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Reducing Cardiovascular Risk Among Pezople Living with HIV: Rationale and Design of the INcreasing Statin Prescribing in HIV Behavioral Economics REsearch (INSPIRE) Randomized Controlled Trial

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Abstract

Cardiovascular disease (CVD) is a major cause of morbidity among people living with HIV (PLWH). Statins can safely and effectively reduce CVD risk in PLWH, but evidence-based statin therapy is under-prescribed in PLWH. Developed using an implementation science framework, INcreasing Statin Prescribing in HIV Behavioral Economics REsearch (INSPIRE) is a stepped-wedge cluster randomized trial that addresses organization-, clinician- and patient-level barriers to statin uptake in Los Angeles community health clinics serving racially and ethnically diverse PLWH. After assessing knowledge about statins and barriers to clinician prescribing and patient uptake, we will design, implement and measure the effectiveness of (1) educational interventions targeting leadership, clinicians, and patients, followed by (2) behavioral economics-informed

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clinician feedback on statin uptake. In addition, we will assess implementation outcomes, including changes in clinician acceptability of statin prescribing for PLWH, clinician acceptability of the education and feedback interventions, and cost of implementation.

Keywords

Cardiovascular disease; HIV; Statins; Behavioral economics; Implementation science

Cardiovascular disease (CVD) is a major cause of morbidity among people living with HIV (PLWH), and its global burden is increasing as PLWH live longer in the current era of HIV antiretroviral therapy.[1–4] In combination with lifestyle modification, statin therapy—the most effective, widely available medication for primary CVD prevention—has the potential to safely and effectively reduce CVD risk among PLWH,[5–14] and is being evaluated in the Randomized Trial to Prevent Vascular Events in HIV (REPRIEVE) study.[15] Unfortunately, statin therapy is under-prescribed for PLWH;[16–20] for example, a recent study using national ambulatory care data showed that clinicians were less likely to prescribe statins to PLWH compared to HIV-uninfected adults.[21]

Factors contributing to low statin prescription rates for PLWH are not well-documented but may be similar to factors for under-prescription of statins in the general population.[22,23] Barriers to statin prescribing may include clinician-level factors such as limited knowledge of prescribing guidelines, low self-efficacy, lack of resources for patient counseling and education, perceptions of patient preferences and medication adherence; patient-level factors such as lack of knowledge about the benefits of therapy and concerns about adverse drug effects; and clinic-level factors such as size and patient volume.[24–31] In addition, peer practices influence clinicians' prescribing behavior,[32,33] and leveraging such influence has the potential to increase adoption of evidence-based therapies.[34] In particular, prior behavioral economic studies have shown that presenting clinicians with feedback about their performance in comparison to "top performers" may stimulate their competitiveness and preferences for a positive self-image, with an overall motivating effect on care quality.[35,36]

The Consolidated Framework for Implementation Research (CFIR), a comprehensive implementation science framework that draws from organizational theory, suggests that drivers of and barriers to implementation and sustainability of evidence-based practices are present at multiple levels, including at the organization, clinician and patient levels, and that barriers at each level must be addressed for successful implementation to occur.[37] Factors impeding implementation of practices and interventions may include individuals' knowledge, self-efficacy, perceptions of the effectiveness and acceptability of the intervention, consumer needs, leadership support and the organization's capacity to deliver the intervention, as well as patient demand for the intervention.[38–45] In the context of these barriers, successful strategies for improving implementation of prescribing behaviors may include highlighting the evidence base through education, simplifying practice guidelines, customizing messages to meet the needs of specific stakeholders, and providing feedback on performance.[46] This framework may inform strategies to reduce

under-prescription of statins to PLWH, but few studies have assessed multilevel barriers to statin prescribing for PLWH or tested multilevel strategies for improving uptake.

Using the CFIR as our conceptual model, INcreasing Statin Prescribing in HIV Behavioral Economics REsearch (INSPIRE) is designed to address organization-, clinician- and patient-level barriers to statin uptake (Figure 1). Our primary aim is to determine effectiveness of a multilevel intervention (clinician and leadership workshop, patient-targeted educational brochure, and clinician feedback intervention) on statin uptake in community health clinics caring for PLWH. To ensure the interventions address relevant barriers, the study will first assess knowledge about CVD prevention and barriers to clinician statin prescribing and patient uptake. Our secondary aim is to assess implementation outcomes, including changes in clinician acceptability of statin prescribing for PLWH, clinician acceptability of the education and feedback interventions, and cost of implementing interventions using health economic methods.

We hypothesize that the education intervention will result in improved knowledge of CVD guidelines and acceptability of statins among clinicians and moderate improvements in statin prescription rates, and that the feedback intervention will result in further improvements in statin-prescribing, over and above the effects of the education intervention.

Methods

The INSPIRE study is a stepped-wedge cluster randomized trial to test the effects of a multi-level implementation strategy with two types of interventions, education and peer comparison feedback, on rates of statin prescribing to PLWH by their clinicians. The interventions are informed by a qualitative study of barriers to CVD prevention among PLWH conducted with clinic leadership, clinicians, and patients with HIV.

Study Setting

The study will take place in seven HIV clinics in Los Angeles County, California: Olive View–UCLA Medical Center, Venice Family Clinic, John Wesley Community Health Institute Inc., Watts Healthcare Corporation, Tarzana Treatment Center, To Help Everyone Health and Wellness Centers, and High Desert. These clinics serve a racially/ethnically diverse population of PLWH, focus on the care of underserved populations, and include a mix of physicians, nurse practitioners, and physician assistants, each of whom have their own unique, non-overlapping patient panels. Primary study participants will be medical clinic leadership, prescribing clinicians (MD, DO, PA, NP) (N=30 estimated), and patients of the HIV clinics (N=75–100 estimated statin-eligible patients per clinic on average).

Study Design

We will use a stepped-wedge cluster randomized trial design to introduce the implementation strategy across the clinics (Figure 2). The stepped-wedge design is a special case of a cluster randomized trial that involves random and sequential crossover of clusters from control to intervention until all clusters are exposed.[47] The stepped-wedge design requires considerably fewer units to achieve statistical power because each cluster contributes both exposed and unexposed observations and acts as its own control. We will

randomize the start dates of the interventions at the level of clinics rather than clinicians to avoid spillover within clinics that could occur if clinicians in a clinic directly or indirectly learn of the intervention from each other.

Intervention 1: Education—The education intervention has two components: (1) a peer champion-led educational workshop for leadership and clinicians and (2) a patient brochure. Implementation science literature defines a champion as "a well-respected individual within an organization who is enthusiastic about a new practice and who can serve as a role model for adopting new practices.[49] For this study, we define a peer champion as a clinician who treats PLWH and regularly prescribes statins. To educate leadership and clinicians, a cardiologist and an infectious disease specialist, both of whom currently prescribe statin therapy to PLWH, will provide a one-hour, in-person peer champion-led education intervention. The workshop will cover topics about CVD risk in PLWH and evidence-based statin use based on 2018 American College of Cardiology/American Heart Association (ACC/AHA) guidelines, addressing knowledge gaps and other barriers elicited through qualitative data collection described below.[48] Coinciding with the education intervention for clinicians, patients will receive an informational brochure about CVD and HIV that similarly incorporates results of the qualitative data collection. Brochures will be displayed in the waiting room and given to clinic staff to distribute to adult PLWH regardless of statin eligibility. After refining the workshop curriculum and patient brochure, we will solicit input from clinics not involved in this study to ensure that final materials are acceptable to clinicians and patients.

Intervention 2: Clinician Feedback—Six months after the education intervention, we will introduce behavioral economics-informed feedback, in which each clinician's rate of provision of statin therapy will be reported back to him or her monthly by email, with language targeted at increasing motivation to prescribe by leveraging social norms and self-image.[36,50–54] Clinicians whose performance is in the top 10th percentile will be told "you are a Top Performer" and be emailed their rate of treatment for statin-eligible PLWH, while all other clinicians will be told "you are not a Top Performer," and be given their rate of statin treatment along with the rate of treatment of "Top Performers."

Qualitative Data Collection and Analysis

Prior to the interventions we will conduct semi-structured interviews with clinic leadership and clinicians and focus groups with patients to inform the development of the peer-champion led educational workshop and patient brochure. After the interventions, we will conduct interviews with clinic leaders and clinicians to assess changes in barriers as well as acceptability of the interventions themselves.

Leadership and Clinician Interviews—Leadership and clinicians from the participating clinics will be invited to participate in semi-structured telephone interviews. We will develop an interview guide based on CFIR domains and constructs (Table 1). This interview guide will be designed to assess current processes around and barriers to CVD prevention and treatment for PLWH, including acceptability of statins. We define "acceptability" as clinicians' and leaders' perception that statins are effective, easy to use, and fit with current

practices; that they have the knowledge and self-efficacy to prescribe statins to PLWH; and that they are motivated and willing to prescribe. Examples of questions include, “How effective do you think statins are for PLWH at risk for CVD,” and “Tell me how well prescribing and managing statins for PLWH fit with your practice at this clinic.” Leadership and clinician interview guides will vary slightly, in that leadership will be asked about perceived barriers to clinician statin prescribing, rather than their own prescribing.

Participants will be contacted by email to set up their interview and then sent a reminder email the day prior to the interview. The interviewer will read a brief consent statement and ask if participants are willing to participate and be recorded. The interviews will consist of broad, open-ended questions, followed by closed-ended questions to clarify responses and obtain greater detail. Interviews will last between 45 and 60 minutes, and participants will be offered $125 for completing the interview.

PLWH Focus Groups—We will conduct four focus groups—three in English and one in Spanish—at three of the participating clinics in the study. Participants will be PLWH currently receiving care at any of the three clinics, age 40 or older, with or without CVD. Each focus group will have between 6 and 12 participants. Participants will be recruited through flyers and call a toll-free number to be screened for the group. Eligible participants will be given the day, time and location of the group.

The semi-structured interview guide for the focus group will include questions about heart health, taking medications for heart problems, and what information patients would like to see in a brochure. At the start of a focus group, participants will be read a consent statement and asked to verbally consent to participate and be recorded. The moderator will follow the interview guide, first asking broad, grand-tour questions and then closed-ended questions to clarify responses. Participants will be provided a meal during the group and compensated with a $50 gift card after the group.

Post-Intervention Interviews—After the education and feedback interventions, we will interview leadership and clinicians regarding barriers to the implementation strategy, as studying the implementation strategy itself is a goal of implementation science research. We will assess acceptability of and barriers to the interventions in order to inform broader implementation and sustainability, if the implementation strategy is found to be effective.

Qualitative Data Analysis—All interviews and focus groups will be recorded and transcribed. To analyze these data and inform the education workshop and brochure, we will conduct a rapid analysis.[55] Rapid analysis involves developing a comprehensive coding spreadsheet with domains for all topics covered during the clinician interviews. Team members read the transcripts and summarize key themes for each domain within the spreadsheet. Themes will then be consolidated into themes most relevant to the clinician workshop and patient brochure and a summary report will be prepared.

Following the rapid analysis, a more in-depth analysis will be conducted. We will use CFIR qualitative research data collection and analysis tools to guide this process.[56] Using Dedoose, a qualitative analysis software program, we will first enter relevant CFIR domains

and constructs into a codebook. Next, two research assistants will mark areas of text pertaining to each domain and construct code. Research assistants will practice with a random sample of 20% of transcript sections, coding independently and reviewing together. If coder disagreement reveals ambiguity in the codebook, we will add additional examples. Training will continue until coders can consistently identify and mark each theme. Next, both coders work on each transcript independently, after which we will measure coder consistency, evidenced by Kappas of ≥ 0.70.[57] Themes that do not fall into one of the domains will be marked as "other." We will categorize these themes and add them to the codebook, and research assistants then will mark text pertaining to these codes. Following the coding, we will analyze and summarize barriers. We will examine themes between sites of different sizes and characteristics.

Quantitative Data Collection and Analysis

Clinician Surveys—We will use surveys to measure changes in knowledge about and acceptability of statin prescribing among clinicians and leadership before and after the interventions. Survey measures are shown in Table 2. Clinician characteristics include demographics (age, race/ethnicity), medical school and residency training information, and length of time in practice and at the clinic.[58] Knowledge about statin therapy includes knowledge regarding statin efficacy and safety in PLWH.[50] Social network and competitiveness are measured as possible predictors of clinician responsiveness to feedback.[59] Attitudes about practice guidelines are also measured as possible predictors of intervention effectiveness.

We will conduct surveys at five time points: baseline; prior to the champion-led education intervention; after the champion-led education intervention; prior to the feedback intervention; and six months after each site receives the feedback intervention. Clinicians and leadership will be administered surveys through an emailed web link to their email address using REDCap's online survey tool. In addition, research staff deliver paper copies of the survey to clinicians who do not respond to the email and provide stamped envelopes for their return. Clinicians and leadership will be compensated $75 for each survey they complete.

Intervention Effectiveness Outcomes—Table 2 summarizes the outcome variables, data collection method, and time point of data collection. The primary effectiveness outcome is the rate of evidence-based statin therapy provided by clinicians during visits by statin-eligible PLWH, measured over the 12-month implementation period. We will obtain monthly electronic health record (EHR) data from all clinics regarding statin use data for PLWH. An office visit is eligible for inclusion in the outcome denominator if 1) the patient is 40–75 years-old, 2) the clinician is enrolled in the study, 3) the clinic visit occurs during the study period (beginning in year 1, prior to barriers assessment), and 4) the patient meets 2018 ACC/AHA guidelines for statin therapy with atherosclerotic cardiovascular disease (ASCVD) risk score greater than or equal to 7.5%. In addition, we will measure lipid testing rates as we have found that absence of lipids data may be a barrier to implementation of evidence-based statin therapy guidelines, especially among women.[60]

Implementation Outcomes—Our clinician-level implementation outcomes are (a) changes in clinician and leadership acceptability of statin prescribing for PLWH and knowledge about statin prescribing, and (b) clinician and leadership acceptability of the champion-led education intervention and the feedback intervention.

Descriptive Analysis—We will use descriptive statistics (mean, standard deviation, frequency) to summarize baseline clinic and clinician characteristics and baseline patient demographic and clinical characteristics. We will summarize outcomes of interest at baseline, during intervention, and after intervention.

Intervention Effectiveness Analysis—Each clinic will cross over unidirectionally in a randomized order from the control condition to the education intervention to the feedback intervention. The outcome of each clinician's statin prescribing rate will be assessed using all patient visit data during the study period. To account for the correlation between repeated observations within the same clinic, repeated visits by statin-eligible PLWH, and the confounding of time and treatment, we will use mixed effects logistic model as the main framework to evaluate the intervention effects on statin prescription:

$$\text{logit}(p_{ijt}) = \mu + \alpha_j + \gamma_{ij} + \beta_t + X_{ijt}\theta + Z_{ij}\theta_z,$$

where p_{ijt} is the probability of statin prescription for statin-eligible PLWH i in clinic j at visit time t, μ is the intercept, α_j is the random intercept for clinic j with $\alpha_j \sim N(0, \tau_\alpha^2)$, γ_{ij} is the random effect to account for repeated visits by the statin-eligible PLWH with $\gamma_{ij} \sim N(0, \tau_\gamma^2)$, β_t is the fixed time effect, X_{ijt} is the 3-level categorical variable to indicate the treatment mode (control, education intervention, or feedback intervention) for statin-eligible PLWH i in clinic j at visit time t with the treatment effects vector θ, and Z_{ij} is the baseline covariate of the statin-eligible PLWH with covariate effect of θ_z. The effect of the education intervention is the difference in statin prescription rates between the education and baseline periods, and the effect of the feedback intervention is the difference in statin prescription rates between the feedback and education and periods. The baseline covariates will include age, sex, and ASCVD risk and we will approximate β_t linearly in time with β. All analyses will be carried out by the intention to treatment principal, in which the treatment mode variable (X_{ijt}) is determined by the scheduled assignment of the intervention based on randomization, but not by the actual timing of intervention deployment. An as treated analysis will also be carried out based on the actual treatment received. Sensitivity analysis will be conducted to include a clinician random effect in the mixed effects model to accommodate for possible correlation of statin-eligible PLWH within the same clinician, if the random effects are identifiable and there are no numerical convergence problems.

The mixed effects model assumes missing at random for missing outcomes for statin-eligible PLWH due to reasons such as missed visits or loss to follow-up. To evaluate the possible impact of non-ignorable missing data, sensitivity analysis will be performed by imputing one statin prescription outcome at each time period (baseline, during and post-implementation) during which a statin-eligible PLWH has no visits. In particular, we will impute the outcome as no statin prescription, and the timing of imputed visits will

be at 6 months before implementation period, at midpoint of implementation period, and at 6 months after implementation period. For missing baseline covariates, we will impute the data with last observations carried forward where applicable or conduct analysis with multiple imputations.

Implementation Outcome Analysis—A mixed-effects model, similar to the statistical analysis plan described above will be used to analyze implementation outcomes. We also will explore whether acceptability variables mediate the relationship between the implementation strategy and changes in clinician prescribing behavior. To understand if the effect of the implementation is mediated through acceptability variables, a causal mediation analysis will be performed.[61] In short, let models for the mediator and the outcome be formulated as:

$$E[m|a,c] = \tau_0 + \tau_1 a$$

$$E[y|a,m,c] = \lambda_0 + \lambda_1 a + \lambda_2 m + \lambda_3 am$$

where y is the percent of statin-eligible PLWH prescribed statins, m is the mediator (e.g. self-efficacy), and a is an indicator of CoC implementation. Additional control variables can be added to these models.

Cost-Effectiveness Analysis—Using health economic modeling methods that we have previously applied in other economic evaluations,[62–65] we will estimate the cost-effectiveness of the implementation strategy using in-trial utilization and cost projections of averted CVD events. This analysis will adhere to recommendations of the Panel on Cost-Effectiveness in Health and Medicine.[66] We will estimate the cost-effectiveness of our implementation strategy from the perspective of the healthcare system on a per-patient basis. To project CVD events, we will use the 10-year ASCVD risk score.[48] Costs will be determined by (1) multiplying wages (based on U.S. Bureau of Labor Statistics values) by the time clinicians spend on the education intervention and reviewing feedback emails and the time analysts spend generating feedback reports (because time spent on these activities theoretically replaces other productive employee activities);[67] (2) estimating the cost of in-trial and post-trial hospital and ambulatory care using EHR data, ASCVD risk predictions, and nationally-representative reimbursement levels from Medicare; (3) using *Red Book: Pharmacy's Fundamental Reference*, a reference for information and pricing on prescription medications to estimate statin medication costs based on the average wholesale prices;[68] and (4) estimating bulk purchase prices for pamphlets and other physical materials provided to PLWH.

The cost-effectiveness of the implementation strategy is estimated using the ratio of the difference in costs to the difference in statin rates and life expectancy between the intervention period and control period. To project long-term cost-effectiveness, we will modify an existing Markov model previously developed of CVD risk reduction interventions

for patients with acute myocardial infarction.[63] This model currently uses a 10-year time horizon.

Sample size and power—Statistical power is estimated based on the primary endpoint of proportion of visits by statin-eligible PLWH with a prescription for statin therapy over the study period. Because of the cluster-randomized stepped-wedge design of the study (where clusters are clinics), our power analysis accounts for the correlation among observations within clusters and correlation between repeated visits of eligible PLWH, although the stepped-wedge design is generally insensitive to the within cluster correlation.[69,70] Literature suggests low within-site correlation (<0.03) with statin prescription.[71–73] Our preliminary data show that each participating clinic has, on average, 2 clinicians who see PLWH (Olive View-UCLA Medical Center has the most, with 4 clinicians). Each clinician has a panel of approximately 250 PLWH per year, of which at least 30% are statin-eligible, based on detailed data from Los Angeles Ambulatory Care Network and Northeast Valley Health Corporation and our independent analysis using national data. Each clinician therefore sees approximately 75 statin-eligible PLWH over the 12-month period. This suggests at least 75 statin-eligible PLWR/clinician × 2 clinicians/clinic = 150 statin-eligible PLWH per clinic. These estimates of statin eligibility are conservative. For example, Northeast Valley Health Corporation reported that >60% of their patients were born before 1977, and statin-eligibility for this age group in the general population is 48.6%. Statin eligibility is also likely to be higher among PLWH because they have higher rates of dyslipidemia and smoking.[74,75] Our preliminary analyses show that statin therapy is provided in approximately 20%−40% of visits. We consider an increase of 10% to be clinically significant. Numerical simulation was performed to evaluate the statistical power for the primary endpoint of change in statin prescription rate. The detailed simulation parameters and results are presented in the Supplement. Simulations showed that logistic mixed effects models maintain type I error rate and have >99% power to detect 10% increase in Statin prescription, with 7 clinics and 150 statin-eligible PLWH per clinic.

Discussion

Our study extends knowledge at the frontier of CVD prevention among PLWH—testing a clinician- and patient-level education intervention and clinician-level behavioral economics feedback intervention informed by implementation science, designed to increase provision of evidence-based statin therapy to PLWH. Prior studies of interventions for CVD risk reduction in PLWH have generally focused on patient counseling and education interventions rather than clinician behavior.[6–8] Some clinician-educational interventions (e.g., interventions to increase implementation of preventive CVD care guidelines) have been shown to improve CVD care for the general population and have the potential to benefit PLWH, but have not yet been tested to improve preventive care for PLWH.[76]

Moreover, few prior interventions for CVD risk reduction have explicitly integrated behavioral economics. Recent evidence suggests that well-designed clinician-targeted behavioral economic interventions can improve the quality of care.[77] In a cluster randomized controlled trial designed to reduce inappropriate (not guideline-concordant) antibiotic prescribing, Meeker et. al.[50] tested a behavioral economic intervention leveraging feedback

and found a significant reduction in prescribing rates. Other preventive CVD care studies have used feedback reports to increase provision of underutilized care, though these studies have not specifically leveraged behavioral economics.[78] Behavioral economics strategies are particularly attractive because they can leverage existing social constructs and infrastructure, such as clinicians' self-image, clinicians' relationships with each other, competition, and social norms.[79]

The proposed multi-level study addresses gaps in the literature on CVD prevention among PLWH and draws upon implementation science to ensure feasibility and sustainability of the intervention. Understanding and improving barriers at all levels – patient, clinician and clinic –ultimately could improve care of PLWH through increased statin prescribing and, ultimately improve morbidity and mortality. In addition, the findings from our study may help facilitate the implementation of findings from the ongoing REPRIEVE study, as well as future guidelines for primary prevention of CVD among PLWH. Statin therapy is currently under-prescribed to PLWH, and evidence that potentially supports broadening the population of PLWH who benefit from statin therapy will magnify the importance of identifying sustainable strategies for treatment dissemination. In addition, REPRIEVE's results may inform risk stratification strategies that more accurately predict CVD events for PLWH compared to the 2018 ACC/AHA risk calculator. Our findings on barriers to statin prescribing may also provide further insight into barriers to implementation of other novel, evidence-based therapies, such as PCSK9 inhibitors, for primary prevention of CVD among PLWH.

Limitations

Our study has several limitations. First, as with all studies with primary outcomes depending on data from EHRs, our data may be subject to variability in measurement or documentation by different clinicians.[80] However, EHR data collection is less likely to be affected by attrition, recall bias, and social desirability bias compared to primary data collection. Second, we may not be able to account for the heterogeneity in practice patterns among our clinics. Third, our study is conducted in community clinics located in Los Angeles County, so results may not be generalizable to other populations or less urban settings. However, these clinics serve one of the most geographically, racially, and ethnically diverse populations in the US, thus increasing potential generalizability. Finally, rather than a randomized controlled trial in which we randomize clinicians to either the education or feedback, we chose a dual-intervention strategy because existing evidence indicates that both addressing knowledge gaps and barriers with education and providing feedback is critical to improving statin prescribing. However, our approach allows us to assess the effects of education interventions alone and in combination with the feedback intervention.

Public health and policy considerations

Our study will be among the first to translate and adapt innovative and highly sustainable (not resource intensive) behavioral economic concepts into clinician practices for CVD prevention in PLWH. Results from our study will inform understanding and development of sustainable clinician-level interventions for pharmacological prevention of CVD, an issue of growing importance to the aging US population of PLWH.

Trial status

INSPIRE began enrollment of clinicians and clinic leadership in March 2019 and have obtained baseline EHR data from clinics. We completed PLWH focus groups in August 2019. We expect to implement our clinician education intervention and patient educational brochures in February 2020. Results from this study are expected in 2021 and are likely to inform implementation of evidence-based therapies for primary prevention of CVD among PLWH.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations:

ACC/AHA	American College of Cardiology/American Heart Association
ASCVD	Atherosclerotic cardiovascular risk
CFIR	Consolidated Framework for Implementation Research
CVD	Cardiovascular disease
HER	Electronic Health Record
PLWH	People living with HIV

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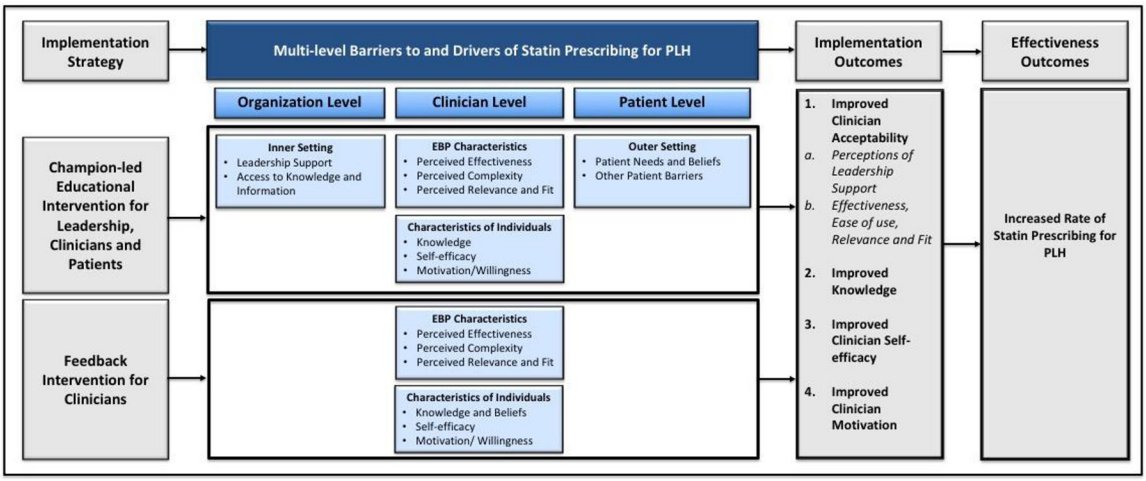

Figure 1: CFIR-Informed Conceptual Framework

EBP = Evidence-based practice

PLWH = People living with HIV

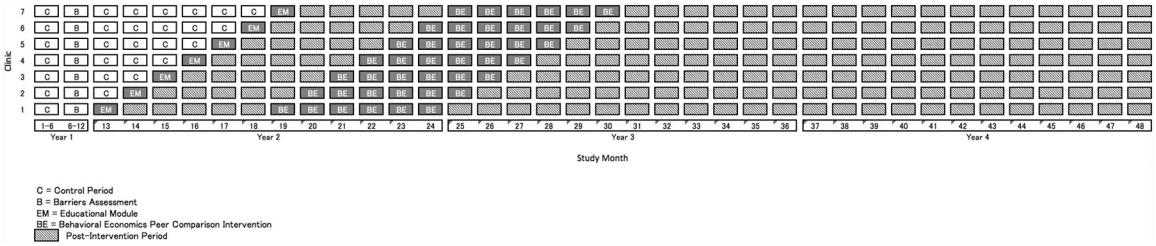

Figure 2.
Study design

Table 1:

CFIR Domain, Construct and Sample Questions in Clinician Semi-Structured Interview Guide

CFIR Domain	Construct	Sample Questions/Measures
Evidence-Based Practice Characteristics	• Effectiveness • Complexity • Relevance/Fit	• How effective do you think statins are for PLWH? • How easy or hard is the process of prescribing statins to PLWH? • How does prescribing and managing statins for PLWH fit with your current practices?
Characteristics of Individuals	• Knowledge, beliefs • Self-efficacy • Willingness/Motivation	• What are your thoughts about PLWH taking statins to treat cardiovascular problems? • How confident are you in your ability to manage a PLWH patient who is on statins?” • How willing are you at this point to prescribe statins to PLWH?
Inner Setting	• Leadership support • Access to knowledge and information	• Do you think your clinic leadership supports statin prescribing for PLWH? • If you wanted information about statin prescribing for PLWH, where would you get it?
Outer Setting	• Patient needs and beliefs	• How open are your PLWH patients to taking statins?

PLWH = People living with HIV

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Table 2:

Outcome Variables, Sources, and Data Collection Time Point

Assessments	Instrument	Collection Method	Pre-implementation	During implementation	Post- implementationimplem
Effectiveness evaluation					
Evidence-based statin therapy rates	N/A	Clinic EHR	✓	✓	✓
Lipid testing rates	N/A	Clinic EHR	✓	✓	✓
Effectiveness covariates					
Clinic Characteristics	Admin Records	Primary review	✓		
Clinician characteristics	NAMCS[58]	Web-based Survey	✓		
Knowledge about statin therapy	Meeker et al[50]	Web-based Survey	✓	✓	✓
Attitudes about practice guidelines		Web-based Survey	✓		
Social network	Green[59]	Web-based Survey	✓		
Competitiveness	Helmreich[81]	Web-based Survey	✓		✓
Implementation outcome measures					
Perceived effectiveness, ease of use, fit with current practices	Moore and Benbasat 1991[82]	Web-based Survey	✓		✓
Self-efficacy	Holt et al[83]	Web-based Survey	✓		✓
Barriers to Statin Prescribing	Grol and Wensing[84]	Web-based Survey	✓		✓
Cost measures					
Clinician time spent reviewing feedback emails	Cost instrument[85]	Web-based Survey			✓
Analyst time spent generating feedback reports	Cost instrument[85]	Web-based Survey			✓