



PURC



Understanding Active Surveillance as a Treatment Option for Men with Low-Risk Prostate Cancer

PURC Active Surveillance Working Group Survey Results

January 2018



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Message from the Chair



Adam Reese, MD

Dear Colleagues,

The PURC Active Surveillance (AS) Working Group was initiated with its first monthly meeting on September 21, 2017. The members of the AS Working Group, including myself, are as follows: Claudette Fronshell, BSN RN – PURC Program Manager, Bret Marlowe – Project Coordinator, David Chen, MD – Fox Chase Cancer Center, Suzanne Merrill, MD – Penn State Health, Brielle Schreiter – Data Abstractor, and Sitha Dy, MSN RN – HCIF intern.

AS is a conservative management approach for men with clinically indolent prostate tumors. This approach allows select men to delay or avoid the morbidity associated with prostate cancer treatment, without compromising cancer control.

The purpose of the AS working group is to explore, characterize and address the landscape of AS practice and utilization with the goals of raising awareness and supporting practitioners and practices.

The recent PURC AS survey generated valuable data characterizing similarities and differences among PURC physicians in AS practice patterns. Whereas the majority of PURC physicians offer AS in their practice, there is variation regarding the criteria used to identify potential AS candidates and the patient's to whom AS is offered. Furthermore, while most practitioners incorporate serial PSA testing and prostate biopsies to confirm AS eligibility and follow patients on surveillance, the use of genomic testing and prostate MRI was more variable.

Clearly this is an area in need of further study in order to accurately identify men with low risk disease for whom AS is appropriate, determine the optimal surveillance regimen for these men, and accurately differentiate patients with progressive disease who require delayed treatment from those who can safely continue on surveillance.

Sincerely,

A handwritten signature in black ink, appearing to be "A. Reese".

Adam Reese, MD
Active Surveillance Working Group Chair

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. Today, the nine (9) participating practices have entered approximately 6,000 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 – Main Line

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 – Main Line
 - 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 Trablusi, 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;
- Genomics 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 November 2, 2017, PURC distributed a web-based survey to all actively participating urologists via email to understand the current practices related to Active Surveillance for men with low-risk prostate cancer. The Active Surveillance Working Group, chaired by Adam Reese, MD, requested the development and distribution of the survey after reviewing data that displayed variation in Active Surveillance practices in men with low risk prostate cancer.

The *Understanding Active Surveillance as a Treatment Option for Men with Low-Risk Prostate Cancer Survey* asked nineteen (19) questions in total. The purpose of the survey was to gain a better understanding of Active Surveillance utilization by providers as a treatment option for men with low-risk prostate cancer at individual practices. In addition to collecting information on the identification of potential Active Surveillance candidates, the Active Surveillance working group also wanted to collect information on confirming Active Surveillance eligibility practices and following patients on Active Surveillance practices.

Survey Response

The PURC coordinating center distributed the survey to 93 active providers in the nine organizations participating in PURC. The survey closed on November 21, 2017. Eight (8) of the nine organizations responded, seven (7) academic organization and one (1) private organization. Of these 93 providers, 35 completed the survey, resulting in a response rate of 38%. Of the 35 providers, 32 entered their current title; twelve (12) identified as MD/DO/Urologist, seven (7) as Assistant Professors, four (4) as Associates, two (2) Chairs, two (2) Chiefs, two (2) Certified Registered Nurse Practitioners, one (1) Director, one (1) Managing Partner and one (1) Clinical Investigator.

Summary of Survey Results

Identification of Active Surveillance Candidates

- Over 80% of survey respondents use pre-defined eligibility criteria to identify potential AS candidates (D'Amico, AUA, NCCN risk criteria, Epstein criteria).
- Urologists appear to lead the initial discussions with patients regarding AS. Radiation oncologists and medical oncologist are rarely involved.
- Most (94.3%) survey respondents would offer AS to healthy men with low risk disease.
- Relatively few respondents would offer AS to men with favorable intermediate risk disease, either due to PSA elevation or Gleason 3+4 disease on biopsy.
- Most survey respondents do not use strict age or ethnicity criteria when determining AS eligibility.

Confirming Active Surveillance Eligibility

- Prostate MRI appears to be the most common test ordered to confirm AS eligibility (ordered by 54% of survey respondents).
- Fewer than 20% of respondents routinely perform repeat prostate biopsy within 6 months of initial biopsy to confirm AS eligibility.
- Fewer than one-third of respondents routinely use genomic testing to confirm AS eligibility.

Following Patients on Active Surveillance

- There is variability in the tests used to follow patients while on surveillance.
- Over 50% of survey respondents perform PSA and DRE every 6 months and prostate MRI and surveillance prostate biopsies every 12 months.
- Nearly all survey respondents recommend a transition to definitive treatment for Gleason upgrading on surveillance biopsy.
- Over 50% of respondents recommend transition for definitive treatment in the setting of: concerning PSA kinetics, increased volume of disease on surveillance biopsy, new nodule on digital rectal exam, or a new lesion on MRI.
- Fewer than 50% of respondents would recommend transitioning to definitive treatment in the setting of concerning genomic testing results

Recommendations

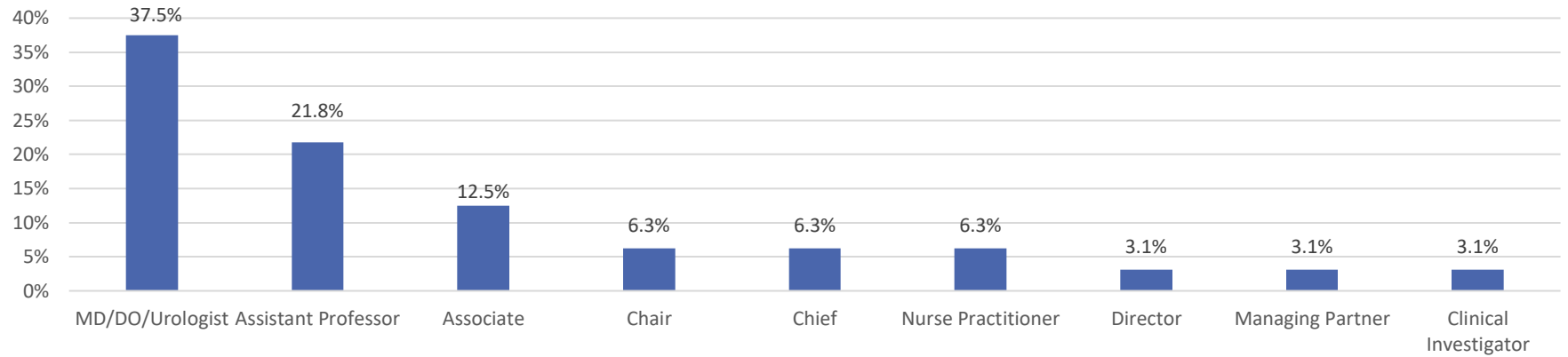
Based on survey results, findings in recent research publications, and AUA/NCCN guidelines, the Active Surveillance Working Group suggests:

- Practitioners should become familiar with the AUA risk stratification system for localized prostate cancer and use these criteria to identify potential candidate for active surveillance.
- Active surveillance should be considered the preferred management strategy for men with very-low risk disease.
- Active surveillance should be offered as a management option for men with low risk disease.
- Active surveillance should not be offered to men with intermediate or high risk disease, with the exception of select men with low volume favorable intermediate risk tumors.
- Confirmatory testing with repeat prostate biopsy, prostate MRI, or genomic testing can be considered prior to enrolling a patient in active surveillance.
- Patients on active surveillance should be followed with serial PSA testing and periodic surveillance biopsies.
- Prostate MRI may be useful in selecting patient for or following patients on active surveillance

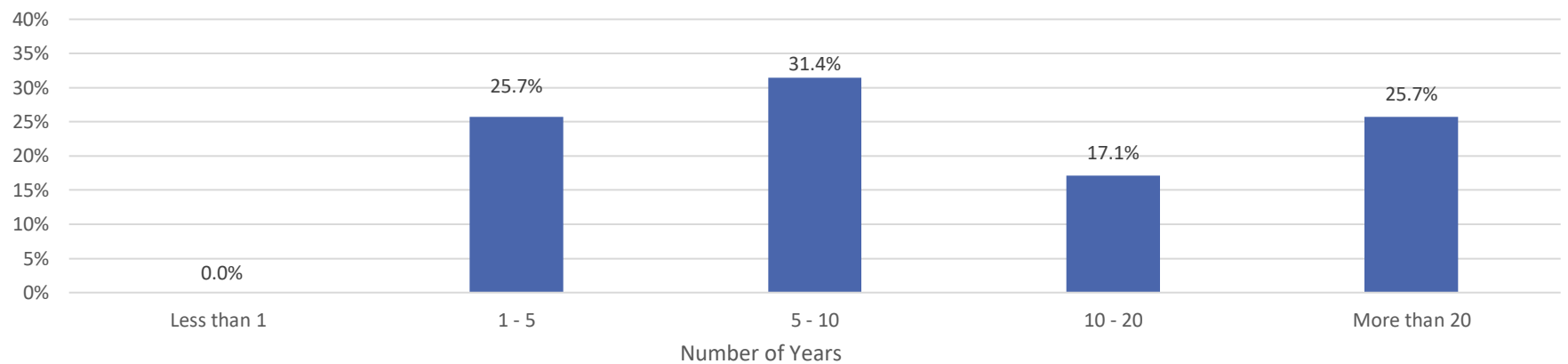
Appendix: Survey Results

Demographics

Title (n=32)



How many years have you been practicing Urology? (n=35)



Identification of Potential Active Surveillance Candidates

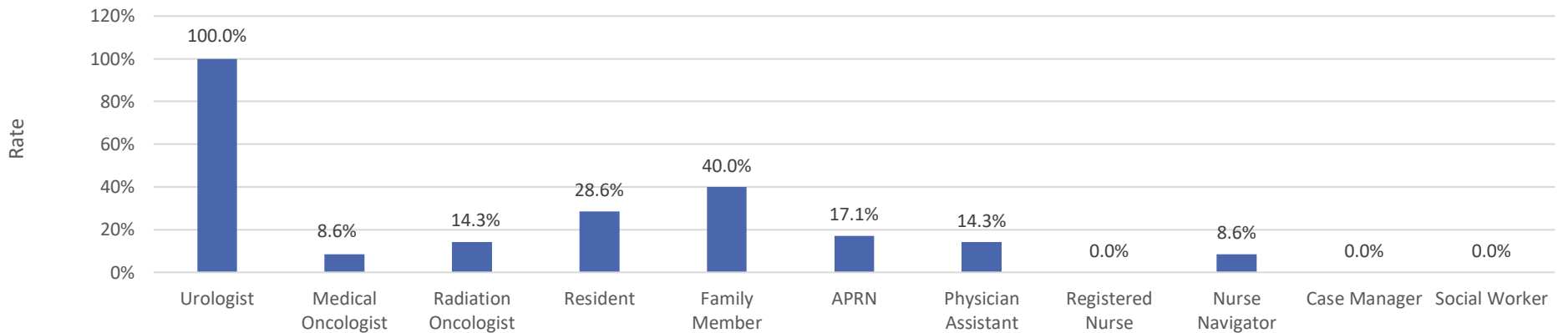
1. Do you use a decision making tool or reference to identify or manage patients on active surveillance? (n=34)



Responses for “YES”:

D’Amico	AUA	Genomic Testing
NCCN	Epstein Criteria	Own protocol

2. Who are involved with the initial discussion regarding active surveillance as a treatment option with the patient? (n=35)



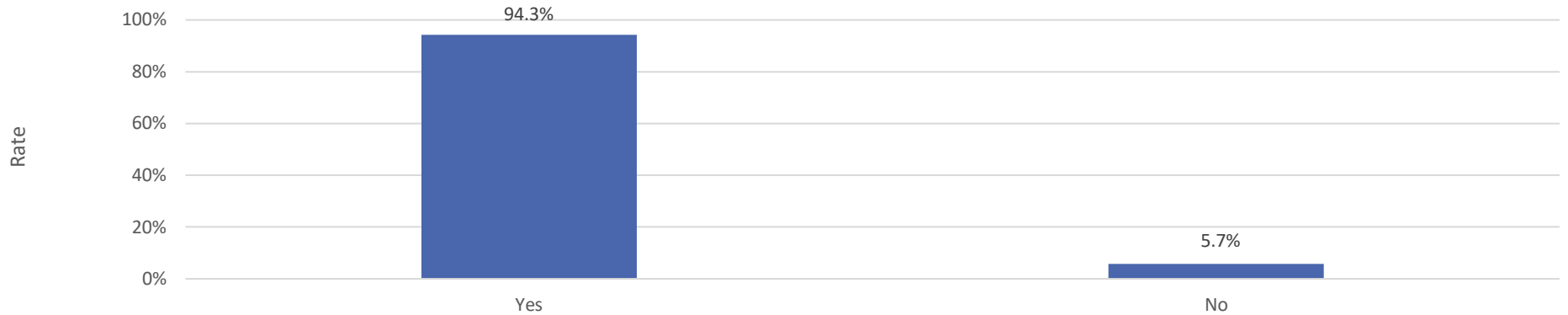
3. In your practice, do you offer active surveillance as a management option for men with low (Gleason score <7, PSA <10.0 ng/mL, and clinical stage <T2) or favorable intermediate risk prostate cancer (low volume Gleason 3+4 on biopsy)? (n=35)



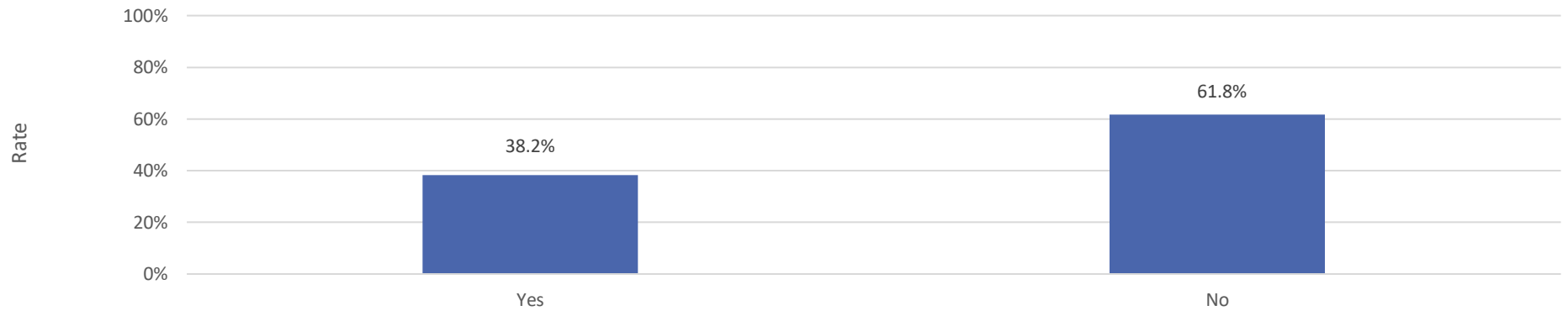
4. Do you use specific eligibility criteria (based on age, PSA, Gleason score, etc.) to identify men in whom you would consider active surveillance? (n=35)



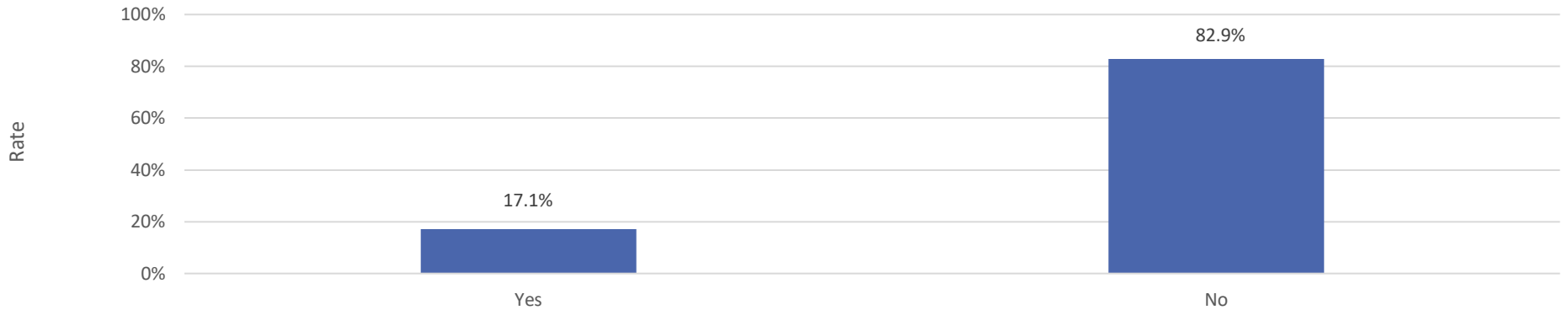
5. A healthy 60-year-old patient presents with clinical stage T1c, Gleason score 6 (grade group 1) in 30% of 2/12 biopsy cores, PSA 4.5 (PSA density 0.11). Would you offer/recommend active surveillance in your practice for this patient? (n=35)



6. A healthy 60-year-old patient presents with Gleason score 6 (grade group 1) in 30% of 2/12 biopsy cores with PSA 16 (PSA density 0.25). Would you offer/recommend active surveillance in your practice for this patient? (n=34)



7. A healthy 60-year-old patient presents with Gleason score 3+4 in 30% of 2/12 biopsy cores with PSA 5.6. Would you recommend active surveillance in your practice for this patient? (n=35)



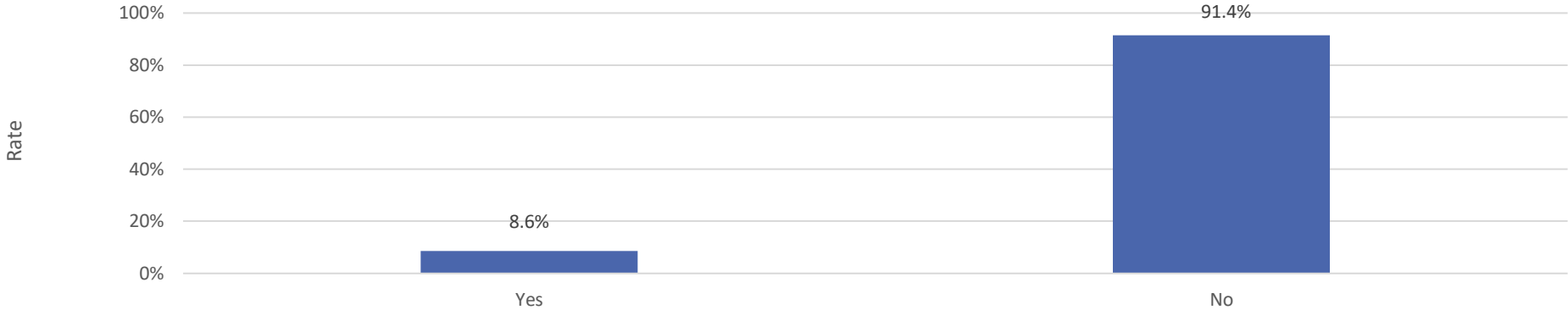
8. Is there a patient age below which you would typically not offer active surveillance to an otherwise healthy patient with low risk prostate cancer? (e.g. 'I do not offer active surveillance to men younger than age 60') (n=35)



Comments:

50	55	56
60	Low 60's/healthy	<60

9. Is there a racial/ethnic group to whom you do not typically offer active surveillance in your practice? (e.g. 'I do not offer active surveillance to African American men') (n=35)

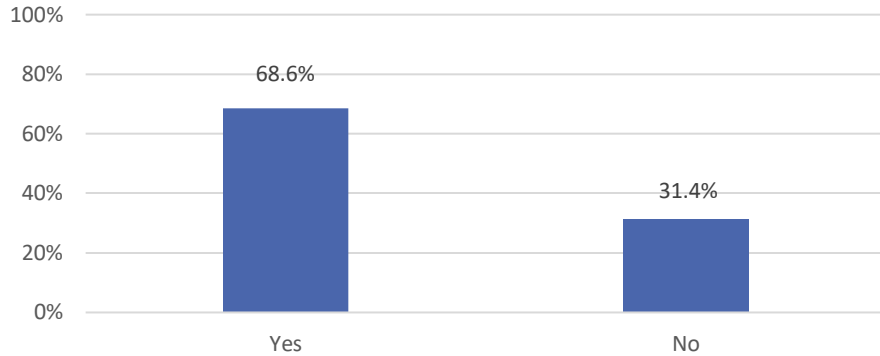


Comments:

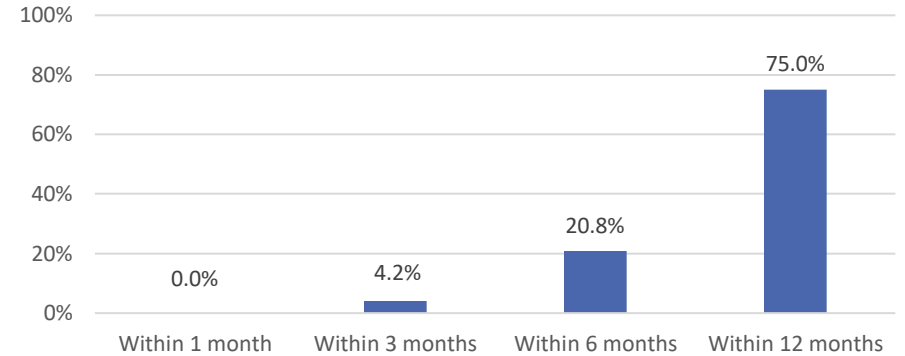
African Americans

Confirming Active Surveillance Eligibility

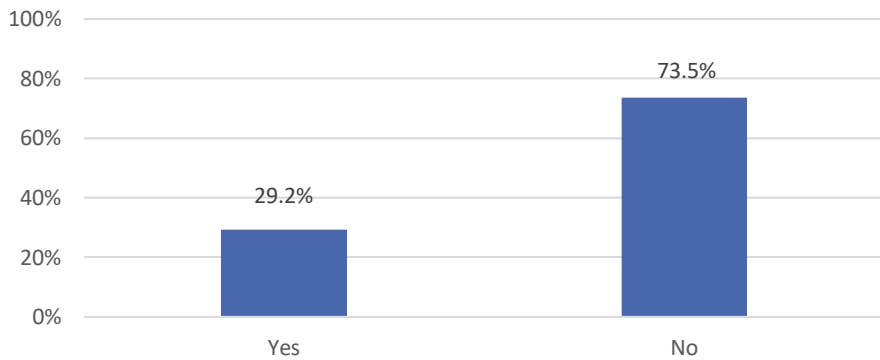
1. After a patient's initial biopsy, do you routinely repeat prostate biopsy prior to placing a patient on active surveillance? (n=35)



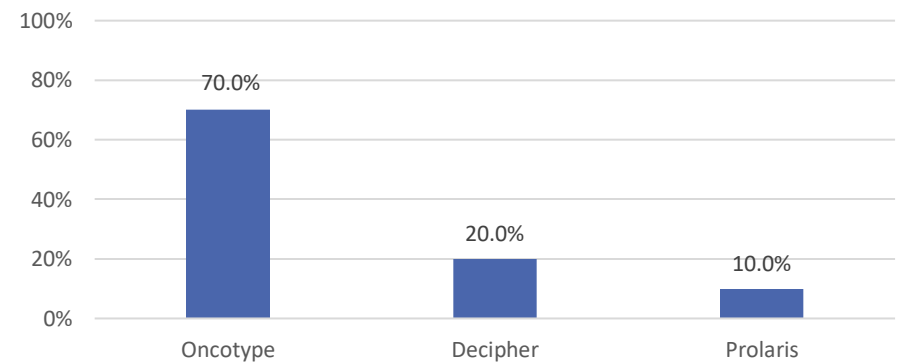
Responses for "YES":



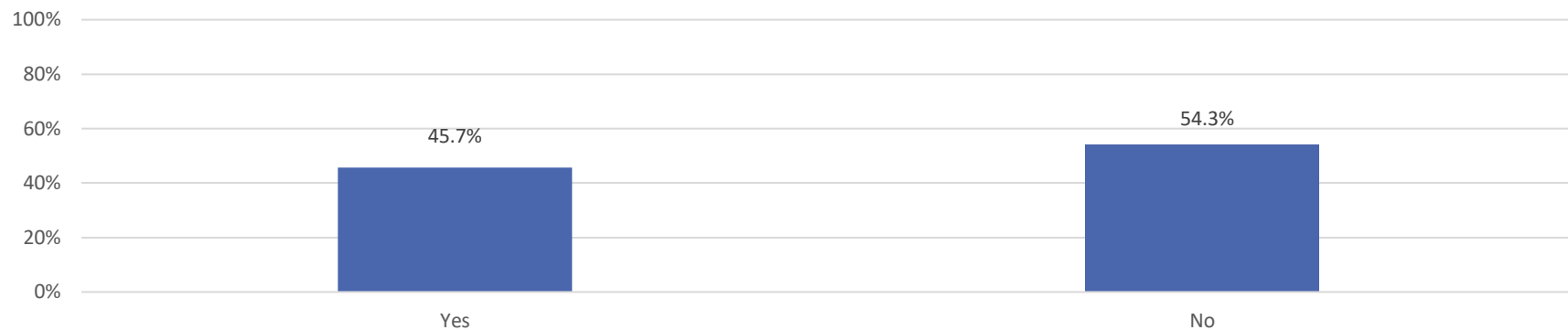
2. After a patient's initial biopsy, do you routinely perform genomic testing to confirm active surveillance eligibility prior to placing a patient on active surveillance? (n=35)



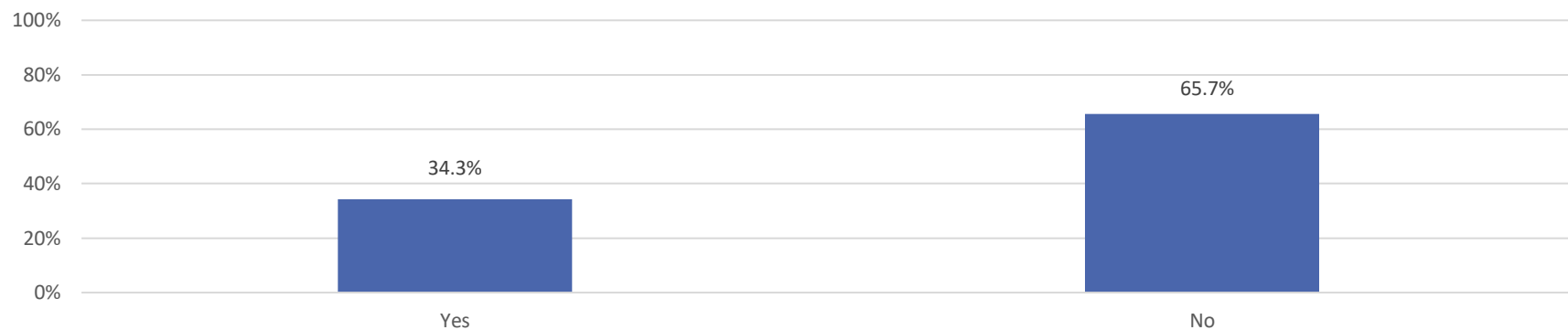
Responses for "YES":



3. After a patient's initial biopsy, do you routinely perform prostate MRI prior to placing a patient on active surveillance? (n=35)



4. After a patient's initial biopsy, are there other confirmatory tests you perform prior to placing a patient on active surveillance? (n=35)



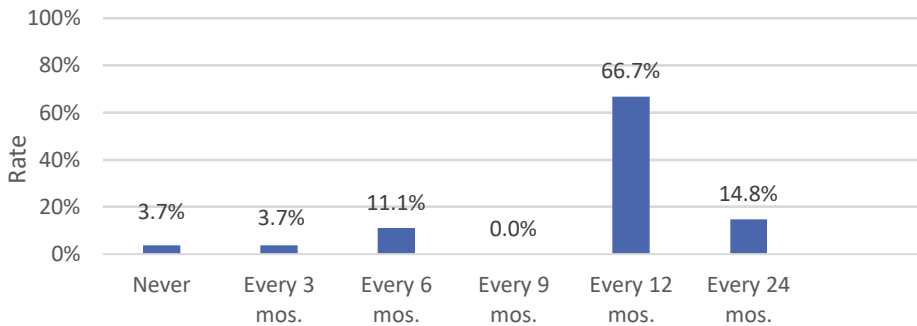
Comments:

Molecular studies	Prostate MRI	mpMRI (+/- fusion)	CT Scans
Confirmatory TRUSbx	Oncotype	Prolaris	Repeat biopsy

Following Patients on Active Surveillance

1. For a healthy 60-year-old male with NCCN low-risk cancer on active surveillance, how often do you perform the following in the first two years?

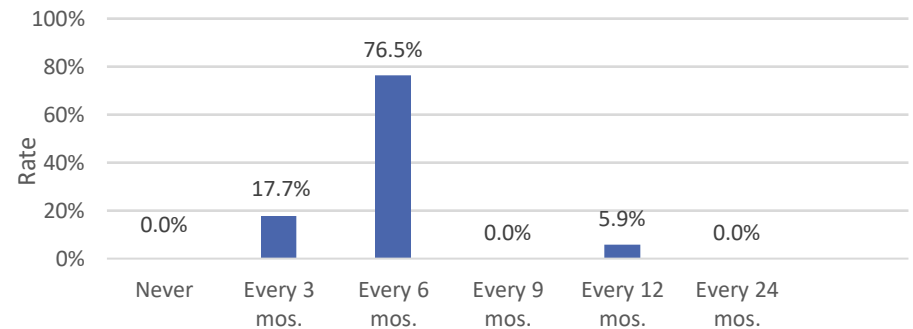
Surveillance Biopsy (n=27)



Comments:

12-18 mos.	6 mos. then annually	Variable- pending PSA
Rising PSA	Abnormal DRE	

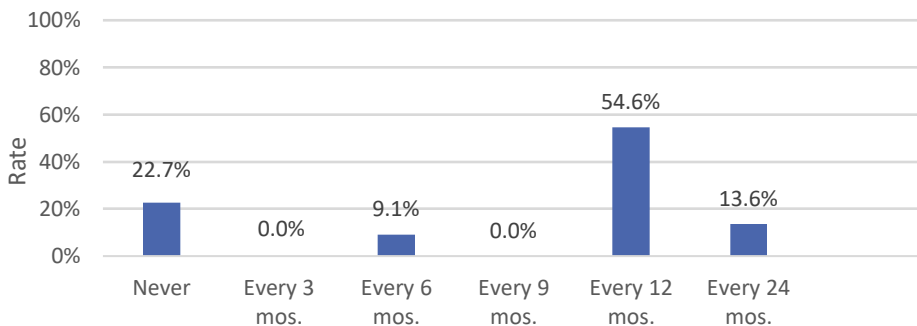
Check PSA (n=34)



Comments:

4 mos.	3-6 mos.
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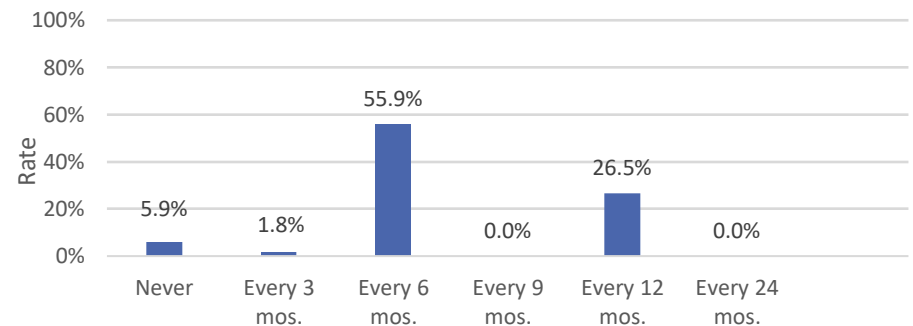
Prostate MRI (n=22)



Comments:

Based on PSA	PRN	Age and other variables
MRI fusion	Abnormal DRE	If patient refuse biopsy
3-4 mos. following biopsy	Surveillance MRI with bx	

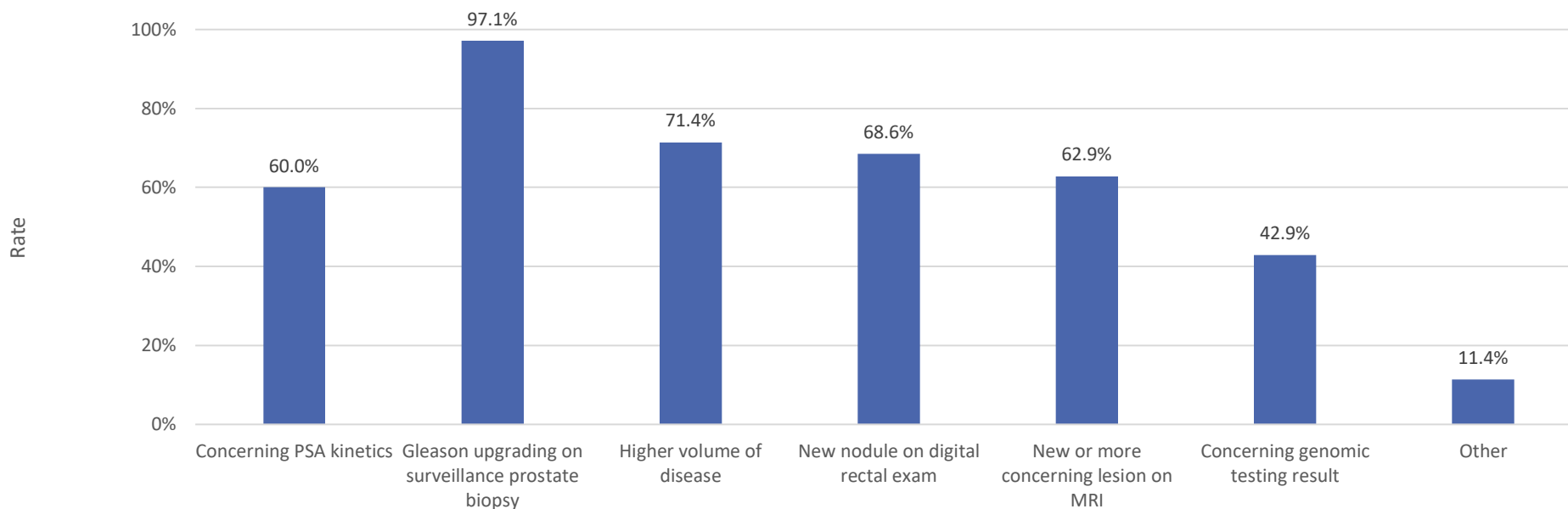
DRE (n=34)



Comments:

With biopsy

2. When following an existing patient on active surveillance, what would prompt you to recommend cessation of active surveillance and transition to definitive treatment (e.g. surgery or radiation therapy)? Select all that applies (n=35)



Responses for “Other”:

Concerning MRI leading to a fusion bx with increase in risk group	Would confirm with biopsy or MRI
Patient psychologically not handling active surveillance	

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