Understanding Current Practice and Utilization of Prostate Cancer Biomarkers among PURC Providers

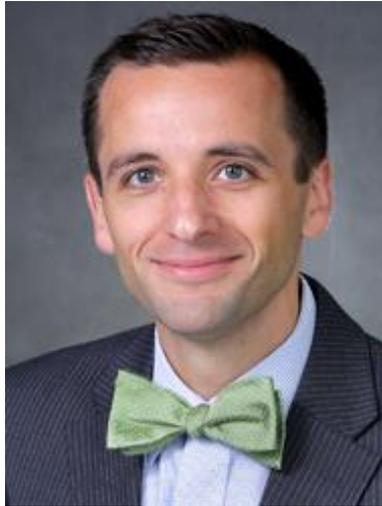PURC Genomics Working Group Survey Results

February 2018

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Message from the Chair

Hello and greetings from the Genomic/Biomarker Working Group! As the newest working group within PURC, we are excited to explore the ways in which the rapidly expanding prostate cancer biomarkers are being utilized across providers and practice sites. Prostate cancer biomarkers have exploded onto the clinical scene, and little data are available regarding their appropriate utilization and efficacy. The continued rapid expansion of available tests creates a challenge for clinicians tasked with appropriate test selection. The ultimate goal of the biomarker working group is to analyze practice patterns, understand factors affecting test utilization, and minimize inappropriate testing. Understanding biomarker utilization within PURC will ultimately improve provider education and reduce patient morbidity. We look forward to using our collaborative data to define the future of appropriate prostate cancer biomarker testing.

Sincerely,

Jeffrey J. Tomaszewski, MD
PURC Genomics Working Group Chair
MD Anderson at Cooper University Hospital

PURC Collaborative Overview

Background

Established in February 2015, PURC is an initiative that brings urology practices together in a physician-led, data sharing and improvement collaborative aimed at advancing the quality of diagnosis and care for men with prostate cancer. Participating practices submit data into the PURC registry on a variety of prostate cancer quality measure categories, including biopsy, imaging, treatment, radical prostatectomy, cancer characteristics, and volume. As of January 2018, the 9 participating practices have entered over 6,200 patients into the PURC data portal.

Collaborative Goals

1. Provide a reliable, sustainable platform for prostate cancer data collection
2. Reduce variation in care delivery and utilization of services for men with newly diagnosed prostate cancer
3. To measure, understand, and influence outcomes following prostate biopsy and radical prostatectomy
4. Improve patient-centered decision making among men faced with treatment choices for clinically localized prostate cancer

Collaborative Participants

Einstein Health Network
Fox Chase Cancer Center
Geisinger Health System
Hospital of the University of Pennsylvania
Jefferson Urology Associates
MD Anderson at Cooper University Hospital
Penn State Milton S. Hershey Medical Center
Temple University Hospital
Urology Health Specialists

Physician Leadership
- PURC Executive Director: Robert Uzzo, MD, FACS; Fox Chase Cancer Center
- Regional Clinical Champion: Marc Smaldone, MD, MHSP; Fox Chase Cancer Center
- Practice Site Physician Champions:
    - John Danella, MD; Geisinger Health System
    - Serge Ginzburg, MD; Einstein Health Network
    - Thomas Guzzo, MD, MPH; Hospital of the University of Pennsylvania
    - Thomas Lanchoney, MD, FACS; Urology Health Specialists
    - Jay Raman, MD; Penn State Milton S. Hershey Medical Center
    - Adam Reese, MD; Temple University Hospital
    - Jeffrey Tomaszewski, MD; MD Anderson at Cooper University Hospital
    - Edouard Trabulsi, MD; Jefferson Urology Associates

Executive Team and Working Groups

An executive team convenes on a triannual basis for the purpose of evaluating collaborative progress and determining collaborative direction. The committee, which consists of physician champions, clinical abstractors, urology leaders, and patient advocates, is chaired by Marc Smaldone, MD, Fox Chase Cancer Center and supported by the Health Care Improvement Foundation. The purpose of the executive team meetings is for members to collaborate and provide expert input into the following:

- Continual analysis and evaluation of regional patterns of care and treatment outcomes;
- Identification of unwarranted variations in care and outcomes;
- Identification of specific care processes associated with better patient outcomes;
- Development and dissemination of improvement strategies and best practices;
- Periodic review of program activities and deliverables to ensure optimal support of participants.

In addition, PURC has established four (4) working groups, which are comprised of providers and clinical abstractors from participating practices. The working groups allow for the opportunity to review registry data, develop measures, identify quality improvement opportunities, and share protocols and experiences. Working groups share their findings and recommendations with the executive team for continued collaborative discussion. The four (4) working groups are as follows:

- Active Surveillance Working Group, Chair Adam Reese, MD, Temple University Hospital;
- Biopsy Working Group, Chair Thomas Lanchoney, MD, Urology Health Specialists;
- Genomic Working Group, Chair Jeffrey Tomaszewski, MD, MD Anderson at Cooper University Hospital;
- Imaging Working Group, Chair Serge Ginzburg, MD, Einstein Health System.

Executive Summary

Survey Development and Administration

On October 20, 2017, PURC distributed a web-based survey to all actively participating urologists via email to assess current practice patterns and utilization of prostate cancer biomarkers among PURC providers. The Genomics Working Group, chaired by Jeffrey Tomaszewski, MD, requested the development and distribution of the survey with the hopes to use the results to identify quality improvement and education opportunities regarding appropriate genomic test utilization.

The *Understanding Current Practice and Utilization of Prostate Cancer Biomarkers among PURC Providers* survey comprises of 15 questions. The survey begins by collecting demographic information about the urologist, including name, urology practice, years of experience, and practice setting. Then, the survey asks questions regarding biomarker utilization and how comfortable the urologists are with the genomic tests' indications and clinical utility data. The next set of questions address when PURC urologists think biomarkers are most beneficial. The survey concludes with three clinical scenarios to further validate how the providers would respond and if providing biomarker education could be of benefit.

Survey Response

The PURC coordinating center distributed the survey to 93 active providers across the nine organizations participating in PURC. Of these 93 urologists, 36 completed the survey, resulting in a response rate of 39%. At least one urologist from all 9 practices completed the survey.

Summary of Survey Results

Biomarker Utilization and Comfort Level
  - 75% of respondents use biomarkers
  - 72.2% of respondents are comfortable with the indications for biomarkers
  - While the majority of respondents are comfortable with the clinical utility data for prostate cancer biomarkers, 41.7% are skeptical. Some urologists expressed that the utility of the data is limited for some patients.
  - Oncotype, a genomic test, is ordered by 51.4% of respondents, and is the most commonly utilized test.
  - PHI, a relatively new biomarker test that is based on mathematical calculations of PSA numbers, is ordered by 11.4% of respondents, resulting in the least commonly utilized test.
  - When asked if additional biomarker education would increase test utilization, 75% of respondents said it would do so.

Biomarker Utility
- Nearly all respondents (97.2%) would recommend a biomarker test that has 98% NPV.
- PURC urologists consider biomarkers most effective for patients with therapeutic risk stratification and treatment selection or persistent PSA elevation and a prior negative biopsy.
- 86.1% of respondents would not recommend a biomarker test for a biopsy naïve patient with an elevated PSA between 2.5 and 10.
- Concern for patient cost and doubt of clinical efficacy are the most common reasons why PURC urologists do not routinely order prostate cancer biomarkers. 11.8% of respondents indicated that their lack of knowledge about biomarkers are the primary factor why they do not routinely order the tests.
- For patients that have had more than one prior negative biopsy, 52.8% of respondents would recommend a diagnostic biomarker test. 11.1% of respondents preferred obtaining an MRI over a biomarker test.

Clinical Scenarios
- Only 5.6% of respondents would recommend a biomarker for biopsy naïve patients with elevated PSA.
- 20.5% of respondents selected an inappropriate biomarker test for a 60-year-old male that had a robotic prostatectomy for pT3aN0Mx Gleason 4+3 prostate adenocarcinoma (negative margins) and an undetectable post-op PSA.
- For patients with persistent PSA elevation and a prior negative biopsy, 36.1% chose an alternative next step to biomarker testing.

Recommendations

Based on survey results, the Genomic Working Group recommends the following next steps:
- Disseminating educational materials to all practice sites and providers regarding prostate cancer biomarker utilization to improve efficiency and reduce inappropriate testing.
- Distributing educational handouts that illustrate cost and insurance coverage for the commonly utilized biomarkers.
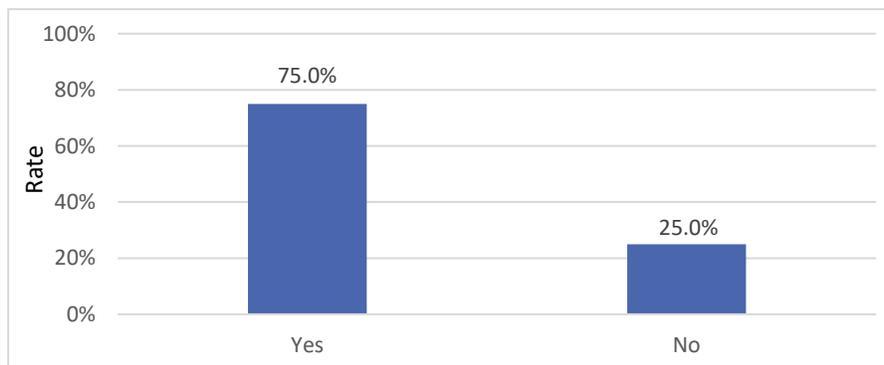
Appendix: Survey Results

1. How many years have you been practicing Urology? (n = 36)
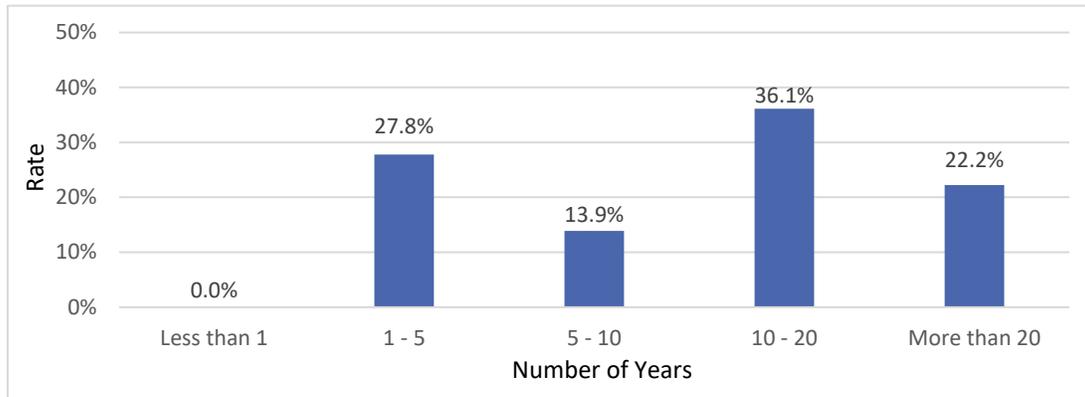
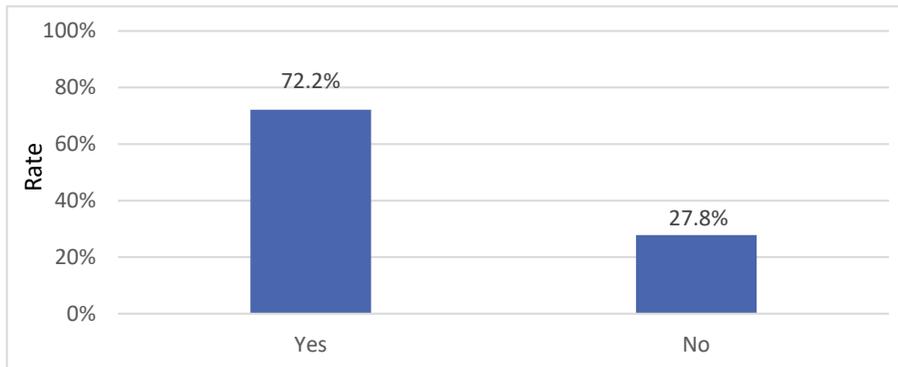**2. What is your primary practice setting?** (n = 36)
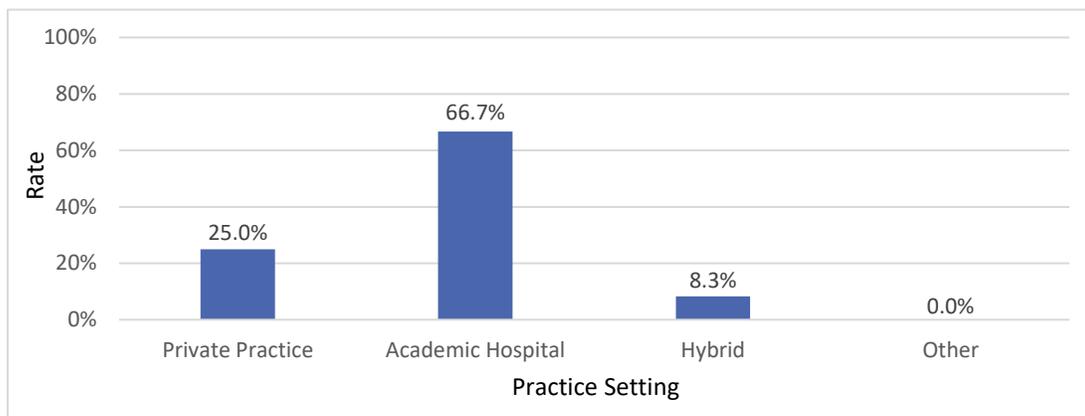
3. Do you use prostate cancer biomarkers in your prostate cancer patients? (n = 36)
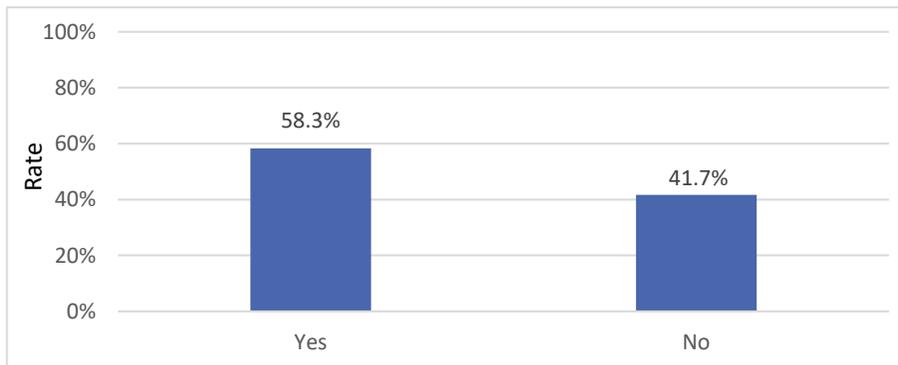

Comments:

- PSA, Free PSA, PCA3

4. Are you comfortable with the indications for the commonly available prostate cancer biomarkers? (n = 36)

Comments:
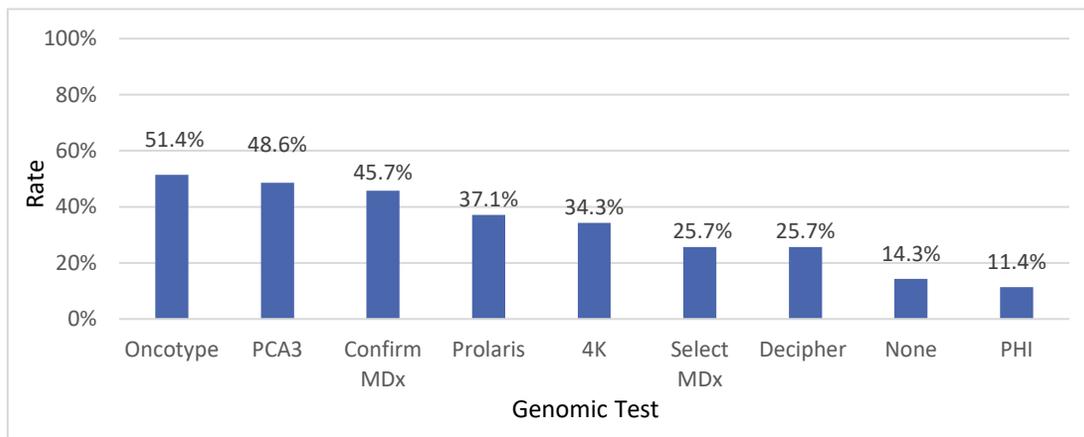- A lot of subjectivity in their indications

5. Are you comfortable with the clinical utility data for prostate cancer biomarkers? (n = 36)
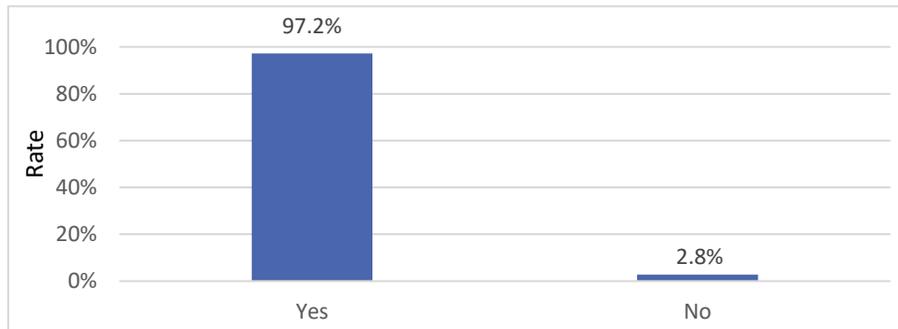

Comments:
- My view: they remain of limited utility, for selected men
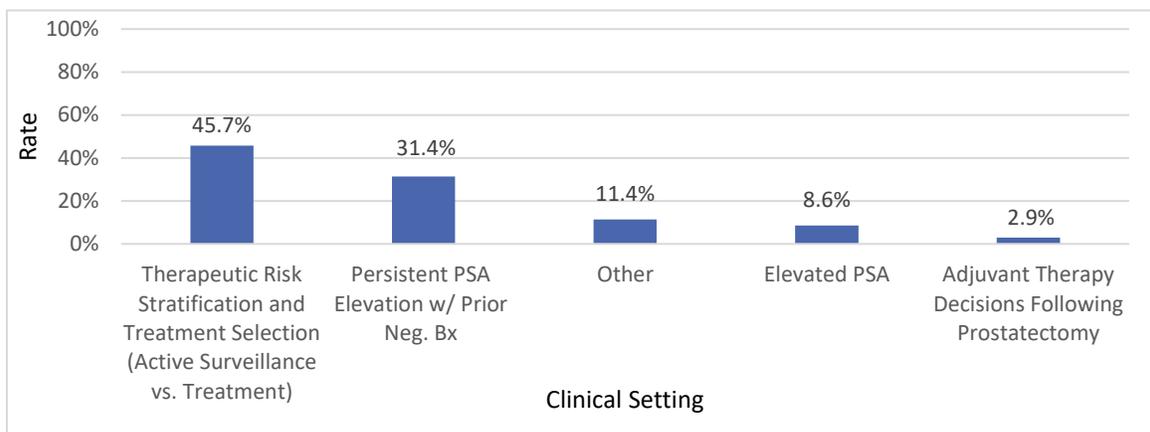- Subjective in their applications

6. Which prostate cancer biomarker tests are you comfortable using, and which do you routinely perform (select all that apply)? (n = 35)

7. Would you recommend a biomarker test that has a 98% NPV, meaning that in case of a negative test only 2% of clinically significant cancers would be missed? (n = 36)

Chart: Bar chart with vertical axis labeled "Rate" ranging 0% to 100%.
- Yes: 97.2%
- No: 2.8%

8. In what clinical setting are prostate cancer biomarkers the most useful? (n = 35)

Chart: Bar chart with vertical axis labeled "Rate" ranging 0% to 100%, horizontal axis labeled "Clinical Setting".
- Therapeutic Risk Stratification and Treatment Selection (Active Surveillance vs. Treatment): 45.7%
- Persistent PSA Elevation w/ Prior Neg. Bx: 31.4%
- Other: 11.4%
- Elevated PSA: 8.6%
- Adjuvant Therapy Decisions Following Prostatectomy: 2.9%

Responses for "Other":
- All of the above clinical settings
- Persistent PSA elevation/negative biopsy AND therapeutic risk stratification
- Use biomarkers for persistent PSA elevation with negative biopsy, therapeutic risk stratification, and adjuvant therapy decisions following prostatectomy
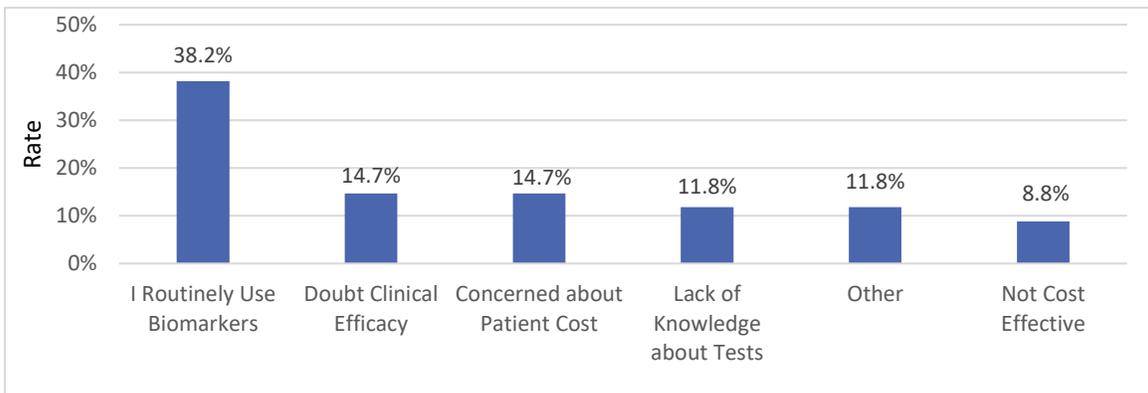
9. Do you recommend diagnostic biomarker test(s) for prostate cancer for biopsy naïve men seeking advice because of an elevated PSA (2.5 - 10)? (n = 36)

Chart: Bar chart with vertical axis labeled "Rate" ranging 0% to 100%.
- Yes: 13.9%
- No: 86.1%
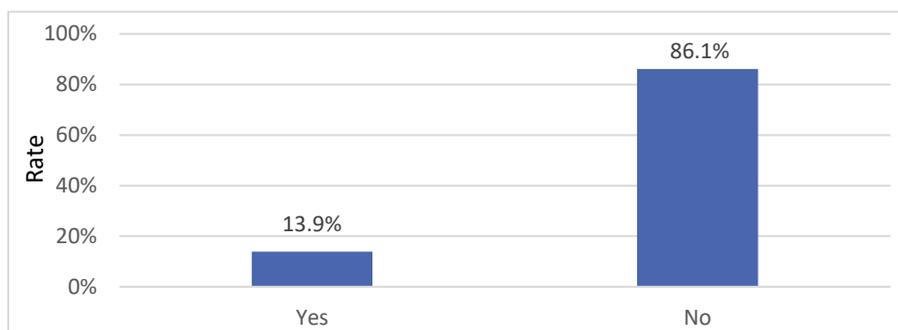
Comments:
- mpMRI has much higher utility in this situation

10. If you don't routinely order prostate cancer biomarkers, which of the following best describes why? (n = 34)

Responses for "Other":
- Limited outcome data
- Doubt about clinical utility compared to MRI and concern for patient cost
- Use in select cases
- Use mpMRI in equivocal cases

11. Do you recommend diagnostic biomarker test(s) for prostate cancer for men who had > 1 prior negative biopsies? (n = 36)
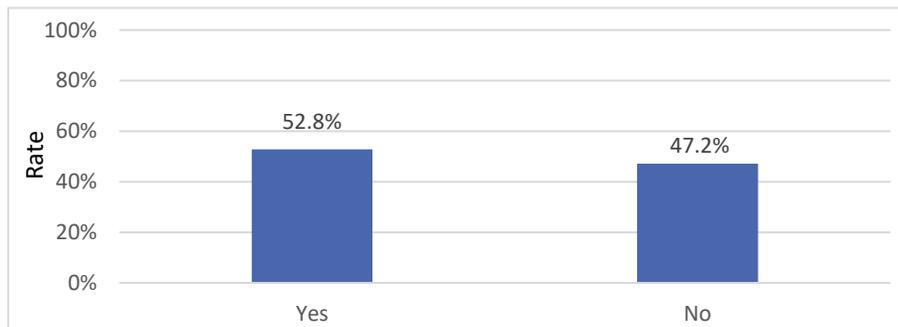
Comments:
- Four respondents indicated they would use MRI in this case
- Occasionally, Confirm MDx or PCA3

12. A 65-year-old male was referred to you by his PCP because he is anxious about having prostate cancer. His PSA is 5.2ng/mL with an estimated prostate volume of 70cc. He has no family history of prostate cancer, a normal digital rectal examination, and no prior biopsies. How would you proceed? (n = 36)
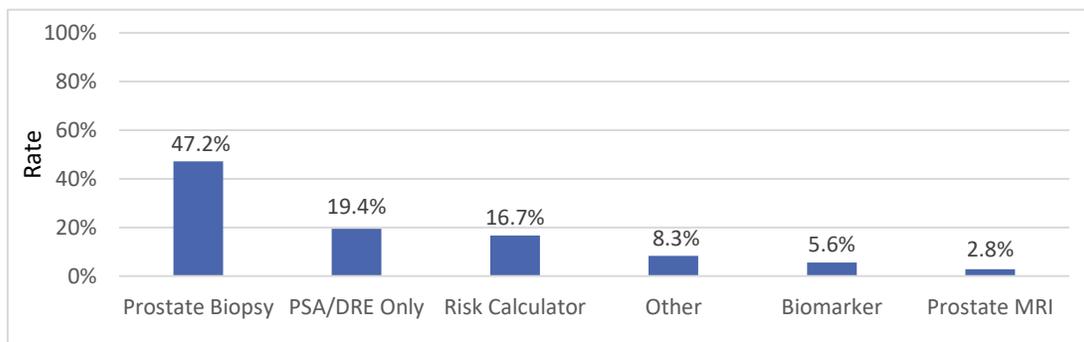
Responses for "Other":
- Repeat PSA: free/total. If elevated still, then Select MDx or 4k
- Shared decision making with current data only
- Repeat PSA and if still elevated, then recommend biopsy

13. **A 60-year-old male undergoes robotic prostatectomy for pT3aN0Mx Gleason 4+3 prostate adenocarcinoma (negative margins). His first post-op PSA is undetectable. Which of the following tests would be most appropriate in this setting?** (n = 34)
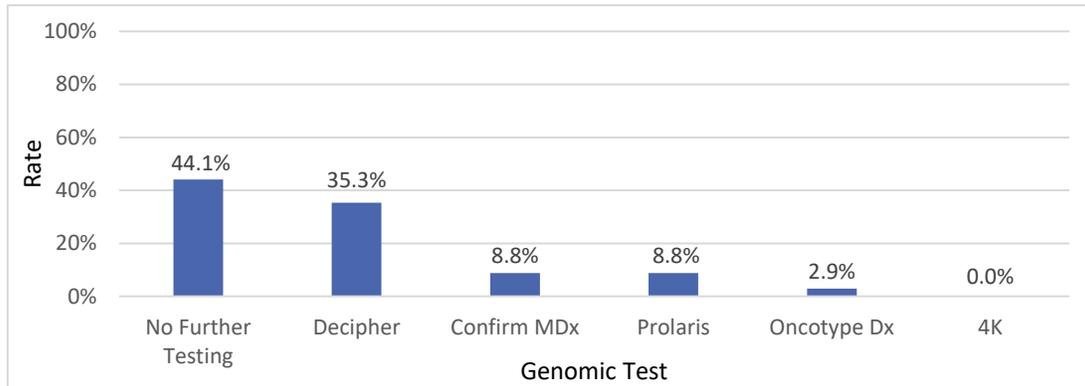
Comments:
- Recommend Adjuvant XRT
- PSA every 3 months
- A single genetic test is not superior to Partin Tables, but a conglomeration of available tests is superior

14. **A 62-year-old male with a PSA of 5.0ng/mL and a prostate volume of 35cc undergoes a 12-core TRUS guided prostate biopsy. All 12 cores reveal benign prostate tissue. His repeat PSA 6 months later is 6.2ng/mL. Which test would be most useful in this setting?**
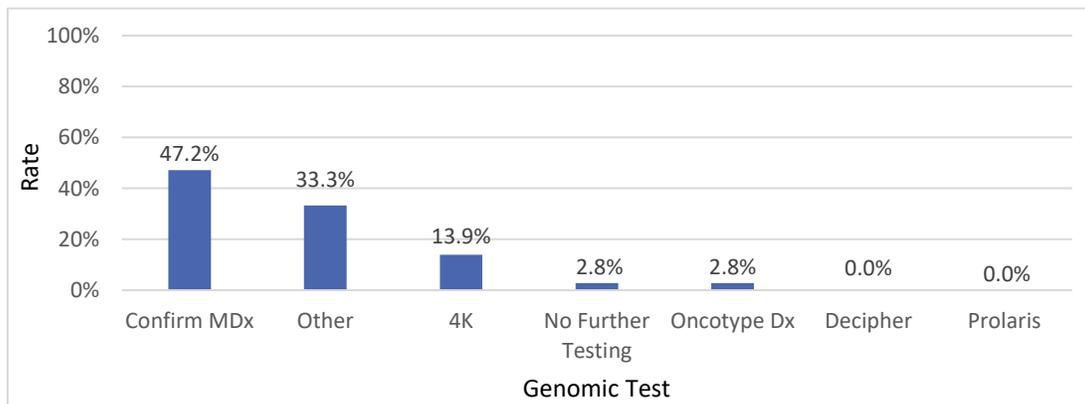
Responses of Other:
- **Order mpMRI**
- **Repeat PSA**
- **Depends on DRE**
- **PCA3 and/or free PSA**

15. Would further education regarding the appropriate utilization of biomarkers increase your likelihood of test usage?
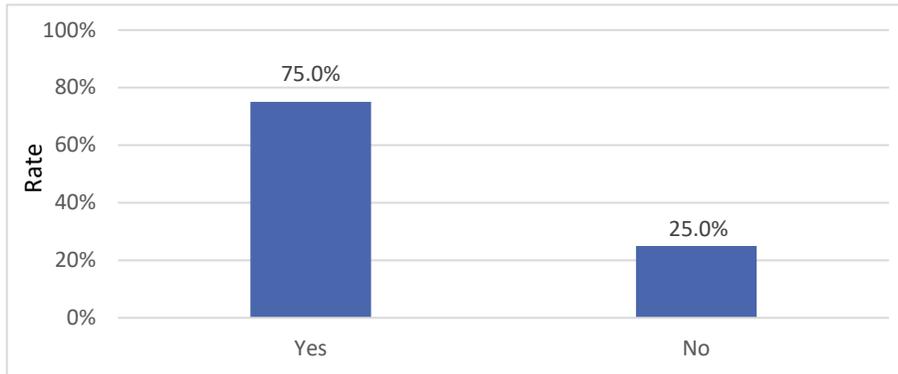
Comments:
- Thought-leader evidence based guideline
- Need convincing of utility
- Would like to view real information about costs to patients and overall cost

If you have any questions about this report, please contact Claudette Fonshell at cfonshell@hcifonline.org or (215) 575-3747.