CIRRCLE Operational Plan Outline -

Purpose: This plan both documents general ‘lessons learned’ by researchers, primary care clinicians and patients/caregivers with limited English proficiency who interact in primary care clinical contexts, and who decide to pursue a joint program of research together. For each of the 8 recommendations below, we present project outputs and outcomes followed by recommendations.

SECTION 1: PRACTICE SELECTION

1) Practice selection: Following AAFP National Research Network (NRN) usual practice’, we developed a “one page description’ of the project and its general aims, which was emailed to all practices participating in the NRN, allowing practices to ‘opt in’ if they thought they met the project’s requirements for practice/patient type, and could meet project deliverables. Because the number of practices serving a substantial population of patients with limited English proficiency (LEP) and interested to participate was limited within the AAFP National Research Network, there was a high amount of variation in practice type and LEP populations served. This heterogeneity created challenges for the project: because the level of engagement and participation was moderately intense (2-3 hours devoted per month), some clinics that fit the criteria initially may found more difficult to participate when changes in staffing or workload resulted (ultimately culminating in the greatest difficulty during the COVID-19 crisis). It seems extremely important not to underestimate to clinics the degree of participation that the project entails (and try to stick to that throughout the project, to minimize the probability that practices will “dropout”. Practices also varied in their perception of the relevance of the project to their work and patient care priorities.

- Recommendation 1: Provide a project one-page descriptions prior to practices joining a PBRN engagement project that clarifies the amount of time that will be required by clinical staff to meet deliverables, as well as the highest priority objectives of the project. This description should clarify the resources that will be provided by the project to help clinics meet their deliverables.

SECTION 2: ORIENTATION & TRAINING

2) Initial orientation and training:

a) Kick-off meeting: this meeting served to orient participants (almost all were site physicians and coordinators) to the purpose of the project. While there was also training and orientation regarding the participatory methods to be used, and participants found this useful, the exercises were limited (both in terms of time and experience) to give site leaders (clinicians and site coordinators) enough confidence to conduct PLA/World Café
sessions with patients on their own. Serendipitously, the PI made site-visits to 2 of the sites at the start of the project (while going to the site for another reason) and provided further ‘hands-on’ training and support to the site PI and coordinator, which enhanced the confidence of leaders at that site. “Research naïve” clinics may benefit from early site visits to learn/gain confidence in the use of the participatory techniques. While the project leaders intended to make site visits to all sites, the COVID-19 emergency made this impossible.

- **Recommendation 2**: Provide on-site training and supervision in engagement methods to site leaders if at all possible, and as early as possible during the project.

**SECTION 3: NEEDS ASSESSMENT/PROBLEM IDENTIFICATION**

3) **Needs Assessment/Problem Identification**:

a) Importance of “hearing the patient’s voice” from every clinical site: We learned that, even though the ‘lived experience’ of receiving optimal (and also non-optimal) primary care was quite similar across clinical sites with different practice structures and processes, and that they cared for a different case-mix of patients (in terms of LEP ethnic groups), it was important for each group of patients and providers to ‘speak their truth, their lived experience’ as a part of ‘on-boarding’ to the project. This will require use of participatory methods and prioritization of the issues that emerge and should not be “short-circuited” to reach a pragmatic end e.g. identification of a study question or development of a study protocol.

b) Methods used:

- **World Café** – when there are a number of distinct questions to be asked on a topic, and anticipated variation in patients/clinicians responses across sites, this approach is useful. Each site can conduct the World Café, brainstorm multiple answers to each question, use direct ranking methods to prioritize the answers, and produce lists of responses can be shared across sites to allow for novel, additional contributions (if there are any, as is usually the case) and comparison across sites i.e. where is the common ground across sites, and what is unique about each site. This approach is best used during the ‘needs assessment’ phase.

- **Participatory Learning in Action (PLA)** — If there is one ‘vitally important question’ about which all sites need to ‘delve deeper’ to identify the ‘richness’ of the perspective in each site and project leaders need to compare and contrast between site, Participatory Learning in Action, which includes brainstorming, sorting of brainstormed ideas and prioritization of sorted ideas should be used [please see refs by MacFarlane et al]. This will generate categories of responses
to the question ("themes") that will likely vary across sites. This approach will allow all participants at each site to identify common ground as well as unique 'themes' of importance to their site; and assist with subsequent clinic-specific ‘tailoring’ of during the intervention development of interventions or the implementation phase of a pragmatic trial.

- Some sites initially struggled as patients found it difficult to understand group discussion questions and/or hesitated to speak out and provide answers to the questions asked. It was important to address these issues and ensure a) that group discussion questions were clearly and concisely asked with enough contextual information provided to help participants respond to the question; and b) that group facilitators received adequate training and support to conduct the groups and encourage participants to respond with confidence, to stay on track regarding the object of the task, to learn how to ‘delve deeper’ when necessary to help participants organize responses into meaningful themes (especially important for PLA sessions).

- **Recommendation 3**: Use broad-reaching participatory methods such as the World Café to help participants identify and prioritize their healthcare process needs and conduct more in-depth exploration using PLA methods to explore a limited set of questions arising from those brainstorm sessions that require more extensive discussion.

SECTION 4: TRAINING IN PARTICIPATORY RESEARCH

4) **Training in Participatory Research Methods**:

a) **Resources kits**: PCORI has conducted a number of projects in which patient-oriented training modules were developed for patients with limited English proficiency. Patient investigators assessed a number of these, and the best (only available to date in Spanish) was a set of materials designed by the University of Miami, Miller School of Medicine, National Partnership for Training Community Health Workers in Patient-Centered Research. The materials use plain language to address the following 7 questions:

- What is research generally, and patient-centered research specifically?
- Ethics: What it means to conduct patient-centered research in an ethical way
- Study assignment and randomization: How to ensure that all research participants have equal opportunities to be chosen?
- Different ways to gather research data
- How to inform participants about their rights and risks associated with a study?
- Following the rules and instructions as part of a team
- How the results of the study are reported and to whom?
b) Patient investigators thought that this set of materials could easily be adapted for patients speaking other languages than Spanish. The slides sets did not attempt to cover each topic comprehensively but could serve as a template for adaptation to the needs of the partnership, i.e. expanding if/when necessary.

- **Recommendation 4**: Adapt Spanish-language U. of Miami National Partnership for Training Community Health Workers in Patient-Centered Research training materials for use by other linguistic groups participating in projects in which there is linguistic discordance between patients and clinicians.

### SECTION 5: OUTCOME MEASURES

5) **Prioritization of outcome measures across practices**: If patients are not sufficiently trained about conducting PCOR, they may not fully understand the ‘point’ of measuring some patient-reported outcomes, which may lead to highly variable session outcomes. One the one hand, this may be beneficial, as it may be an important way of identifying potential variability (or lack thereof) between patients or across participating PBRN practices, so that outcome measures included in PCOR/CER studies show variability between patients or practices. This variation may be responsive to interventions. On the other hand, if patients don’t understand the point of a question, they may answer erratically, confounding appropriate analysis.

a) **Example**: Outcome measure development: We used a direct ranking method (embedded within the World Café method) for patient participants to rank from most to least important to use a range of patient-reported health outcome measures that might be used in any project with any health or healthcare outcome. Our objective was to identify and prioritize surveys that measure the degree to which an intervention “moves the dial” on health or healthcare outcome that were most important to patients. In some practices, patients appeared to give higher priority to surveys/outcome measures that represented ‘problem areas’ for the practice. For example, if “trust in clinicians” was ranked low as a priority, outcome measures that measured that parameter were not highly prioritized in that practice, whereas it was highly ranked in practices for which this was a problem.

- **Recommendation 5**: Adequately pilot the use of patient-reported outcomes in LEP populations that will be used in subsequent studies to ensure that patients clearly understand it, and that there is variation across patients and practices in the priorities assigned to patient-reported outcome measures. Use patient-engaged methods as described in Recommendation 3 to prioritize which methods are most important to LEP patient populations.
SECTION 6: IDENTIFICATION OF RESEARCH QUESTION

6) **Identification/developing consensus on the joint-project health intervention/outcome focus (or foci if more than one), research questions and approach that partnership will take during the proposal development phase:** Using participatory methods in our current PCORI Eugene Washington Capacity Building project, we learned that:

   a) Participating clinics highly prioritized use of an intervention that combined participatory research and implementation science, i.e. the combination of Participatory Learning in Action and the Normalization Process Theory to implement an intervention (a specific treatment program, whatever it is) into routine primary care delivery, and to study “how does that work in practice for both clinicians and patients”. Such an approach could be used for a variety of health outcomes, i.e. it is not specific to any one health or healthcare outcome. It has been used in prior studies in primary care clinics but is not in itself a ‘health or healthcare intervention’. It is rather a research approach to implement any intervention in primary care.

   b) Successful proposals for national large-scale funding require a lead investigator with a credible track-record in prior funding and publications on a specific topic that is deemed of value to research by the funder. This varies by funding body, i.e. funding proposals targeting a specific Program Announcement made by the National Cancer Institute may require different questions and methodological approach to be used than proposals submitted to PCORI. Both require projects to be focused on improving health outcomes for a defined group of patients with a particular, specific health problem, who are cared for in particular treatment settings— for Comparative Effectiveness Research, they must compare two or more previously tested ‘intervention’ program. Proposals are more likely to succeed at obtaining funding that implement interventions for which there is good evidence (from earlier, appropriately “powered” research studies); that implement an intervention that produces a powerful impact on the health outcome within a brief period of time without excessive risk, effort or cost to patients or clinicians; and (for implementation science projects) that are feasible to implement in practice.

   c) Even though patients and stakeholders prioritize to conduct research to improve a health or healthcare outcome that is of high important to LEP patients in their community, or that they serve, it may not be feasible to obtain funding to improve that outcome in practice, if the available interventions have not yet been tested and demonstrated to actually change the health outcomes that patients/clinicians prioritize. Pilot studies are necessary to justify the implementation of interventions in a large-scale study. Conducting initial pilot studies to develop such an intervention itself requires funding, which is not usually available from national funders.
d) Practices provided feedback that potential study interventions benefitting LEP patients should be directly related to the health or health care problems experienced by those patients. Clinics participating in the CIRRCLE project differentially ranked different health problems e.g. different clinics ranked the different health problems differently — the same problem was ranked highly by some practices and low by others. Gradually, the central theme that emerged was the importance of promoting optimal patient-clinician communication (whether in terms of language interpretation or other issues) as well as trust. Offering patients/clinicians options that are unrelated to their stated/prioritized health or healthcare problems, e.g. because those study options are feasible for researchers to obtain funding for, only confuses the patients and undermines their trust in the study team.

- **Recommendation 6**: While practical, detailed examples of possible intervention options provide an opportunity for PBRN clinics and LEP patients served by them to prioritize what PCOR/CER intervention would be of interest for their practice (or those like them), the options provided should be directly related to health and/or healthcare problems identified by patients. This is true even if it means that pilot studies will need to be funded and conducted before interventions can be tested in a full-scale trial.

### SECTION 7: PROPOSAL DEVELOPMENT

7) **Additional remaining steps in proposal development (once the project focus is decided upon)**: While the following steps include those identified as important in PCORI methodological standards, patient, clinician and stakeholder groups must discuss each of them when building PCOR proposals and come to agreement on the logistics that will be involved for a given project, in a given patient population. Patients and clinicians who took part in this project provided guidance regarding the elements that must be addressed.

a) Careful definition of a study question and hypothesis should be determined via participatory discussions, e.g. Does a 12-month complex health system intervention that uses participatory learning in action discussions to improve patient-clinician communication change measures of patient-clinician communication and trust (provided by both LEP patients and their clinicians) significantly more than usual care in primary care clinics that serve these patients?

b) Study oversight:
   - Identify who needs to be involved in project Steering Group decision-making, how they will give input in the study, to what they will give input and when

c) Develop messaging and marketing for patients, caregivers, and providers
   - Identify community resources relevant to patient engagement and support
• Network across communities to identify their constituents, visit communities as we develop community coalitions
• Details must be worked out regarding how the partnership members will work together e.g. patient and clinician engagement in the study, the amount of effort that each will need to expend; the risks each will take; the potential benefit to each; and potential direct benefits to patients i.e. remuneration or other benefits. Usually, it is the lead researcher’s responsibility to develop the ‘first draft’ of the proposal to specify all these details, and patient/clinician partners then ‘react’ to those details and suggest ‘what won’t work’ or ‘what is missing’.

d) Recruitment and retention
  • Clinics
    o Provide input on how best to incentivize partnering clinics to follow patients and collect relevant data in a timely manner, and to implement full intervention
    o Give input on how best to keep clinic/staff engaged in study
  • Patients
    o Help design a patient-facing informational brochure about the study
    o Help determine how best to identify and follow patients and determine study-eligible patients
    o Advise on methods for monitoring and maintaining completeness of patient enrollment

e) If additional pilot studies are of higher priority
  • Identify what needs to be piloted, i.e. what information do we need in order to proceed to a full trial of the adapted intervention?
  • Develop or describe each part of the intervention, and how you will measure its impact on patient or clinician outcomes.
  • Identify options for funding additional pilot studies (if needed) and decide on how to pursue those, who will do what, and in what order.
  • Discuss how you will “keep the partnership together” over a possibly extended time without any funding for project-related activities—as this may be necessary during the conduct of a pilot project.

f) If the implementation of a ‘pre-tested’ intervention in primary care is of higher priority, refine the study question(s) that will be asked. This includes:
  • The intervention that will be tested as well as the ‘control’ or comparison intervention (both need to have been tested or at least characterized so that it is clear how much of an effect they have on the health outcome in question). It is usually not acceptable to funders to test a novel combination of intervention
elements that have never been tested together before without conducting a pilot study. ‘Control’ interventions should also be tested.

- The difference between the 2 interventions should be great enough that a feasible number of practices would choose to participate, and the intervention could be implemented. This may depend on the amount of effort required, i.e. testing the effect of a particular medication would be more straightforward than testing the implementation of a complex-to-use digital tool.
- The other thing on which the size of the study i.e. number of practices depend is the ‘main outcome’. If we can measure the ‘main outcome’ for all participants, and there is a good range of values in that outcome, e.g. hemoglobin A1c values, the total number of participants needed to conduct the study will be less than if the outcome is a rare event only happens to a few participants.
- Biostatisticians can usually help partnerships to decide if a study that is too large or complex to attempt with the resources that will be available from the funder.

g) Develop or describe each part of the intervention, and how you will measure its impact on patient or clinician outcomes

- Even when all this happens, sometimes the funders see ‘holes’ in what is proposed, the proposal is then unsuccessful. Sometimes funders provide detailed feedback for what they think needs to change to make the proposal acceptable— and sometimes not. It is best usually is to submit a proposal to different funding bodies for ‘non-overlapping’ funding e.g. projects that use the same intervention to study different outcomes or different somewhat interventions to study the same outcome, so that the partnership can move forward on its agenda if only 1 of the applications is funded.
- Help develop training for patients or clinicians so that everyone knows their roles and what they need to do

h) Outcome measurement

- Identify all the measurements/outcomes that are important to patients and clinicians and how you will collect them, including what forms or software you will use, and what are the instructions for filling out each form
- Decide what you will do if a patient or clinician decides not to answer a question

i) Quality improvement

- Guide development and reporting of the QI metrics most meaningful for providers and healthcare systems
j) Data analysis
   - Engage biostatisticians early, before writing the proposal, to be sure that you can measure the outcome you are proposing to measure in the population you are studying with sufficient accuracy that you will have reliable results.

k) Dissemination (sharing the results)
   - Identify who will own the data and make decisions about what can be done with it.
   - Make a plan for how you will share the data widely — a dissemination plan
   - Leverage stakeholders’ networks to maximize the reach of the study results
   - Identify any barriers to sharing the information to key audiences, e.g. language, health literacy, access to computers
   - Identify the most effective strategies to share the results and ensure timely and effective communication to patients and caregivers, community leaders, hospital administrators, policy makers
   - Educate local (e.g., county commissioners, mayors) and state policy makers (e.g., state senators) to understand the kind of research we are doing, why it is important, why we are uniquely positioned to do this and become a national leader in this field, to understand barriers to providers and patients

   • Recommendation 7: Detailed discussion about the different elements of conducting a project that benefits LEP patients and their clinicians must be conducted to decide on details of a PCOR/CER study before it is submitted for funding, using a participatory approach that fully engages patients on each element that will be required for the study that benefits LEP patients. These discussions should lead to consensus on all logistical elements of the project and should start with the determination of a testable study question.

SECTION 8: PROCESS EVALUATION

8) Process evaluation: We used the Center for Health Equity’s Community-based participatory research framework to evaluate the success of our partnership to include all voices in the data acquisition, analysis and decision-making process. Partners responded positively and engaged enthusiastically in this process at the end of year 1. We used an external facilitator to facilitate the process. The main learnings were:

   a) Engagement and bidirectional communication are challenging but worthwhile.
   b) Focus groups are eye-opening and a valuable approach to teach clinical staff.
   c) Not everyone is in charge of their own domain....the “inner setting” is a common barrier to community and population health responsiveness.
d) There wasn’t enough time/skin in the game/money for some to feel they were impactful throughout the project.

e) All learned that conversations take time: it is totally worthwhile to slow down to have time for community and other stakeholders to express their perspectives.

- **Recommendation 8**: Conduct participatory process evaluations to ensure that the project engagement objectives are operating as intended. The Univ. of New Mexico Center for Health Equity’s Community-based participatory research framework is highly recommended.