

320: The 17-gene genomic prostate score assay: Initial commercial experience of 4,000 patients

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## **Introduction & Objectives**

The Oncotype DX<sup>®</sup> Prostate Cancer Assay (Genomic Health Inc. Redwood City, CA) is a biopsy-based gene expression assay that has been clinically validated to predict the likelihood of aggressive prostate cancer (PCa) at time of diagnosis (adverse pathology and biochemical recurrence). Here we report the commercial clinical laboratory experience from the first 4,000 patients tested.

## **Material & Methods**

4,000 samples that passed pathology review and RT-PCR quality measures were included. The Genomic Prostate Score (GPS, scale 0-100) was calculated based on the validated algorithm of 12 cancer-related and 5 reference genes. NCCN<sup>®</sup> clinical risk group classification was provided by submitting physicians. All submitted biopsy samples were centrally reviewed at GHI for Gleason score (GS). Descriptive statistics for the GPS were obtained.

## **Results**

Greater than 99% of assays submitted were successful. Assays were received from 11 countries (majority USA). The mean GPS for the cohort was 24.9 (median 23, range 0-97). 3,162 samples (79.1%) were GS 3+3 (mean GPS 23.1, range 0-97) and 838 samples were GS 3+4 (mean 31.7, range 0-83). By age, 444 patients (11.1%) were <55y, 1,685 (42.1%) 55-65y, 1,871 (46.8%) >65y, with a mean GPS result of 21.2 (range 0-90), 23.5 (range 0-97), 27.0 (range 0-82) respectively. Of patients with NCCN risk classification provided (n=3,814), 29.7% (n=1,131) patients were classified as very low, 38.9% (n=1,484) low, and 31.4% (n=1,199) low-intermediate risk, and had a mean GPS of 22.2 (range 0-78), 23.3 (range 0-97), and 29.4 (range 0-90), respectively. Use of the GPS changed risk assessment in 25.4% (967/3,814) of patients with a pre-assigned NCCN risk. Among NCCN low risk patients, GPS changed risk assessment in 48.0% of patients; risk assessment decreased from low to very low in 36.9% and increased from low to low-intermediate in 11.1% of cases.

## **Conclusions**

The GPS results in the first 4,000 commercial biopsy samples displayed a broad range within each GS, age, and NCCN risk group, suggesting a wide spectrum of individual tumor biology within current clinical risk assessment categories. The risk reclassification by the GPS in this large commercial database is consistent with the results of the UCSF validation cohort. Use of the GPS improved risk stratification for men with newly diagnosed PCa, providing physicians and their patients personalized information to make educated treatment decisions regarding the initial management of their disease.