Protocol

SPREAD-NET: PRactices Enabling Adapting and Disseminating in the Safety NET

NCT02325531

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INSTRUCTIONS:

- ***All sections are required**. If a section does not apply to your project please enter "N/A." The level of detail required for each section will vary with the complexity of your project.*
- *If your study has multiple aims, break each section down to address each aim of the study, as appropriate.*
- ***Delete all instructions (italics).***
- *See the Research Compliance website for guidance and information on a number of topics including vulnerable populations, consent, inclusion of non-English speakers, genetic research, and data sharing.*
- *If you are doing a data-only study with no prospective or interventional components, use the **Data Only Protocol Template** instead.*

1. Protocol Title

SPREAD-NET: Practices Enabling Implementation and Adaptation in the Safety Net

2. Objectives

We propose to compare the effectiveness of different 'support strategies' at helping diverse community health clinics (CHCs) sustainably implement an intervention shown to reduce patients' cardiovascular disease (CVD) event risk. Kaiser Permanente developed and implemented the 'ALL Initiative' (a.k.a. 'ALL'), a clinic-level intervention designed to increase rates of adult patients with diabetes mellitus (DM) or CVD who are prescribed cardio-protective medications (statins and ACE-Inhibitors) according to evidence-based guidelines. After ALL was shown to be highly effective in Kaiser Permanente's integrated care setting, our team demonstrated the feasibility of adapting it for successful implementation in 11 CHCs - with the help of substantial implementation support. The next step in this body of research is to identify the amount and type of support needed to effectively implement and sustain this intervention in a greater number of CHCs. To that end, we will conduct a trial in which 30 CHCs are cluster-randomized to receive low, medium, or high-intensity support in implementing ALL. We will conduct this work with CHC members of OCHIN, a community health information technology network that hosts one of the nation's largest CHC electronic health record (EHR) platforms; study CHCs share a single, linked EHR. Guided by the Practice Change Model and RE-AIM framework, we will use mixed-methods to:

Aim 1: Compare how effectively the low, medium, and high-intensity strategies support the CHCs' implementation of ALL, and assess change in rates of clinic patients with (i) guideline-appropriate cardioprotective prescriptions, and (ii) controlled blood pressure and low-density lipoprotein, as associated with implementation supported by the different strategies;

Aim 2: Assess the strategies' effectiveness at supporting intervention sustainability over 3 years; and

Aim 3: Identify clinic characteristics associated with success at different levels of support. Our team includes CHC clinicians, and experts in dissemination and implementation (D&I), health economics, and health services research mixed-methods. Our study is designed to inform future implementation of ALL as well as other interventions known to improve outcomes among CHC patients with DM / CVD. Our results could also have high impact on D&I science, by comparing practical, generalizable methods for supporting the implementation of clinical innovations in CHCs and other ambulatory settings.

Research questions: What are the characteristics of clinics that achieve sustained change even with less implementation support, and of those that do not achieve change even with more support?

3. Background

A major barrier to the timely dissemination of evidence-based interventions is a lack of knowledge about efficient, replicable strategies for supporting the implementation of tested interventions in routine care. This is particularly relevant to intervention implementation in safety net Community Health Centers (CHCs*).[1-16]

Disseminating successful interventions in diverse primary care settings could significantly improve the health of patients with DM / CVD nationwide. Yet few studies have focused on comparing effective strategies for supporting change in health care settings.[5,79-91] **Thus an important barrier to the widespread dissemination of evidence-based interventions such as ALL is a lack of knowledge about the most effective *strategies for supporting sustainable implementation* in diverse care settings.**[1,3,5,8-11,15,21,22,24,42,44,79-88,92-97] This limitation is particularly problematic for the Community Health Centers (CHCs) in our health care 'safety net',[1,13,14] which care for millions of underserved patients, and are expected to serve millions more through the Affordable Care Act.[98-100] Rapid, effective implementation of interventions shown to improve care delivery and health outcomes could ensure that CHC patients benefit from cutting-edge clinical knowledge. Although the need is well-acknowledged, we know of no previous randomized trial comparing strategies for supporting consistent, reliable implementation of evidence-based care in CHCs.[7,10,12,101]

This study will address the lack of knowledge about effective implementation support strategies. We propose to compare the effectiveness of 3 replicable strategies for supporting the implementation of the ALL Initiative in CHCs. These strategies have been shown to be effective and feasible in CHCs. We will conduct a pragmatic trial in which 30 CHCs are cluster-randomized to receive low, medium, or high-intensity implementation support.

We propose to address an important barrier to such dissemination - the **lack of knowledge about the most effective strategies for supporting CHCs' implementation of evidence-based interventions**.[1,13,14,45,79-91,93] This work is positioned to have broad impact. Understanding how to efficiently support implementing the evidence-based ALL Initiative in CHCs could reduce CVD event risk in patients with CVD / DM nationwide, improving health outcomes and reducing care costs. While this project focuses on ALL in CHCs, we will discover generalizable strategies for implementing ALL in other primary care settings and also for supporting CHCs' implementation of other interventions shown to improve CVD /DM outcomes, and other morbidities.

4. Study Design

We will conduct a cluster-randomized, prospective, pragmatic trial with 3 arms (Figure 3). In months 1-18, we will collect baseline data via a survey of all study sites, and refine the toolkit. At the start of Implementation Year 1 (study month 19), 30 CHCs will be randomized to receive low, medium, or high-intensity support in implementing the ALL Initiative. Guided by RE-AIM and the Practice Change Model, we will use mixed methods to assess how effectively the different levels of intensity support intervention uptake, guideline-based prescribing, and patient health (Aim 1), and sustainability over 3 years (Aim 2). We will identify clinic-level factors associated with each support strategy's effectiveness and sustainability (Aim 3), and adapt as possible. We will also conduct a cost analysis.

Arm 1 ('Low' intensity support) components: TOOLKIT. The point person will receive the implementation toolkit (paper and electronic form) at the start of Implementation Year 1. Toolkit components are ready for

use except as noted. EHR-based tools, built in OCHIN's EHR, will be activated at that time. The toolkit will include annual 1-hour 'Basic Webinars' open to the study point person, and hosted by the research team.

Arm 2 ('Medium' intensity support) components: Arm 2 CHCs will receive the TOOLKIT as above. TRAIN-THE-TRAINER: The study 'point person' will receive extensive implementation training at a 2-day in-person meeting in Portland, OR. Our implementation specialists will teach participants how to use the ALL toolkit and how to train others to use it. Training content will include necessary elements as identified by (i) our previous research, (ii) the baseline survey), (iii) the study team and the SPREAD-NET advisory group. Trainees will be asked to train staff at their clinic within 6 weeks after the in-person event. ADAPTIVE WEBINARS: The point people will join quarterly 1-hour webinars hosted by the research team. One webinar will include the content from the Toolkit's 'Basic' webinars. The other three will include content to reinforce and augment information from the in-person training, and to address factors that the Practice Change Model identifies as influential on intervention implementation in primary care settings. These webinars will provide a forum for group discussion and best practice sharing. We will adapt the webinar's content to address identified staff needs or implementation barriers we directly observe through visits and online diaries. This will engage staff in customizing the implementation support they receive. The webinars will be open to any interested clinic staff from Arms 2-3.

Arm 3 ('High' intensity support) components: All components as in Arm 2, plus PRACTICE FACILITATION site visits from the study team 'implementation specialist.' Visits will last 2-3 days, with 2 or more visits in implementation year 1, and 3 or more over the course of implementation years 2-3. The specialist will provide support as needed; anticipated activities include staff presentations, observational coaching on how the tools are presented to clinic staff and used in the clinic workflow, and tailored problem-solving support to help address identified barriers. Clinical questions arising at these visits will be fielded by our RN practice facilitator, and the site clinician champion. Advisory group clinicians will be asked to provide further support if needed.

5. Study Population

a. Number of Subjects

Quantitative: 30 CHCs will be randomized to receive low, medium, or high-intensity support in implementing the ALL Initiative.

Qualitative: Study clinic providers and staff at OCHIN will participate in qualitative data collection efforts as described below.

b. Inclusion and Exclusion Criteria

Describe how individuals will be screened for eligibility and the criteria that define who will be included or excluded in your final study sample.

Describe the plan for disposition of data collected during recruitment/screening in the event of a screen failure or when a potential subject is contacted but declines participation (e.g. destroyed immediately, destroyed at end of study, retained for separate analysis or so that subjects are not contacted repeatedly about participation after they have declined, etc.)

Inclusion criteria.

Quantitative data: ~20,000 OCHIN patients from 30 clinics. Data will be extracted monthly from OCHIN's EHR including (a) Study population identification (age, CVD / DM, prescriptions); (b) Patient and (c) Clinic characteristics; (d) Patient outcomes (last BP, LDL results and measurement dates; issued prescriptions and dates); and (e) Process measures (e.g., tool use, encounters). (f) Cost analysis data will be collected as well.

Qualitative data: Ongoing phone calls with 30 point people. Site Visits: 18 visits in total. Breakdown: 6 clinics per year X 3 years. Interviews: 208 in total. We anticipate 108 formal (Breakdown: 6 clinics X 18 interviews) and 100 telephone (6 clinics X 12 interviews, plus 28 follow-up interviews).

Exclusion. Pregnant and lactating women will be excluded, as the ALL medications are contraindicated for pregnancy.

c. Vulnerable Populations

Regulatory Categories: *Indicate whether you will include or exclude each of the following populations. This refers to subjects who are known members of these populations upon recruitment or at any time during the study. You may not include members of these populations unless you describe this in your inclusion criteria.*

- *Children*
- *Pregnant women*
- *Neonates of uncertain viability or nonviable neonates (up to 28 days post birth)*
- *Prisoners (NOTE: The KPNW IRB does not have the appropriate membership to review research involving prisoners. Consultation with KFRI will be required.)*

Justify the inclusion of any of these populations. Describe additional safeguards to protect the rights and welfare of these subjects.

Neonates (i.e., newborns) of uncertain viability or nonviable: Exclude
Children: Exclude
Decisionally/cognitively impaired: Include
Economically/educationally disadvantaged: Include
Non-English Speakers: Include
Employees who are specifically and intentionally targeted to be included in this study population because of their workplace and/or employee status: Include
Elderly: Include
Prisoners: Prisoners are excluded or not anticipated to become study subjects

d. Setting

Describe the sites or locations where your research team will conduct the research.

If this is a multi-site study:

- *Specify what procedures are being performed at this site or by this site's personnel (consider recruitment, consent process, study procedures, data analysis, etc.).*
- *State how each site will satisfy its IRB review requirements. Indicate if you are asking this site's IRB to rely on another IRB or if another institution would like to rely on this site's IRB and include this information in the eIRB IRQ.*

OCHIN member clinics (29 total): Winding Waters, Scappoose / OHSU, Santa Cruz County, Mosaic, Community HealthNet, Progressive Community Health Center, Truckee Tahoe Medical Group, Monterey Health Department, La Pine, Placer County, SW Montana, Neighborhood Family Practice

Michigan State University (MSU)
Mid-Atlantic Permanente Research Institute (MAPRI) – KPMAS

e. Recruitment Methods

Describe in detail how study participants will be recruited and enrolled. For example, will you openly recruit through the use of advertisements, websites, or brochures? Will you do targeted recruitment through the use of existing records or referral? If you will contact potential participants for recruitment, include the method(s) of contact and number of contact attempts that may be made.

Upload in the eIRB all recruitment materials, including brochures, advertisements, mailings, scripts, and website materials (screen shots). ***Note:*** *If your materials are yet to be developed, these must be submitted to the IRB as a modification request and approved prior to use with study participants.*

Describe, by position / title, who will be recruiting and enrolling participants (providing the particular names of research team members is not necessary).

Investigators sometimes plan to re-contact and re-recruit participants for future follow-up studies. That is, investigators may anticipate that participants for a currently proposed study will be logical participants in a future study. If there are any such expectations or plans for the participants in the currently proposed study to be re-contacted for follow-up studies, describe this. (And, note that participants should be informed of this potential for re-recruitment during the current study's consent process.)

Clinic recruitment will be led by Chris Nelson (Co-I) at OCHIN. Chris will follow-up with each clinic (who agreed to participate in the study during the proposal stage) by sending them an introductory email, FAQ handout and MOU. Patient data will be identified by the OCHIN DM registry. Staff and providers will be recruited by each OCHIN clinic's point person, specifically looking for local opinion leaders and / or as having strong positive or negative feelings about the intervention and support strategies used.

f. Consent Process

Describe how you will obtain and document consent, including:

- *Where, when and how the consent process will take place.*
- *A process to ensure ongoing consent.*
- *Steps that will be taken to minimize the possibility of coercion or undue influence.*
  Any steps that will be taken to ensure the subjects' understanding.

  This research will use a consent procedure which does not include, or which alters, some or all of the elements of informed consent; or waives the requirement to obtain informed consent in its entirety. We are requesting a waiver of informed consent in its entirety for the quantitative and qualitative aspects of this study.

  All of the following four statements are true: The research involves no more than minimal risk to the subjects; The waiver or alteration will not adversely affect the rights and welfare of the subjects; The research could not practicably be carried out without the waiver or alteration; and Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

  Explanation of Minimal Risk Research: Quantitative data (OCHIN patient data): OCHIN's EHR will be a Limited Data Set and will not include PHI. Data collection will not affect patients. Qualitative data (OCHIN providers and staff): Regular phone calls, site visits and interviews will include questions regarding views of the ALL initiative implementation, and not about individuals' health. Data collection will not affect providers or staff.

  Explanation of Waiver or Alteration of Informed Consent: The waiver or alteration of informed consent will not adversely affect the rights and welfare of the subjects.

Quantitative data (OCHIN patient data): consenting participants would require the release of full PHI rather than a LDS, therefore increasing their risk.
Qualitative data (OCHIN providers and staff): Obtaining consent would *interfere with the clinic workflow*

Modifications to the Consent Process

- *If you will not obtain consent or if you will be using only an abbreviated consent, explain how this will not adversely affect the rights and welfare of the subjects, why it is not practicable to obtain full consent, and, if appropriate, what additional pertinent information will be provided to subjects after participation.*
    - *Example 1: If part of your study involves retrospective review of existing data for many individuals, it may not be practicable to collect the data you need if you had to contact each individual to get permission. As long as confidentiality of the information is protected, such data collection poses minimal risk to the subjects and would not adversely impact their rights or welfare.)*
    - *Example 2: Studies that require 100% participation in order to obtain valid results, such as studies where an entire clinic is randomized to participate in an intervention, may not be practicable to conduct if informed consent is required.*
- *If you will conduct screening or any other research procedures before obtaining full informed consent, describe this and explain how the above criteria are met with respect to that part of the study.*

Non-English Speaking Subjects

- *If subjects who do not speak English will be enrolled, describe how the consent discussion will take place and indicate if translated consent forms or short forms will be used.*
- *Confirm that an interpreter will assist with the initial consent process and subsequent study visits.*

Assent of Children and Parent Permission

- *Describe your plan for obtaining parent permission. The permission of one parent is generally sufficient for minimal risk research, or for greater than minimal risk research if there is the potential for direct benefit to the child.*
- *Note that for studies involving greater than minimal risk with no prospect of direct benefit to the child subjects, permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.*
- *Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission.*
- *Indicate whether assent will be obtained and documented from all, some, or none of the children. If assent will only be obtained from some children (because of very young age, severe cognitive impairment, etc.), indicate which children will be required to assent and which will not.*
- *When assent of children is obtained, describe whether and how it will be documented.*
- *When subjects might reach the age of majority during the study, describe the plan to obtain consent from these subjects at that time using an adult consent form.*

Adults Unable to Consent/Decisionally Impaired

- *Describe the process to determine whether an individual is capable of consent.*

- *List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child. See the KPNW Policy on Surrogate Consent for Research for more information.)*
- *Describe the process for assent of the subjects. Address the following:*
    - *Whether assent will be required of all, some, or none of the subjects. If assent will be obtained from some subjects, indicate which subjects will be required to assent and which will not.*
    - *If assent will not be obtained from some or all subjects, an explanation of why not.*
    - *When assent is obtained, describe how it will be documented.*
- *Describe the plan to obtain consent if subjects might regain capacity to consent during the study.*

HIPAA Privacy Rule Authorization – if study will use or disclose Protected Health Information (PHI)

- *Describe the plan to obtain a signed Privacy Rule Authorization from each subject.*
- *If you will not obtain signed Privacy Rule Authorization or if you want to eliminate any required language from the authorization, explain:*
    - *Why the research could not practicably be conducted without the waiver or alteration (for example, you may not be able to do the research, or part of the research, if you needed to contact each individual for permission because of lack of contact information or a large number of individuals);*
    - *Why access to and use of the PHI is necessary for the research; and*
    - *Why the use or disclosure of PHI for the research poses no greater than minimal risk to the subjects' privacy (must have an adequate plan to protect the PHI from improper use or disclosure, a plan to destroy identifiers at the earliest opportunity consistent with the purpose of the research, and, when applicable, written assurances from collaborators that PHI will not be reused or re-disclosed to any other entity).*

    Not applicable.

6. Study Procedures

Describe:

- *All research procedures being performed and when they are performed, including timing and amount of all samples collected for research purposes.*
- *Measures taken to lessen the probability or magnitude of risks (monitoring for safety, preventing complications, etc.).*
- *All drugs and devices used in the research and the purpose of their use, and their FDA approval status.*
- *Data collection tools (upload all surveys, scripts, and data collection forms).*
- *What data will be collected, including long-term follow-up.*
- *The duration of an individual subject's participation in the study.*

NOTE: *It should be clear exactly which procedures will be conducted for the research as opposed to procedures the subjects would undergo (in the exact manner described in the protocol) even if they were not participating in the study.*

Describe procedures that will be followed when subjects withdraw from the research, including withdrawal from intervention but continued data collection.

Describe any anticipated circumstances under which subjects will be withdrawn from the research without their consent.

If the study involves genetic testing or collection of genetic information, describe this.

*If the study involves **anonymous or coded genetic research and consent for genetic research will NOT be obtained**, confirm here that you will check the genetic exclusions database in order to comply with the Oregon Genetic Privacy Law.*

Qualitative data:

The All Staff Survey. All staff at the SPREAD-NET (S-N) study clinics (~30 anticipated) will be asked to complete this paper survey, which is designed to assess each clinic's readiness to change.

Clinic Information Form (CIF) Survey. One person, e.g., clinic manager or quality improvement coordinator, at each of the study clinics will be asked to complete a paper survey which is intended to collect factual information about the clinic that will be used to help understand how best to support implementation of the ALL Initiative.

Bi-weekly phone calls with point people. Once the ALL initiative has been implemented in the study clinics (estimated March 2015), each clinic's study point person will participate in regular telephone calls with study staff at KPCHR and OCHIN. These calls will be biweekly to start; the number of calls per month may taper off over time. Calls are expected to last 15- 30 minutes. No PHI will be collected, nor will data be collected from or about patients. The format of the calls will be fairly unstructured; in general study staff will solicit information on barriers and facilitators to the uptake of the ALL initiative, including use of the study tools and fit into clinic workflows. The attached 'Topics for point person calls' document lists subjects that may be covered during these calls. Phone calls will be recorded by study staff using KPCHR-approved digital recorders that are encrypted and password protected for security and confidentiality, and transcribed by a KPCHR approved transcriptionist as necessary. Recordings and transcripts will be sent through KPCHR's secure file transfer site.

Site visits. In study years 2.5-4, we will conduct in-person observations at 6 clinics per year, to collect in-depth data to augment the data collected in the diary entries. We will purposively select CHCs for site visits that will optimize our learning, such as CHCs that are excelling with lower levels of support. At each visit, 2 members of our qualitative team will spend 2 days at the CHC. Ethnographic methods (field observation, opportunistic and semi-structured interviews) will be used. Such methods are uniquely suited to the study of organizational behavior as they facilitate in-depth understanding of change processes, workflows and routines, and barriers and facilitators to change. At these visits, we will explore the implementation process, toolkit use and barriers and enablers of practice change, including understanding clinic workflow for DM / CVD patients, and how ALL supports medication decision-making.

Additional interviews. In years 3-4.5, our qualitative team will conduct telephone or video-based semi-structured interviews with staff at each CHC that we do not visit in person. The interviews will be designed to elicit further information about how ALL was implemented, how effectively each arm's strategy supported that implementation, and barriers to effectiveness. We will also likely conduct more informal, follow-up interviews to fill in knowledge gaps identified during subsequent data collection and analysis.

Other qualitative data sources. Our team will also collect 'archival' data related to the process evaluation (e.g., email / telephone discussions with CHC staff; clinic policies; concurrent QI initiatives, as well as conduct regular debriefings with practice facilitators (arm 3)).

Quantitative data: This data will be extracted monthly from OCHIN's EHR will include: (a) Study population identification (age, CVD / DM, prescriptions); (b) Patient and (c) Clinic characteristics; (d) Patient outcomes

(last BP, LDL results and measurement dates; issued prescriptions and dates); and (e) Process measures (e.g., tool use, encounters). Cost data will be collected as well.

7. Data Analysis

a. Analysis Plan

Describe the data analysis plan, including any statistical procedures.

When applicable, provide a power analysis.

Describe any procedures that will be used for quality control of collected data.

Survey data analyses. Survey results will be used for two purposes. (1) Summary results will be used as a 'diagnostic tool' to identify materials needed to train Arm 2-3 clinics at the in-person training and subsequent webinars. We will use descriptive statistics to summarize the responses to the surveys and identify prevalent aspects to be included in the trainings. (2) Results will be used to measure the clinics' baseline characteristics, which will be included in longitudinal analyses as covariates. We will test for baseline differences in patient and clinic characteristics between study arm clinics using chi-square and t-tests to determine if differences exist. Qualitative survey results from open-ended questions will be content-analyzed by our qualitative team using standard methods[225,226]

Specific Aim 1 & 2 analyses. For Aim 1, we will use an interrupted time-series design with three-level hierarchical linear models to assess differences in the impact of the intervention's implementation, across the 3 support strategies, on quantitative outcomes (patient health [Effectiveness], guideline-based prescribing [Reach]). This method is commonly used to compare changes in rates across time pre- and post- implementation. Time in monthly intervals will form the 1st level of the model, person the 2nd, and clinic the 3rd; these models do not require patient-level data at all time points. We will include a dummy-coded variable for study arm (reference group = 'High'-intensity support) and clinic level covariates (as guided by the Practice Change Model components) at model level-3, and patient level covariates at level-2. The level-1 model will be specified as a segmented regression model, to yield an estimate of the level and slope across time of rate of the outcomes of interest in the 2 years pre-implementation, and changes in the level and slope of these rates in the 12 months post-implementation. Change in level provides an estimate of the immediate effect of the intervention. Change in slope gives an estimate of effect across time. We will include a cross-level interaction of study arm with time, change in level, and change in slope; the interaction of change in slope by study arm tests if the change from pre to post intervention in the trends in the rates over time differs across arms. Similarly, the interaction of change in level by study arm tests if the immediate effect of the intervention differs across study arms. Separate analyses will be conducted for percent of patients with guideline-appropriate prescriptions for ACE/ARBs, statins (our primary outcomes), and with last BP under control, and last LDL under control (secondary outcomes) (Table 5). Aim 2 analyses will use the same approach, adding time points through 36 months post-intervention [Maintenance]. The time period variable will have 3 levels (pre-intervention, 12 months post-, and 13-36 months post-intervention). Of interest is whether the slopes (rate of change) or level in the last time period differ across the 3 arms.

Statistical power. Segmented regression is a powerful statistical technique in diverse applications, but formal power analyses may not be feasible as estimates of the model parameters are not available prior to the study. We will meet or exceed the 12 points pre- and post-intervention used in similar segmented regression analyses, as is adequate to detect even modest effect. To illustrate our power to detect changes between study arms, we conducted a

power analysis using data from our current study. At 12 months post-intervention, 60%, 63% and 46% of control clinic patients and 68%, 76%, and 58% of intervention clinic patients were appropriately on statins, ACE, and both, respectively. We can detect differences of this magnitude between any two arms of the study with power of .95 to .99 if the intra-class correlation is .01, and power of .76 to .99 if the ICC is .02 with an alpha level of .05.

Additional analyses (Minimal support needed to achieve treatment thresholds): While our primary analyses will measure implementation impact as described above, we will also conduct secondary analyses, for both the patient health and guideline-based prescribing outcomes, in which we will define thresholds of intervention impact. Thresholds will be defined as a target percentage of clinic patients with (i) guideline-appropriate prescriptions; (ii) last LDL <100; and (iii) last systolic BP <135. Targets will be determined based on baseline data and in consultation with the SPREAD-NET advisory group, which includes CHC clinicians. We will then assess the minimal amount of implementation support needed to achieve threshold results. We anticipate based on our first study that these targets will be approximately (i) 75%; (ii) 70%; and (iii) 80%, respectively. Logistic regression will be used, with study arm (reference group = High support) predicting a binary outcome for threshold achieved by 12 months.

Qualitative analyses (Aim 3). Led by Dr. Cohen, our expert qualitative team will analyze data from the weekly diaries, site visits, archival data, observation, and interviews, to gain in-depth knowledge of the change process. Data collection and analyses will be concurrent and iterative, permitting us to identify salient constructs and knowledge gaps while implementation is ongoing, incorporate this knowledge into subsequent data collection, and guide adaptation of the support strategies. A grounded theory approach coupled with an immersion-crystallization process will be used to identify themes and patterns in the qualitative data. The aim will be to understand what happens during implementation from the participants' perspective, including barriers and facilitators, the extent to which toolkit elements are used or adapted [Adoption], and the impact of each support strategy on implementation success [Implementation]. Particular attention will be paid to factors leading to a given practice excelling or struggling in response to the offered implementation support. Our team will use Miller and Crabtree's 5-phase analysis strategy, as team members have previously done successfully.

b. Sharing of Results with Subjects

Describe whether results (study results or individual subject results, such as results of standard or research lab tests and genetic tests) will be shared with subjects or their providers.

If the study carries a risk of incidental findings, describe your plan for evaluating these and determining whether and how subjects or their providers will be given this information.

If laboratory results will be shared with subjects or their healthcare providers, verify that the laboratory conducting the test is CLIA certified.

Not applicable.

c. Data and Specimen Banking

Indicate if specimens may be used for future research and whether that may include genetic research (see above regarding requirements for anonymous or coded genetic research).

State if data or specimens will be sent to a separate repository.

If data or specimens will be banked in a repository for future use as part of this protocol submission, describe here (or in a separate document) where they will be stored, how long they will be stored, how they may be accessed, and who will have access to the specimens. Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

Not applicable.

8. Privacy, Confidentiality, and Data Security

Describe the steps that will be taken to protect subjects' privacy during recruitment, consent and study procedures.

Describe the plan for storage of data and specimens, including:

- *Where the materials will be stored.*
- *How the materials will be labeled.*
- *Any other steps that will be taken to ensure security (e.g., training of staff, authorization of access, password protection, encryption, physical security, and separation of identifiers from data and specimens, certificates of confidentiality).*
- *Plan to destroy/archive or retain data and/or specimens at the end of the study.*

If you will collect any data from participants electronically (including email, website, etc.), explain:

- *How the data will be collected.*
- *How the information will be secured (encryption, password protection, etc.; may require consultation with IT department).*
- *Any risks to the participants' privacy posed by using these methods (describe in consent, as applicable).*
- *How you will verify the participant's identity.*

If any data or specimens will be sent outside of this site, list each recipient (may list by role or category if the information is the same for several different entities). For each recipient, describe:

- *What will be sent.*
- *Whether the materials will be fully identifiable (PHI, if health information), a Limited Data Set, de-identified, or aggregate (See Types of Compliance Data – Quick Reference for more information).*
- *How the materials will be transferred securely (for instance, Secure File Transfer).*
- *NOTE: If you are sending full PHI outside this site, you must have a RAMP review. Complete and upload the Risk Assessment Tool.*

Quantitative data: This will be stored at OCHIN.
Qualitative data: This will be stored at CHR.

CHR investigators and project staff sign annual confidentiality pledges and receive IRB training and Certification every three years. Data from the community clinics will come through OCHIN, and OCHIN will use similar safeguards to ensure confidentiality when handling data. OCHIN will use unique patient identification codes and all data sources will be linked through a secure relational database at OCHIN. Data will only be shared with CHR through a secure data transfer web site. After data have been linked and transferred, they will be de-identified for analytical purposes. OCHIN and CHR will use a state-of-the art file transfer application to provide secure file transfers. This application transfers data from a secured sending website to a secured receiving website. CHR's standards meet the standards required f

or DHHS level 1 security. In addition, back-end checks will be conducted periodically to *ensure data reliability.*

9. Provisions to Monitor the Data to Ensure the Safety of Subjects

This is required when research involves more than Minimal Risk to subjects. Describe:

- *Who will monitor the study data for safety.*
- *Who will verify data accuracy and conduct quality assessments.*
- *How objectivity in the monitoring process will be ensured.*
- *What data and/or events will be reported to the monitor or monitoring board and how frequently.*
- *The procedures and methods that the monitor or board will use to evaluate the data.*
- *Criteria for taking action on monitoring findings (for instance, stopping rules, reporting, protocol changes, changes to monitoring frequency or plan).*
- *For studies monitored by a DSMB/C, describe the committee membership and structure, meeting format, and quorum requirements. Upload the board/committee charter, if one exists.*

10. Risks and Benefits

a. Risks to Subjects

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.

Risk of breach of confidentiality is common to almost all research studies. Avoid indicating that study participation is expected to be "risk-free" or without risk.

If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.

If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.

If applicable, describe risks to others who are not subjects and risks to Kaiser Permanente.

b. Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits.

Indicate if there is no direct benefit. Do not include benefits to society or others.

***Note:** Compensation is not considered a benefit and should not be included in this section. See Compensation to Participants section.*

11. Costs to Participants

Describe any costs that participant may be responsible for due to participating in this study (for example, co-pays; paying for treatment, therapies, or other interventions, or the delivery of these) and how you will inform participants of these costs prior to their enrollment in this study.

12. Compensation to Participants

Describe any compensation provided to participants, for example, for time inconvenience, discomfort, travel, or in the event of research related injury.

If applicable, describe how you will inform participants of this prior to their enrollment in the study, including if payment will be prorated if the subject withdraws early from the study.

***Note:** payment may not be withheld as an incentive for participants to complete the study.*

13. Resources Available (delete if not applicable)

Describe any special resources or expertise required to conduct the study.

14. Drugs or Devices (delete if not applicable)

If the research involves drugs or devices and is investigator-initiated, indicate whether there is any possibility that the results will be reported to FDA (e.g. as part of a new drug application [NDA] or premarket approval application [PMA]).

If this is a device study and you think the device is Non-Significant Risk, include justification here or upload it as a separate document along with any available device information (instructions for use, etc.).

If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (Non-Significant Risk device), confirm that you will comply with all applicable FDA requirements for investigators. Also see the ICH-GCP guidance for a summary of investigator and sponsor responsibilities in clinical trials.

Address the items listed below as applicable.

Drug Studies:

- *Confirm that you will follow applicable KP pharmacy policies and procedures.*
- *Describe your plan for drug storage, handling, and accountability, including distribution, return, and destruction of the drug(s).*
- *If applicable, upload a copy of the Investigator Brochure for each drug. (If this is not an Oncology study, you must also send an additional copy to the Regional Formulary and Therapeutics Committee.)*

Device Studies:

- *Describe the device, the manufacturing process, and the device labeling, including safety instructions or warnings. If available, this may be addressed in separately uploaded device information (such as instructions for use).*
- *Describe device storage, handling, and accountability, including how access to the device will be limited to appropriate personnel and how you will ensure the device will be used only for appropriate study subjects.*

15. Multi-Site Coordination (delete if not applicable)

If this site will be the coordinating center for any activities, describe those activities here or in a separate document.

Describe the processes to ensure communication among sites, such as:

- *All sites have the most current version of the protocol, consent document, and HIPAA authorization.*
- *All required approvals have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data as required by local information security policies.*
- *All local site investigators conduct the study appropriately.*
- *All non-compliance with the study protocol or applicable requirements will reported in accordance with local policy.*
- *Communication of problems, interim results, and study closure.*

16. Community-Based Participatory Research (delete if not applicable)

Describe involvement of the community in the design and conduct of the research.

Describe your plan for ensuring that community research partners are appropriately trained in human subjects protection.

NOTE: *"Community-based Participatory Research" is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based Participatory Research begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.*

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