Breast cancer chemoprevention with selective estrogen receptor modulators (SERMs) and aromatase inhibitors (AIs) is underutilized, despite several randomized controlled trials demonstrating a 50-65% decrease in breast cancer incidence among high-risk women. Women with atypical hyperplasia (AH) or lobular carcinoma in situ (LCIS) have a 4- to 10-fold increased risk of breast cancer and derive up to a 70-80% relative risk reduction with SERMs or AIs. Reasons for low chemoprevention uptake include inadequate time for counseling, insufficient knowledge about SERMs and AIs, and concerns about side effects. We hypothesize that standard educational materials combined with decision support tools will increase chemoprevention informed choice compared to standard educational materials alone among women with AH or LCIS.

We have developed web-based decision support tools, RealRisks for high-risk women and BNAV (Breast cancer risk NAVigation tool) for healthcare providers. Our patient-centered decision aid, RealRisks, is available in English and Spanish and has been rigorously tested in multi-ethnic high-risk women of varying health literacy, numeracy, and acculturation. After exposure to these tools, we have demonstrated an improvement in accurate breast cancer risk perceptions, chemoprevention knowledge and informed choice among multi-ethnic high-risk women. Our objective is to integrate these tools into clinic workflow via the electronic health record (EHR) and expand their use in a multicenter trial targeting women with AH or LCIS. To evaluate effectiveness (Aim 1) and implementation (Aim 2), we will conduct a hybrid cluster-randomized trial at 40 sites of standard educational materials combined with RealRisks and BNAV or standard educational materials alone among 384 women with AH or LCIS. We will leverage the clinical trials infrastructure of the NCI Community Oncology Research Program (NCORP), including minority/underserved sites. Our primary effectiveness endpoint is chemoprevention informed choice at 6 months after enrollment (Aim 1). Secondarily, we will assess chemoprevention knowledge, perceived breast cancer risk/worry, and decision conflict at baseline, 6 and 12 months, as well as shared decision-making and chemoprevention uptake/adherence. For the implementation component of the trial (Aim 2), we will evaluate the impact of portal integration of the decision support tools using surveys and key informant interviews of healthcare providers, including specialists and primary care providers, and high-risk women with AH or LCIS to better understand barriers and facilitators to chemoprevention uptake. We will use the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework for the implementation evaluation.

This proposal seeks to overcome important barriers to chemoprevention uptake among diverse women with AH or LCIS, a population of high-risk women that is more likely to benefit from SERMs and AIs. Providing EHR-integrated decision support for patients and providers has the potential to improve informed shared decision-making about breast cancer chemoprevention, which is sustainable and may be widely disseminated.