substances; b) identifying a goal/outcome that will reduce or avoid risk; c) identifying potential steps to reach the goal of reducing/avoiding risk; d) evaluation of usefulness of steps discussed; and e) planning how to act on the best solution. Coping scenarios will provide examples of positively dealing with situations that place individuals at risk for on-going drug use. The importance of positive social relationships will be discussed in supporting compliance with HCV treatment. The CHW will also facilitate referrals to community agencies. The intervention will be gender-sensitive; for example, women may be engaged in discussing empowerment and the impact of depression on risk behaviors, while men may be engaged in discussions on risk behaviors.

In weeks 7-8, continued discussions on problem-solving skills related to HCV/HIV risk reduction. Participants placed in stable housing will be assessed to determine new needs relative to maintaining housing security, employment opportunities, etc. An incentive of $10 will be provided after each week, totaling $80 for the 8-week period.

Fidelity of Program Implementation. During Phase 1, after the intervention is refined, the CAB will work on developing the protocols and manuals and process measures to strengthen the fidelity of the program. A Program Manual will standardize training; an operations manual will outline study constructs, measures and timeframes for data collection, recruitment and randomization.

Process Measures. Process logs will be designed to ensure fidelity and include: 1) attendance and content log of educational sessions; 2) medication completion log; 3) lab results log; and 5) referral attendance.

Training of CHW/RN. The CHW and RNs will undergo special training to present the CAB/FGS designed intervention. Mock sessions will be held with the two CHW and RN by the MPIs and the Project Coordinator (PC) to assess their skills in presenting the intervention. After each mock session, the MPIs and PC will provide feedback on how well they functioned. This process will continue until all skills are optimal.

The CHW and RNs will be trained as extended care providers by Los Angeles County experts in the field of HCV, following their structured teaching protocol. The CHW/RN staff will also be trained by experts in drug and alcohol addiction and mental health to supplement their knowledge of key resources in the community and become competent facilitators of risk reduction. They will be trained to deal with reactions of individuals who are determined to be HCV, HIV or HBV positive, in communication skills, and in providing psychosocial support. The Partnership for Health approach, to adherence (designated by the CDC as a good-evidence model) will be followed, which focuses on strengthening the client/provider relationship [(109)].

The CHW will meet with the RN twice weekly and receive support with the education sessions, implementing the program, delivering the DAA, and in organizing the paperwork. CHW will be trained to fill out logs that record any side effects relative to the doses received and will receive oversight for monitoring any medication side effects on RedCap. All medical concerns will be reported to the HCV treating physician. Adverse events with DAA (≤5%) may include fatigue,

headache, nausea, diarrhea, and insomnia[108].

Statistical considerations. One challenge is the likelihood that participants may interact with each other post-randomization, given that participants are drawn from the same community (Skid Row). Upon enrollment, CHW/RNs will explain to participants in the intervention group the value of waiting until study completion to discuss details of the intervention with others in the community. We acknowledge that while this may increase internal validity of our study, it may also inflate type 2 error, given that drawing support from others in their social circle may be a related benefit to our community-based approach that could increase adherence, bolster commitment, and thus enhance treatment effects.

Moreover, there may be variability in outcomes at the level of the intervention administrators and over time given staggered recruitment every 2 months. Indeed, CHW may become more skilled over time. These potential sources of bias will be examined by testing the intraclass correlation (ICC) within administrators at baseline, month 2, and 5 month follow-up and over recruitment schedule, following recommendations for IRCT[110] . Values closer to 0 indicate that the particular administrator or recruitment period did not account for variability in the results (i.e., independence was achieved) [111]. This will help control for type 1 error. High ICCs will be accounted for in statistical analysis via the implementation of mixed-models that can include this clustering as a random effect and intervention group as the fixed effect [110, 111]. Due to the pilot nature of this proposal, randomization across CHW/RNs will not occur prior to administration of the intervention; however, potential administrator effects, although we believe unlikely, will be accounted for in subsequent R01 design.

See section **4.4**. Statistical Design section for full details of the analytic strategy.

The Clinic-based Standard of Care (cbSOC) Program (control group). This program will be delivered by a clinic-based MD or clinic-based NP at the clinic site. ES will be hired and trained to do the interviewing/survey administration and follow-ups at the clinic-based site. The clinic NP will conduct, per usual care at the study clinics, the education and monitoring of these participants who will interact with the clinic-based-MD and/or NP monthly over the 8 week program. Usual care will include: 1) HCV pre-treatment education; 2) one month supply of DAA; 3) monitoring adverse events; and 4) responding to questions on HCV. Referral to drug/alcohol and housing programs will be provided over standard of care. The cbSOC participants will not receive the community delivery of the DAA, or case management, or accompaniment to needed services.

ADMINISTRATION AND DOCUMENTATION OF THE HCV MEDICATION.

Administration: A recommended dosage of three tablets of Mavyret™ (total daily dose: glecaprevir 300 mg and pibrentasvir 120 mg) taken orally once daily with food for 8 weeks for Treatment-Naïve Patients (all HCV genotypes 1, 2, 3, 4, 5, or 6) with no cirrhosis will be prescribed by clinic-based MD or clinic-based NP for both the groups. Each Mavyret™ tablet contains 100 mg of glecaprevir and 40 mg of pibrentasvir. The tablets are pink, oblong-shaped, film-coated, and debossed with “NXT” on one side.

The cbSOC Program (control group) will receive the medication on a monthly basis from the clinic MD or NP. For the intervention group (CHW/RN) the dose will be delivered/administered by CHW/RN on a daily basis after prescription.

Documentation of all client notes on referrals made and appointments kept will be captured on REDCap by enabling signatures on the tablets for both the participant as well as the research staff administering the dose. This process will not only capture signatures but also date / time stamp the process thereby maintaining the fidelity of the program.

Missed Doses. Interruptions in HCV dosing will be assessed individually, with a focus on resuming the schedule. If a dose of Mavyret™ missed and it is:

- Less than 18 hours from the time Mavyret™ was due, then the participant will be advised to take the missed dose with food as soon as possible. They can then take their next dose at your usual time.
- More than 18 hours from the time Mavyret™ was due, then the participant will be advised to not take the missed dose. They can then take their next dose as usual with food.

Medication Adherence. We will use pill count to measure adherence in both groups. The total number of missed doses will be divided by the total number of doses for this measure. This will be repeated by the evaluation staff who will conduct follow-up at month 2 to view any remaining pills in the pill bottle and will be documented on RedCap.

In addition, for the intervention group (CHW/RN), the daily DOT delivery of Mavyret™ pills administered by CHW will be documented on RedCap tablet each time s/he observes the participant swallow a pill. For the cbSOC Program

(control group), the clinic based MD/NP will conduct a pill count monthly, based on the medications left in the pill bottle each month the participant is scheduled to pick up the next supply.

INSTRUMENTS AND MEASUREMENTS. Data will be obtained at baseline, 2- and 5-month assessments. All measures have been utilized with homeless populations previously and have supported psychometrics[112, 113].

I. **Socio-Demographic information** will include variables such as site, age, birth date, gender, race/ethnicity, education, religion, employment, relationship status, country of birth, history of incarceration, homelessness and substance use, pregnancy status (if female), etc. The Locator Guide will record name and address of the participant, hangout locations, etc. (assessed at baseline, 2-month, and 5-month; race and age assessed only at baseline).

II. **Brief HCV, HBV, and HIV-Related Health History** will be assessed by 5 items covering prior hepatitis/HIV test results, date, history of liver disease, and history of completed treatment for HCV, HBV or HIV and assess for symptoms of cirrhosis at baseline.

III. **Drug and Alcohol Use vs Dependency During the Past 2-3 months**, will be assessed by the Texas Christian University (TCU) Screen II[114, 115] at Baseline, 2- and 5-month follow up. Yes/No to each drug will be assessed for use vs dependency. The total score ranges from 0 - 9; higher scores (≥ 3) correspond to the DSM drug dependence diagnosis.

IV. **Mental Health** will be assessed by the MHI-5 at Baseline, 2- and 5-month follow up.; well-demonstrated reliability for detecting psychological disorders[116] with reliabilities of .77 and .71 for women/men, respectively[117].

V. **HCV.** HCV status will be assessed by the research RN, using the OraQuick HCV Rapid Antibody Test (OraSure Tech.), a rapid assay for the presumptive detection of HCV antibody in fingerstick capillary blood, with sensitivity and specificity similar to FDA-approved assays. A reactive result will be confirmed by collecting blood from a subsequent venipuncture for testing for HCV RNA in blood, by polymerase chain reaction (PCR) as a marker for HCV viremia[118]. 75% of those screened HCV AB+ will be HCV RNA+. HCV RNA by PCR will be tested at Baseline and 5-month follow up.

VI. **HBV** status will be assessed by the HBsAg test if found to be HCV RNA + at baseline. We anticipate that 5-10% will be found confirmed HBsAg+ who will be excluded from the study.

VII. **HIV**. Tested via Alere Determine™ HIV-1/2 Ag/Ab Combo with confirmation for those not previously tested or have no validation[103, 104]. Results will be obtained within 20-30 minutes at baseline.

VIII. **Cirrhosis and Decompensation** testing will be conducted by the APRI Score (Hepatic Function Panel and CBC and Platelet Count, respectively every month if found to be HCV RNA+. Those with Cirrhosis and Decompensation will be excluded and referred to a hepatologist.

IX. **SVR12.** Tested at 5-month follow up (12 weeks after treatment completion) by HCV PCR RNA as a marker for HCV viremia[118].

X. **Medication Adherence**. We will use pill count to measure adherence in both groups. The total number of missed doses will be divided by the total number of doses for this measure. This will be repeated by the evaluation staff who will conduct follow-up at month 2 to view any remaining pills in the pill bottle and will be documented on RedCap.

In addition, for the intervention group (CHW/RN), the daily DOT delivery of Mavyret™ pills administered by CHW will be documented on RedCap tablet each time s/he observes the participant swallow a pill. For the cbSOC Program (control group), the clinic based MD/NP will conduct a pill count monthly, based on the medications left in the pill bottle each month the participant is scheduled to pick up the next supply.

Primary and secondary outcome variables are described in question 4.3 Outcome Measures (Study record: PHS Human Subjects and Clinical Trials Information form).

4.2.b. Primary Purpose **Treatment**

4.2.c. Interventions

Intervention Type	Behavioral (e.g., Psychotherapy, Lifestyle Counseling)
Name	Community Health Worker/Registered Nurse (CHW/RN) Intervention
Description	We plan to deliver care within a multidisciplinary team trained in HCV assessment and treatment. A team of two CHW and a research RN will compose the CHW/RN team. In the CHW/RN group, each participant will be assigned to one of two CHW, who will deliver all components of the program including daily DOT delivery of Mavyret™ and assess HCV side effects under the guidance of their RN. Recruitment will be staggered: each CHW may be assigned 7-8 participants or 15-16 (total study enrollment) every 2 months until target sample size (n=54 for intervention group) is achieved. After the first dose of DAA (see below for rationale of choosing DAA), the CHW will run a brief (20 min) weekly 1:1 education and 20 min case management session over the 8 weeks (see details of weekly elements below). The CHW will also be involved in facilitating medical, mental health, substance use, social service, legal appointments for participants, housing referrals, and accompany the participants to the appointments.

Intervention Type	Behavioral (e.g., Psychotherapy, Lifestyle Counseling)
Name	clinic-based Standard of Care (cbSOC) program
Description	This program will be delivered by a clinic-based MD or clinic-based NP at the clinic site. ES will be hired and trained to do the interviewing/survey administration and follow-ups at the clinic-based site. The clinic NP will conduct, per usual care at the study clinics, the education and monitoring of these participants who will interact with the clinic-based-MD and/or NP monthly over the 8 week program. Usual care will include: 1) HCV pre-treatment education; 2) one month supply of DAA; 3) monitoring adverse events; and 4) responding to questions on HCV. Referral to drug/alcohol and housing programs will be provided over standard of care. The cbSOC participants will not receive the community delivery of the DAA, or case management, or accompaniment to needed services. Outreach to find patients lost to follow-up will be conducted by the clinics' outreach teams.

4.2.d. Study Phase **Other** **N/A**

Is this an NIH-defined Phase III clinical trial? No

4.2.e. Intervention Model **Parallel**

4.2.f. Masking **Yes**

Participant **Care Provider** **Investigator** **Outcomes Assessor**

4.2.g. Allocation **Randomized**

4.3. Outcome Measures

Name	Completion of HCV treatment and SVR12

Type	Primary
Time Frame	2 month follow up and 5 month follow up
Brief Description	Completion of HCV treatment of a 7 day per week x 8 week treatment of DAA as measured by the CHW/RN daily or pill count by the cbSOC RN monthly and SVR12 Cure (HCV RNA < 25 IC/ml, detectable or undetectable) as tested at 5-month follow up (12 weeks after treatment completion) by HCV PCR RNA as a marker for HCV viremia[118]
Name	Drug and Alcohol Use
Type	Secondary
Time Frame	2 month follow up and 5 month follow up
Brief Description	Drug and Alcohol Use vs Dependency During the Past 2-3 months, will be assessed by the Texas Christian University (TCU) Screen II [115,116] at baseline, 2- and 5-month follow up. Yes/No to each drug will be assessed for use vs dependency. The total score ranges from 0 - 9; higher scores (> 3) correspond to the DSM drug dependence diagnosis.
Name	Mental Health
Type	Secondary
Time Frame	2 month follow up and 5 month follow up
Brief Description	Mental Health will be assessed by the MHI-5 at Baseline, 2- and 5-month follow up.; well-demonstrated reliability for detecting psychological disorders[116] with reliabilities of .77 and .71 for women/men, respectively[117].
Name	Shelter Factors
Type	Secondary
Time Frame	5 month follow up
Brief Description	Shelter Stability will be assessed by length of time residing in shelter vs elsewhere at 5 months
Name	Health Care Access
Type	Secondary
Time Frame	2 month follow up and 5 month follow up
Brief Description	Health Care Access will include number of healthcare visits made and purpose during the duration of the intervention
Name	
Type	
Time Frame	
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4.4. Statistical Design and Power

Based upon our prior studies, [3, 16], we conservatively anticipate that 25% of 460 persons screened (n = 115) will be eligible and willing to undergo ongoing testing for HCV. Allowing for a 94% approval by the physician for HCV treatment, we estimate 108 will be enrolled in the study. Using the intention to treat approach, patients lost to follow-up within the 3 month follow-up will be categorized as not having achieved the primary outcome of SVR12 [87]. We assumed 55% SVR12 in real-world conditions under cbSOC (10% higher than found among substance-using patients for an earlier DAA). The sample size of 108 would give us 80% power at alpha of 5% to detect an improvement of 80% SVR 12 in the CHW/RN arm. This approach will generate preliminary estimates of SVR12 for both arms and help inform a future RCT.

Statistical analysis. Initial analysis will include descriptive statistics. We will then screen for outliers and deviations from normality; results will be considered in subsequent analyses. Patterns of missing data will be examined using logistic regression (0=missing; 1=complete) and will be reported in results. As based on our prior research, we expect very little missing data on key independent variables[3, 16]. Missing data on independent variables or continuous dependent variables may be imputed using multiple imputation and related methods as appropriate [119] and intention-to-treat approach will be implemented for SRV12 [120]; complete case analysis will be utilized for secondary variables (e.g., mental health, stable housing). Reliability for computed scores will be assessed using Cronbach's alpha.

Next, a series of t-tests and chi-squares will examine differences between groups (CHW/RN vs. standard care). Then, for each dependent variable of interest, key predictors and covariates will be examined using a series of t-tests, chi-squares, and ordinary least squares (for continuous outcomes) and logistic (for dichotomous outcomes) bivariate regression models.

Dependent variables at 2- and 5-month assessments will be examined using mixed effects models to account for both fixed (e.g., treatment group) and random (e.g., treatment administrator) effects. For dichotomous outcomes (e.g., yes/no SVR12), risk ratios will be examined using a Poisson distribution with robust variance, which tends to generate more appropriate effect size estimates than a logit-based approach [121]. Covariates that are statistically significant or theoretically-relevant will be accounted for in final models using a hierarchical variable entry strategy.

Further analyses will explore potential mediators and moderators to build a basis for development of process models and a larger RCT. In addition, mediation analysis will serve as evaluation of the extent to which the CHSCP and other related models, such as BMVP, explain the observed mechanisms of action. We will use structural equation modeling (SEM) to conduct path analysis of variables informed by the CHSCP [122]. This approach will allow the estimation of the direct, indirect, and total effects of the intervention on SVR12 through multiple hypothesized mediators. Possible mediators of the effectiveness of the intervention include housing stability and social support, which may affect SVR12. We will model SVR12 as a categorical endogenous variable within the SEM framework using probit estimation. Standardize coefficients, standard errors, and 95% confidence intervals will be estimated for each path. The fit of the model will be evaluated by evaluating the chi-square statistic and the Standardized Root Mean Square Residual. The CALIS procedure in SAS v. 9.4 will be used to perform this analysis with $p < .05$ considered statistically significant for two-sided tests.

4.5. Subject Participation Duration: **5-6 months**

4.6. Will the study use an FDA-regulated intervention? **No**

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status

4.7. Dissemination Plan

The Investigators are committed to the open and timely dissemination of research outcomes. The MPIs ensure that they will follow all the required NIH Policy on Dissemination of NIH-funded Clinical Trial Information. Plans for disseminating the findings of this research as follows:

1. Clinicaltrials.gov: The study will be registered on Clinicaltrials.gov website once the proposed grant application is funded and no later than 21 calendar days after the enrollment of the first participant. The summary of results will also be submitted to the website no later than one year after the trial's primary completion date. University of California Irvine (UCI) and the investigators will make sure that all the regulatory requirements are met. UCI Office of Research has an internal policy in place to ensures that clinical trials registration and results reporting occur in compliance with policy requirements and can be found on this link: https://www.research.uci.edu/compliance/human-research-protections/researchers/guidelines-for-registering-in-a-clinicaltrialsgov-registry.html#nih
2. Informed consent documents: As per the policy the informed consent documents will include the following specific statement relating to posting of clinical trial information at *ClinicalTrials.gov*

   In the UCI IRB consent form in the section "WHO WILL HAVE ACCESS TO MY STUDY DATA?" we will include the following statement (*This statement must be included verbatim*):

   "ClinicalTrials.gov is a Web site that provides information about clinical trials. A description of this clinical trial will be available on http://www.clinicaltrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

3. The results will be disseminated through publications in interdisciplinary journals and presentations at professional national or international conferences in a timely fashion. The strategies for dissemination of results will be discussed at quarterly meetings with the research team. The strategies will include 1) determining the best, currently available method of sharing data among all investigators; 2) submitting abstracts to appropriate professional conferences for presentation of results; 3) identifying manuscripts, journals, authors, and timeline for publications that address the study's specific aims; and 4) determining appropriate secondary data analyses.

4. NIH Public access policy: The investigators will submit all the final peer-reviewed journal manuscripts that arise from this proposal to PubMed Central immediately upon acceptance for publication.

5. We know that research is most effectively disseminated using multiple vehicles, ideally with face-to-face interaction. So, in addition to the above, dissemination activities will also include:
   a. Interactive Workshops: For the workshop, we will invite contributors, including key regional stakeholders and community health clinics, as well as national policy makers to discuss their program and policy implications.
   b. Academic and other centers: We will work with our local Academic Network as well as other organizations, which will also be promoting the dissemination of research to non-academic audiences, who will advise and support dissemination to the public. Additionally information will be collected and networks established throughout this study to further inform and strengthen the strategy.

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