with breast cancer. Tumor-only CGP identified a missense variant in *TP53* with a high variant allele frequency (67.7%). Given the patient's son's history of acute myeloid leukemia, Li-Fraumeni syndrome (LFS) was suspected, and confirmatory testing was recommended. The test result was negative, which helped exclude the diagnosis of LFS.

Conclusion: Our protocol represents a comprehensive approach to management of PGPVs that uniquely addresses both cancer predisposition syndromes and other genetic diseases. The protocol's structured framework, particularly its emphasis on initial phenotype assessment and confirmatory testing criteria, helps to ensure appropriate variant evaluation and disclosure. While this strategy may identify more variants with lower levels of evidence, it allows for the detection of rare genetic diseases that may be missed in cancer-focused protocol. Though developed at a single institution, this systematic approach could be applicable to other institutions implementing CGP. Regular updates will be necessary as testing technologies evolve and new evidence emerges regarding the clinical significance of germline variants.

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Biomarker testing patterns among patients newly diagnosed with non-small cell lung, prostate, and bladder cancer

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Introduction: Clinical biomarkers can provide valuable insights into the diagnosis, prognosis, and disease progression and offer the potential to select targeted treatments for patients with cancer based on an individual's variant profile. This study aimed to characterize biomarker testing patterns among patients newly diagnosed with non-small cell lung cancer (NSCLC), prostate cancer, and bladder cancer treated within a large oncology network of community-based providers located in the West South-Central United States.

Methods: Using a database of discrete structured and non-structured data, and electronic medical records, we retrospectively analyzed the diagnostic and treatment journeys of individuals newly diagnosed with NSCLC, prostate cancer, or bladder cancer between January 1, 2018, and June 30, 2022. Several data sources, including iKnowMed (EMR), Ellkay CareEvolve (Genetic HL7 interface), and the Molecular Data Warehouse, were used and covered approximately 1.7 million unique patients. Baseline demographics and clinical characteristics were summarized descriptively, and the proportion of patients who received biomarker testing was determined.

Results: Among patients with NSCLC (n=16,924), prostate cancer (n=18,743), and bladder cancer (n=3717), testing patterns and time to treatment initiation varied widely. Both broad panel and single gene tests were performed on 42%, 25%, and 50% of patients with NSCLC, prostate, and bladder cancer, respectively. Among patients with Stage IV disease (n=11,394), 45% (NSCLC; n=2926), 23% (prostate; n=941), and 27% (bladder; n=194) received biomarker testing, excluding patients whose tests were ordered and results interpreted by hospital pathology staff. Overall, the mean time from disease diagnosis to first biomarker test was 60 days for patients with NSCLC, 156 days for patients with prostate cancer, and 115 days for patients with bladder cancer, with variations observed by patients' reported race/ethnicity. In particular, among Hispanic patients with NSCLC (n=1694), the mean time from diagnosis to testing was 36 days. In patients with prostate cancer, the mean time was 214 days for Non-Hispanic Black or African American patients (n=1332) and 301 days for Non-Hispanic Asian patients (n=152). Among non-Hispanic Black or African American patients with bladder cancer (n=136), the mean time was 272 days. The mean time from testing to any treatment initiation was 28 days, 113 days, and 92 days for patients with NSCLC, prostate cancer, and bladder cancer, respectively. The time from testing to treatment in the Non-Hispanic Asian group across all cancer types was 66 days (NSLC), 253 days (prostate cancer), and 180 days (bladder cancer). Hispanic patients with prostate cancer (n=2369) had a shorter mean time from testing to treatment initiation (51 days) than the overall cohort (113 days). Additionally, Non-Hispanic Black or African American patients with bladder cancer (n=136) had a longer mean time from testing to treatment initiation (265 days) than the overall cohort (92 days). Among all patients who were tested and had an actionable mutation, 15% (NSCLC), 8% (prostate cancer), and 5% (bladder cancer) received targeted therapy. During the study period (ie, 2018 to 2022), the mean time from ordering a biomarker test to receipt of results decreased for each cancer type: 29 days to 24 days (NSCLC), 78 days to 19 days (prostate cancer), and 67 days to 27 days (bladder cancer). Overall, biomarker testing rates generally increased year-on-year from 2018 to 2022.

Conclusion: These findings suggest that although biomarker testing, overall, is suboptimal in the community practice setting, there was an improvement in terms of the increase in the percentage of patients tested during the study period and the reduction in time between the test date and receipt of results. These data indicate an opportunity to build upon these early improvements noted, while also evaluating current barriers to biomarker testing and the educational needs of community practitioners.

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Withdrawn