Title

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Abstract OT-21-01: Personalized breast cancer screening in a population-based study: Women informed to screen depending on measures of risk (WISDOM)

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Abstract

Background: WISDOM is a 100,000 healthy women preference-tolerant, pragmatic study comparing traditional annual screening to personalized risk-based breast screening. The novelty of WISDOM personalized screening is the integration of previously validated genetic and clinical risk factors (age, family history, breast biopsy results, ethnicity, mammographic density) into a single risk assessment model that directs the starting age, timing, and frequency of screening. The goal of WISDOM is to determine if personalized screening, compared to annual screening, is as safe, less morbid, enables prevention, and is more accepted by women. The study is registered on ClinicalTrials.gov, NCT02620852.

Methods: Women aged 40-74 years with no history of breast cancer, DCIS or previous double mastectomy can join the study online at wisdomstudy.org. Participants can either elect randomization or self-select a study arm. Then, they provide electronic consent and sign the Release for Medical Information via DocuSign. For all participants, 5-year risk of developing breast cancer is calculated according to the Breast Cancer Surveillance Consortium (BCSC) model. Participants in the personalized arm undergo panel-based mutation testing (BRCA1, BRCA2, TP53, PTEN, STK11, CDH1, ATM, PALB2, and CHEK2), and their 5-year risk is calculated using the BCSC score combined with a Polygenic Risk Score (BCSC-PRS) that includes 229 single nucleotide polymorphisms (SNPs) known to increase breast cancer risk. The SNPs and mutations are assessed by saliva-based testing through Color Genomics. Five-year risk level thresholds are used to stratify participants as low-, moderate- and high risk. Risk stratification determines age to start, stop, and frequency of screening in the personalized arm.

Accrual: As of July 2020 the WISDOM Study is open to all eligible women in the United States. To date, 38,762 eligible women have registered, and 28,706 women have consented to participate in the trial. The median age is 56 years. Seventy-seven percent of participants are Caucasian, 2% African-American, 5% Asian, and 8% of self-reported Hispanic ethnicity. WISDOM is partnering with Blue Cross Blue Shield Association for regional plan opt-in coverage, self-insured companies (Salesforce, Genentech, Qualcomm, CalPERS) and Medi-Cal (Inland Empire Health Plan) using a coverage with evidence progression approach.

Accrual expansion and diversity: To ensure that resulting data are meaningful and potentially practice-changing for all populations of women, the WISDOM Study is enhancing the diversity of our participant population by establishing WISDOM sites in diverse areas with large African-American (Alabama, Louisiana, Illinois) and Latina (Florida) populations. These new recruitment sites, intentionally selected for the diverse communities they serve, have established partnerships with community organizations and outreach navigators. Additionally, we have translated the WISDOM Study to Spanish to facilitate access by Latina communities. With the engagement of patient advocates and community partnerships, expanding diversity in the study population will strengthen our scientific knowledge of breast cancer risk and improve access to personalized breast cancer screening recommendations for all women. Enrollment will continue through 2022.

Conclusions: Results of 5 years follow-up will enable us to demonstrate whether personalized screening improves outcomes for future patients and it improves healthcare value by reducing screen volumes and costs without jeopardizing outcomes.

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