STUDY PROTOCOL

(Version 2.0)

Connecting Healthy Women

PCORI| Patient Centered Outcome Research Institute

University of Arizona IRB | Project Number: 1404306715

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September 15, 2016

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I. INTRODUCTION

Background Information and Scientific Rationale

Under the provisions of the Patient Protection and Affordable Care Act (ACA), many more previously uninsured individuals will have access to healthcare coverage, including through Medicaid. While obtaining healthcare coverage can improve health outcomes,[1, 2] the newly insured still face challenges in using the healthcare system effectively and efficiently. They face challenges in finding and connecting with a primary care provider, and preventable hospitalizations and emergency department use has been found to increase, especially in Medicaid populations.[3-5] In addition, medically underserved minority and poor communities who historically have had limited access to health care services are largely unprepared to maximally benefit from evidence-based approaches to prevention and wellness. Many individuals and communities lack the necessary tools to prioritize their own health care needs, take advantage of these health services, or effectively participate in their own health decision making. For example, low health literacy has been found to be 3 to 5 times more common in minority populations, especially Hispanic adults.[6] Low health literacy is associated with increased hospitalizations and emergency room use, lower use of preventive measures (mammography, influenza vaccine), poorer ability to take medications appropriately, and poorer overall health status and higher mortality.[7-9] Recent immigrants less likely to have a usual source of care[10] and both Blacks and Hispanics are less likely than Whites to identify a doctor's office as their usual source of care.[11-14] Having a usual source of care, and especially a regular doctor,[15-17] is associated with better access to care,[15, 17, 18] and lower unmet needs,[17] and better utilization of preventive services[12, 16, 19-25] for both parents and their children.[26-28] Increasing community level capacity for effective and efficient healthcare utilization is essential to narrow the most pressing health disparities and achieve the Healthy People 2020 objectives.[29]

The stubborn health disparities that impact ethnically diverse and low-income populations are exacerbated by a complex array of social determinants and by fundamentally dysfunctional interactions with the health care system. Even after accounting for educational attainment, communication with health care providers is generally poor, and racial/ethnic and other linguistic minorities experience this phenomenon more acutely than white non-Hispanic individuals.[36] Racial, ethnic and gender discordance may also exacerbate the already uneven power dynamic that is inherent to the doctor-patient relationship. Furthermore, limited access to evidence-based health information that is tailored (in terms of gender, culture, language, and literacy level) to the needs of the individual effectively disenfranchises the communities that may have the most pressing health needs. In totality, these factors lead to generally low rates of participation in medical decision making and low levels of satisfaction among low-income and ethnic minority patients.[76] The proposed intervention is designed to address this problem by testing the effectiveness of community health workers trained according to a community-developed curriculum and functioning as personal educational and navigation aides to effectively empower

low-income women as consumers of the health care product, and in this way allowing them to take charge of their health.

II. OBJECTIVES

The overarching question addressed by this study is: Does access to a trained community health worker (CHW) improve newly enrolled Medicaid health plan members' engagement in the healthcare system? Specific research questions to be addressed by the proposed study include the following: 1) Does access to a CHW improve the likelihood of members identifying a primary care provider and completing a primary care intake visit during the year [primary outcome]; 2) Will the CHW intervention improve the use over the next year of each of the five reproductive preventive service recommendations made by USPSTF for women in this age group? 3) Will the CHW intervention lead over the next year to a decreased likelihood to use the emergency department and of preventable hospitalizations? 4) Does access to a CHW improve members' ability to make informed choices with regard to their use of the healthcare system and own health? 5) How many and what types of new Medicaid members take advantage of access to a CHW? 6) What resources are required to make these CHWs available to this population? Through our partnership with the University Family Care (UFC) health plan we will be able to perform subgroup analyses to explore differences by age group race/ethnicity, rural/urban, and border/non-border communities on both uptake (who chooses to use CHW services) and outcomes of the proposed intervention.

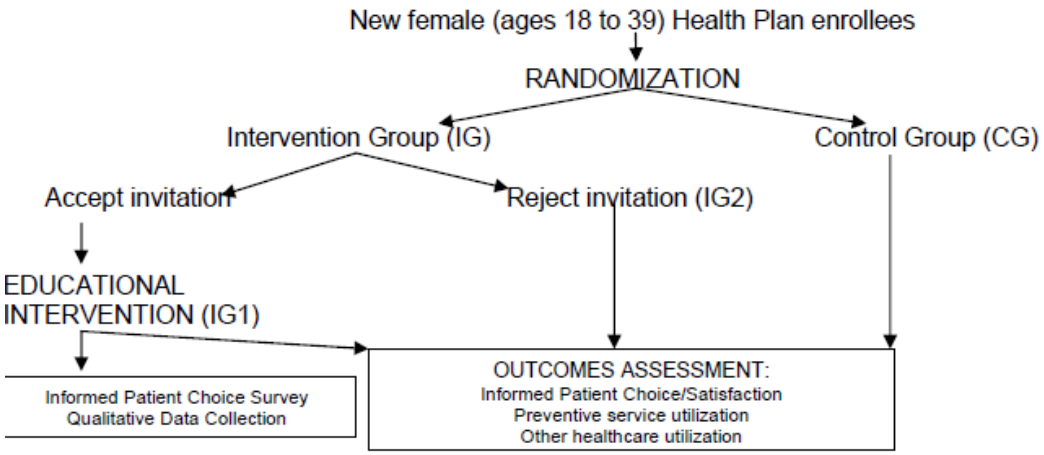
III. STUDY DESIGN

This project will use a mixed qualitative/quantitative pre/post study nested within a randomized controlled effectiveness trial. The intervention is conducted within the setting of a large regional Medicaid health plan that has a significant presence in southern Arizona. **The target population will be newly enrolled female health plan members between the ages of 18 and 39** who will be randomly selected to be invited to access a Community Health Worker (CHW) (the intervention arm), and those not selected will constitute the usual care control group. The University Family Care health care plan will provide the research team with a dedicated health plan analyst that will interface with the research team to set up the biased coin randomization process and procedures for the health plan claims data pulls, merges and de-identification, and the delivery of other member data including demographic characteristics, medical/pharmacy claims and member satisfaction surveys.

Once participants are randomized into the intervention arm they will be contacted by the Community Health Worker, who will be a University of Arizona employee, who will set up an individual confidential appointment with the potential participant. Appointment times and locations will be modified to meet the needs of the individual participant. Based on our experience, delivering CHW health education content, we anticipate that locations will vary and

include homes, health and community centers, schools, libraries, churches, supermarkets, as well as youth athletic events and neighborhood gatherings.

Study Schema



IV. STUDY ENROLLMENT

Study Population

Focus Group Participants

The first part of the project will recruit participants for a series of focus groups which will help finalize curriculum content and study surveys. A total of 30 participants will be recruited according to the following eligibility criteria:

1) Newly enroll members: University Family Care members who have recently enrolled in the health care plan. Less than 3 months from enrollment.
2) Previously enrolled and engaged: University Family Care members who are older enrollees (more than 3 months) and have had an appointment with their primary care physician.
3) Previously enrolled and not engaged: University Family Care members who are older enrollees (more than 3 months) and have not had any interaction with their family care provider.

Intervention Participants

Participants eligible for the intervention will include newly enrolled women in one of Arizona's state-wide Medicaid health plans (University Family Care) who are ambulatory and community-dwelling, and between the ages of 18-39.

Exclusion criteria includes: men, any women enrolled in the Medicaid plan that are not within our study's age range (18-39). We will not be actively recruiting pregnant women but if someone that is pregnant decides to participant, she will not be excluded from the study.

Recruitment Methods

Focus Group Recruitment

Recruitment will take place during the fall 2014 through spring 2015. Each focus group will range between 8 to 10 participants for a total of 30 participants in this component of the study. The purpose of the focus groups is to gather data in order to create questions to be used in the member satisfaction survey that will be administered with the potential participants in the next component of the study (e.g., the 1000 planned enrolled participants).

Participant recruitment will be facilitated by the University Family Care team who will identify potential participants and make the first study invitation. Since recruitment for focus group will be the first effort in reaching out to participant, UFC will start by testing 2 approaches for recruitment: 1) invitation by mail and 2) invitation by telephone. Once members agree to be in the study, referrals will be emailed to the program coordinator who will call the potential participant with more information about the study and dates for focus groups.

The study coordinator will use the following script to explain the project to participants. Depending on the primary language of the participant, the sample script for recruitment will be available in English or Spanish.

Sample Script for Recruitment for Focus Groups

Hello. You are invited to participate in a research study to learn about your thoughts about your use of health care services, any challenges you face in your health and obtaining healthcare, and how you would describe a successful interaction with your health care services provider.

We would like to interview a group of health plan participants and get your input. The benefits to you of doing this study are that you might learn some new things about yourself, your health care plan and you might enjoy sharing your ideas and feelings about accessing health services and limitations within the health services to health information. In addition, your participation in this study may help me and others better understand how to help women and families in our community navigate health care services and resources.

The research team and investigators will be the only people who know that you are participating in this study. Anytime I use the information you give me, I will always identify you with a fake name (if you would like, you can decide what name I use for you). When I interview you with a group of other health plan members, I would like your permission to record our interview and also take notes to remind me about what we talked about. I, my principal and co-investigators, and the research team will be the only ones who get to listen to these recordings. When I am not

using the recordings, they will be kept on a secure computer server that only we have access to. When I am not using the notes, they will be kept in a secure locked cabinet that only I have the key to. After I have finished with this study, all of these recordings will be kept on a secure locked cabinet for a time period required by The University of Arizona.

As part of your participation in this study, I will interview you with a group of 8 to 10 other health plan members about your use of the healthcare system, barriers/challenges you have encountered in obtaining healthcare and how you would describe a successful interaction with your health care provider. I have a few general questions I want to ask the group. If you want to share personal experiences, you may, but that is not expected. You will receive compensation for participating in this group interview.

The most important thing for you to remember while you are participating in this study with me is that there are no right or wrong answers to the questions I ask you. All I am looking for is your opinion or ideas or feelings, and if I ask you to tell me more, or explain your answer, it is because I want to be really sure I understand what you are telling me. Always remember that in this situation you are the expert, or teacher, and you are explaining to me what health resources are needed in your community.

You should also know that you can decide to not participate in this study, or stop doing it at any time after you have started—this is your decision. If you decide to stop doing this study, your decision will not affect any future contact you have with the University of Arizona.

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

Intervention recruitment

The intervention participants will be recruited monthly from the Arizona state-wide Medicaid health plan, University Family Care, newly enrolled women ages 18-39. Once members agree to be in the study, referrals will be emailed to the program coordinator who will forward the member's contact information to CHWs to call and schedule appointments. Potential participants will be called with detailed information about the study; overall purpose, benefits and what to expect if they decided to participate. This first phone call will also include a review and confirmation of study eligibility. If the participant agrees to be in the study, the CHW will schedule an appointment to conduct the 50 min face to face presentation. This first presentation will include 20 minutes for consent and baseline survey and 30 minutes for the educational content.

Sample Script for Recruitment for Intervention

Hello. You are invited to participate in a presentation by a community health worker, along with a short pre and post presentation survey, to learn about your satisfaction with services provided by the community health worker and your medical provider (s).

***The purpose** of the community health worker presentation is to provide you with knowledge about the appropriate reproductive health screening recommended for your age group and to share information about resources that are available to you through your health care plan.*

*We would like to get input from a large group of health plan members. **The benefits to you** of doing this study are that you might learn some new things about yourself, your health care plan's services and you might enjoy sharing your ideas and feelings about health topics and health resources.*

In addition, your participation in this study may help us better understand how to help women and families in our community navigate health care services and resources.

I, the principal and co-investigators, and the research team will be the only people who have access to your results of the pre and post surveys. All of the surveys and consent forms will be kept in separate locked cabinets. The project will also be asking for your permission in the form of signed a Protected Health Information for Research (PHI) to access to the following information from the University Family Care health plan: 1) Selection and use of a primary care provider; 2) Use of preventive services; and 3) Use of emergency and hospital services.

You will be asked to complete a 15 minute questionnaire at the beginning of the 30-minute Community Health Worker presentation. Booster telephone support calls will occur at 2 and 4 months after the Community Health Worker presentation to help you come up with questions you might want to ask your doctor specific to preventive services. At month 6, you will receive a call from a research team member to administer a 15 minute 6-month survey identical to the survey that was completed before the community health worker presentation. Compensation will be provided for your participation in the community health worker presentation.

We will provide presentations to 1000 participants each year for a total of three years. The most important thing for you to remember is that your participation in this study is completely voluntary. You should also know that you can decide to not participate in this study, or stop doing it at any time after you have started—this is your decision. If you decide to stop doing this study, your decision will not affect any future contact you have with the University of Arizona. An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

V. CONSENT PROCESS

Prospective participants will be informed that their participation is voluntary at the initial conversation about the study by the research team. During the initial conversation, prospective participants will also be informed about the consent process that will take place on the day of the interview or intervention presentation, including the need for the focus group interviews or interventions to be recorded.

The actual consent process will take place on the day of the focus group interview or the day of the intervention presentation (depending on which part the participant is being consented for), before the interview begins, for approximately 20 minutes. The facilitator (the PI, Co-PIs, or community health educator), will hand to each of the participants a written consent form explaining the purpose, procedures, and voluntary nature of the interviews. Since each interview or intervention will be conducted either in English or in Spanish, depending on the participant's language preference, consent forms will be available in English or Spanish (see Informed Consent forms in English). When the consent forms and questionnaires are introduced to them, all participants will be reminded that participation is voluntary and that they may withdraw at any time. The facilitator/CHW will then review the consent form orally as the participants follow along with their copy. The facilitator/CHW will then have participants sign the consent form. An additional copy will be provided to participants to keep for their own records.

Participants in the intervention group will also be informed that agreeing to the study will include signing the consent form along with the Protected Health Information for Research (PHI) form which will allow the University Family Care health plan to provide the research team with the following data for each participant that provides a signed consent and PHI form: 1) Selection and use of a primary care provider; 2) Use of preventive services; and 3) Use of emergency and hospital services.

Immediately prior to the interview, the facilitator will repeat the information verbally that participation is voluntary and that individuals may withdraw or refuse to answer any questions at any point in the study with no effect on their status with the University of Arizona. Of course, all participants will receive and sign consent forms that clearly state the voluntary nature of participation and that they may withdraw themselves at any time (see Informed Consent forms).

VI. STUDY INTERVENTION

Once the health plan analyst randomizes the newly enrolled Medicaid members, potential participants will be contacted by the health plan's call center. A brief verbal overview of the intervention including time requirement and content to be covered will be provided. The potential participants who have been randomly assigned to the intervention group will then be offered the opportunity to set up an individual confidential appointment with a community health worker (CHW) at her earliest convenience.

The call center will provide the research office a list of interested participants and their contact information. Once that list is received by the research office, a CHW will be assigned to each

potential participant. The assigned CHW will call to introduce herself, to answer lingering questions about the intervention and proposed encounter and to confirm the participant's acceptance into the intervention. At that time, the CHW will confirm language and location preference, date/ time of proposed meeting, and the contact information for the research office for any questions.

The intervention will include an initial 50 minute face to face meeting. The CHW will meet with the participant and complete the informed consent process. The participant will be asked to complete a questionnaire at the beginning of intervention presentation performed using a touch tablet device. The questionnaire prior to the presentation will gage baseline knowledge, patient preferences, informed decision making, and health literacy. Following the questionnaire, there will be a 30 minute intervention presentation. Lately, two boosters follow up call sessions at 2 months and 4 months post initial session.

1. First face-to-face presentation

The appointment will take place in a public location that is convenient for the participant and that is within the locations that have site authorization. These locations include all ***county public libraries*** and ***Pima county health departments***. The initial appointment will take approximately 50 minutes and will include:

1.1 Description of the intervention\study
1.2 Consenting process
1.3 Completion of research surveys\evaluation materials
1.4 Half hour presentation and questions

1.1 Description of the intervention

Community Health Workers will describe the purpose of the intervention and allow enough time for questions. The main purpose of this research project is to help recently enrolled members to navigate their health care plan and also help them learn about their benefits and their rights and covered reproductive health services/ screening.

1.2 Participant consenting

Since this intervention is part of a research study, individuals will be asked to provide consent to participate. Participants will be presented with two consent documents for this study: *1) Subject Consent Form, and 2) Authorization for the Use and Disclosure of Protected Health Information (PHI)*.

1.3 Data collection: completion of research surveys

Community health workers will administer the baseline survey according the QxQ document specifications. These surveys will be completed using the study iPads. CHW will be trained on the administration of the survey as well as the use of the survey software.

1.4 Educational Slides

The educational content has been designed as a power point presentation which will be delivered on an iPad. Each participant will receive their own copy of the UFC handbook to review during the presentation and a study handout with important resources. The educational presentation is organized to cover the following PCORI questions:

1) *Given my personal characteristics, conditions and preferences, what should I expect will happen to me?*
2) *What are my options and what are the potential benefits and harms of those options?*
3) *What can I do to improve the outcomes that are most important to me?*
4) *How can clinicians and health care delivery systems help me to make the best decisions about my health and health care?*

The content is designed as a presentation\reference guide to engage in a conversation and not necessarily as a script to follow verbatim. Notes in the form of bullet points are encouraged to help assure the delivery of all key areas of the intervention.

1.5 Conclusion

At the conclusion of the intervention, the patient will be encouraged to reach out to the CHW by telephone or electronically if she has any subsequent questions or concerns, and appointments for the two booster telephone calls will be scheduled. Finally, in consideration for her time and participation, the participant will be provided with a $40 gift card.

Fidelity Checks

All intervention presentations will be recorded by the CHW. The recording will start once the participant agrees to be in the study and signs all consent documents. The study coordinator will then randomly choose recordings to review intervention fidelity. These reviews will serve as an opportunity to continue training and expand on any specific area that may need additional information.

VII. STUDY FOLLOW UP

Booster Calls

Follow up calls will be done at 2- months and at 4-months after the first face to face meeting. At the end of the first meeting, CHWS will schedule a date for the first follow up call and give them a card with the appointment.

During the 2-month follow up call, CHW will elicit and address patient questions or concerns regarding:

- Women's health related preventive services
- Interactions with the health plan
- Interactions with the local healthcare system, including the identification and engagement with a primary care provider.

During the 4-month follow up call, ask the participant if they had a visit with the doctor and review the following:

- Other things you should know:
  - Do you know when and how to renew your insurance coverage?
  - How to know if your health care coverage has changed?
  - What happens if you decide to move to a different area?
  - What happens if the size of your family changes?
  - What are your member rights?

Areas discussed during each telephone call can be switched depending on the need of the participant and on whether the participant has seen their provider.

On each of these follow-up calls, CHWs will assure the participant that she can always call with questions or concerns regarding their health care plan.

6-Month Telephone Survey

At month 6, the participant will receive a call from a research team member. The 20 minute 6-month informed patient choice survey is identical to the survey that was completed at baseline along with participant satisfaction questions. This survey will be confidential with an identifying number matching pre and post surveys. A $40 gift card incentive will be offered to complete this survey.

VIII. APPENDICES

1. Subject Consent Form
2. Authorization for the Use and Disclosure of Protected Health Information (PHI)
3. Focus group recruitment script (English/Spanish)
4. Intervention recruitment script (English/Spanish)
5. Focus group recruitment letter (English)
6. Focus group recruitment letter (Spanish)
7. Intervention recruitment letter (English)
8. Intervention recruitment letter (Spanish)