Title: A randomized controlled trial of video-education or in-person genetic counseling for men with prostate cancer (ProGen)

Background: Approximately 10% of men with advanced prostate cancer (PC) have pathogenic/likely pathogenic variants (PV) in cancer susceptibility genes and their identification may lead to targeted therapy. Genetic testing (GT) can also guide cancer surveillance and prevention for family members. While GT is recommended for men with potentially lethal PC, traditional testing models are strained, and access limited. The ProGen study examined a novel pretest model aimed at providing access to GT while promoting informed consent.

Methods: Inclusion criteria were: potentially lethal PC (metastatic, localized with Gleason score ≥8, rising/persistent PSA after local therapy), diagnosis age ≤ 55 years, prior malignancy, family history suggestive of a PV and/or at oncologist's discretion. Consented subjects from 3 sites were randomized 3:1 to video education (VE) or in-person genetic counseling (GC). Subjects who consented to GT had 67 genes analyzed (Ambry, USA) with results disclosed by telephone by a genetic counselor. Outcomes included GT uptake, PV prevalence, and survey measures of satisfaction, distress, genetics knowledge, family communication, and impact on cancer care (obtained at the time of intervention, and at 1, 4, and 12 months after result disclosure). Two-sided Fischer exact tests were used for between-arm comparisons.

Results: Over a 2-year period: 662 subjects were randomized, VE or GC were completed by 604 subjects (VE: 93.1%, GC: 88.8%) of whom 596 subjects (VE:98.9%, GC:97.9%) consented to GT. To date, 591 subjects have completed GT (VE: 99.3%, GC: 98.6%). At the time of intervention, most subjects agreed or strongly agreed that their assigned arm was useful (VE: 95%, GC: 88%). Differences were not statistically significant. Notably, 84 PV were identified in 78 subjects (13.2%), with *BRCA1/2* PV accounting for 32% of subjects with a positive result (*BRCA2*:21, *BRCA1*:4).

Conclusions: In this randomized trial, both novel VE and traditional GC yielded high GT uptake without significant differences in outcome measures of acceptability and satisfaction. VE enabled access to critical GT results while maintaining the core tenants of informed consent. PV were found in 13.2% of subjects, 32% of whom had *BRCA1/2* PV. Analysis of collected survey data to inform strengths and limitations of VE as compared with pretest GC will be presented.