EH21-338: Observational and Prospective Study on the Performance of Inherited Risk Assessment for Predicting Prostate Cancer from Prostate Biopsy (GenBx)

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Prospective study on the performance of inherited risk assessment for predicting prostate cancer from prostate biopsy

Analytical plan

Outcome variable: Diagnosis of PCa from prostate biopsy.

Inherited risk assessment: Rare pathogenic mutations (RPMs) in 11 guideline-recommended genes and genetic risk score (GRS) based on published GWAS (genome-wide association studies)-significant SNPs. Patients will be classified into three groups based on inherited risk: high-risk (RPMs+ and/or GRS ≥1.5), low-risk (RPMs- and GRS <1.5), and intermediate-risk (remaining subjects).

Other variables: Age, race/ethnicity, body mass index (BMI), PSA, as well as Prostate Health Index and MRI results if they are available.

Blind design: Prostate biopsy will be performed prior to inherited risk assessment. Inherited risk assessment will be performed blinded to the biopsy outcomes.

Data analysis:

1. Descriptive analysis of prostate cancer detection rate in three inherited risk groups.
2. Trend test for higher prostate cancer detection rate in patients with increasing inherited risk (low, intermediate, and high) using a chi-square test for linear trend.
3. Association of inherited risk (high vs. remaining) with diagnosis of prostate cancer using multivariate logistic regression adjusting for age, race, BMI, and PSA.