‘Fourth Trimester’: A Web-based Tool for Postpartum Care to Increase Information Accessibility and Address the Complex Needs of Underserved Women
(P-20167)

Protocol Version: 4

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1.0 Project Overview

In the United States, the postpartum period is a critical time for both maternal and child health, the mortality rate is the highest among other developed, high income countries and more than half of all maternal deaths occur postpartum, from one day to one year after birth. This poor outcome is linked to the racial and ethnic disparities that disproportionately affect black women who are 3-4 times more likely to experience maternal mortality than white women. Recently, the American College of Obstetricians and Gynecologists recognized the deficiencies in postpartum care and coined the term the 'fourth trimester' to mark the time following the birth of the infant through the first 3-months postpartum, and updated its recommendations to address these challenges. With impacts to health outcomes and healthcare costs, there is a need to holistically bridge the gap for low-income and/or ethnically diverse groups of women to address the physical, cultural, and knowledge barriers to accessing quality postpartum care. To improve the rate at which underserved women are disproportionately affected by maternal mortality and morbidity, we need to engage women leading into and specifically during the postpartum period to identity areas of need, and to provide tools which reduce barriers for women to get appropriate postpartum care. Technology offers innovative solutions to challenges around equal information access. Pregnant women often turn to the internet to find out more information about their health and their developing babies health. Yet, studies find that mothers are not finding sufficient resources to match their postpartum needs. To address this gap in care, we will develop a mobile tool designed to increase accessibility to information and practical approaches for addressing the complex needs of women in this 'fourth trimester'. This tool will specifically focus on underserved women who are at greatest risk of adverse postpartum outcomes. We propose to complete three major tasks:

AIM 1: Gather input from key stakeholders to inform the design, key content, and interactive technological components of the mobile tool. To achieve this aim we will conduct formative qualitative research with pregnant women and women who have gone through the postpartum experience.

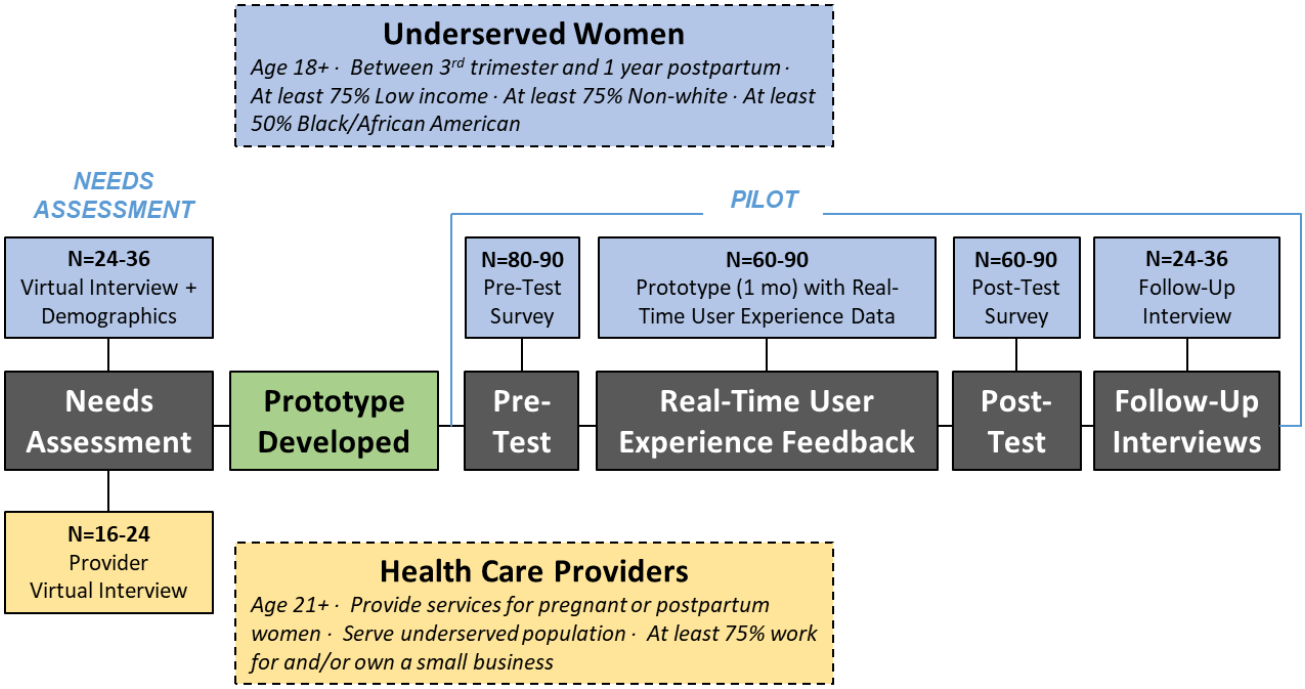
AIM 2: Develop a prototype to demonstrate the goals of the complete tool including sample content and interactivity, a detailed outline of content, and interactive features including real world examples and peer support. In collaboration with our clinical experts, we will draw on the knowledge gained in formative research in combination with relevant evidence-based practices to develop the prototype.

AIM 3: Demonstrate the acceptability, usability, feasibility and dissemination potential of the tool with input from key stakeholders and end-users in preparation for the Phase II effectiveness study. We will use quantitative and qualitative methods to assess the feasibility of the content, approach, and effectiveness of the program and identify the key measures for the Phase II study.

2.0 Research Design and Methods

The image below outlines each of the major activities occurring during each step, including those involving human subjects research. All study staff will be trained and certified in the protection of human subjects, and will be required to complete human research subjects training through either the Collaborative Institutional Training Initiative (CITI) Training Program or the Association of Clinical Research Professionals (ACRP) Human Subjects Protection Training. All data collection will be conducted by trained HealthCore and Orange Square research study staff and, in the case of limited interviews/focus groups, by an Orange Square subcontractor with specific expertise in this population. This subcontractor is serving as part of the Orange Square study team in a limited role. All electronic data collection will be conducted under Orange Square's study-specific Qualtrics license. Only HealthCore and Orange Square research staff will have access to this Qualtrics account. Lisa Marceau, HealthCore study PI and qualified qualitative researcher, will conduct study specific training for all study staff involved in the screening, recruitment, and conducting of focus groups and interviews. Training will include: a review of the study protocol, recruitment processes, screening procedures, participant communications, informed consent, and the appropriate methodology for conducting focus

groups and other study data collection activities. Ms. Marceau will have direct oversight over all data collection activities.



3.0 Current Status

Analysis, manuscript preparation and program development are currently underway. Additional protocol information is reserved to protect proprietary data and IP.