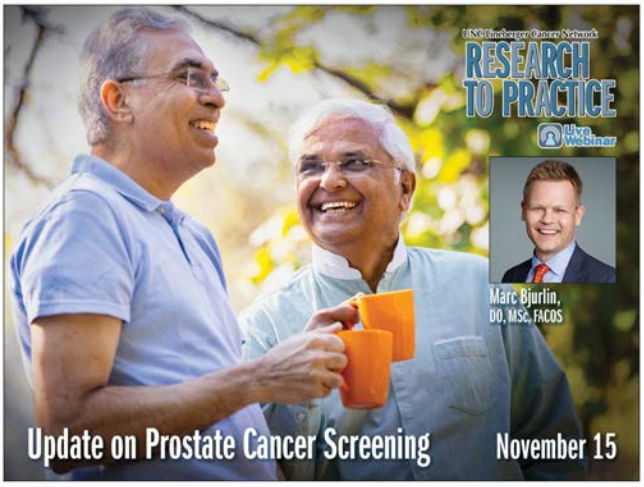

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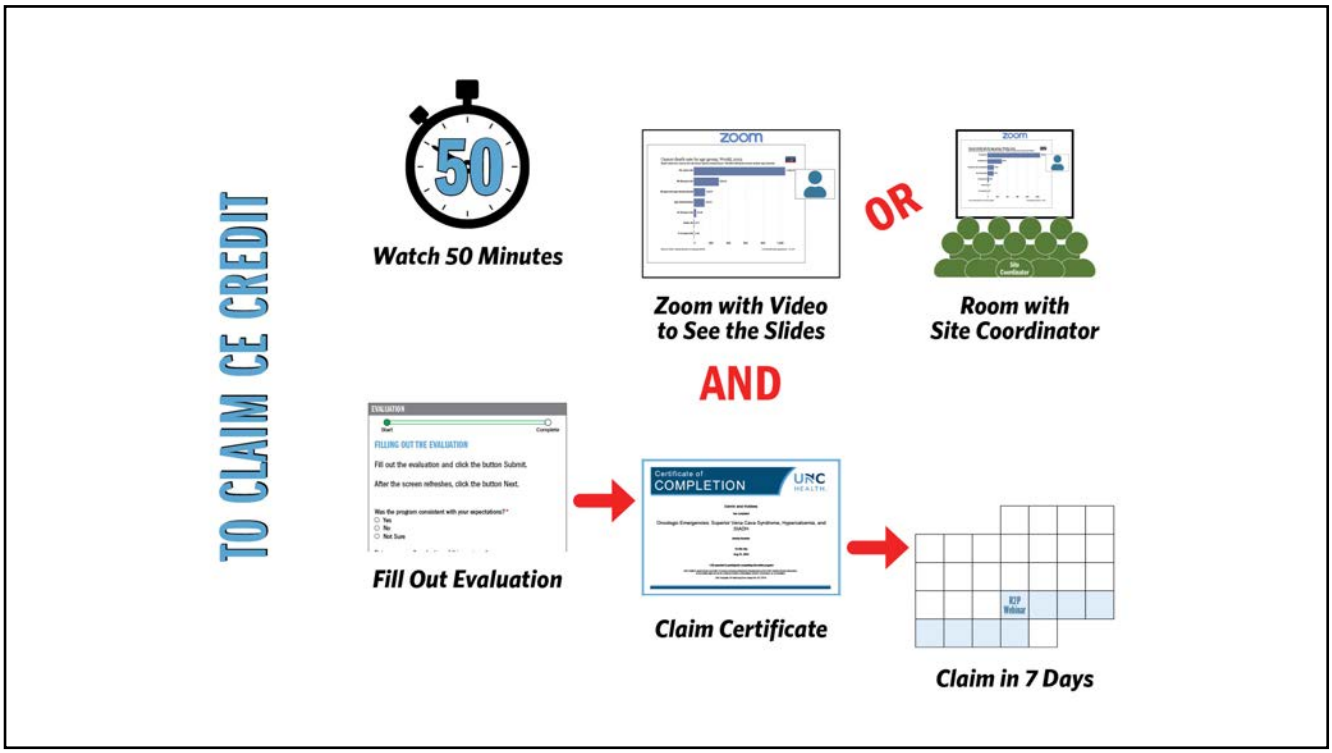
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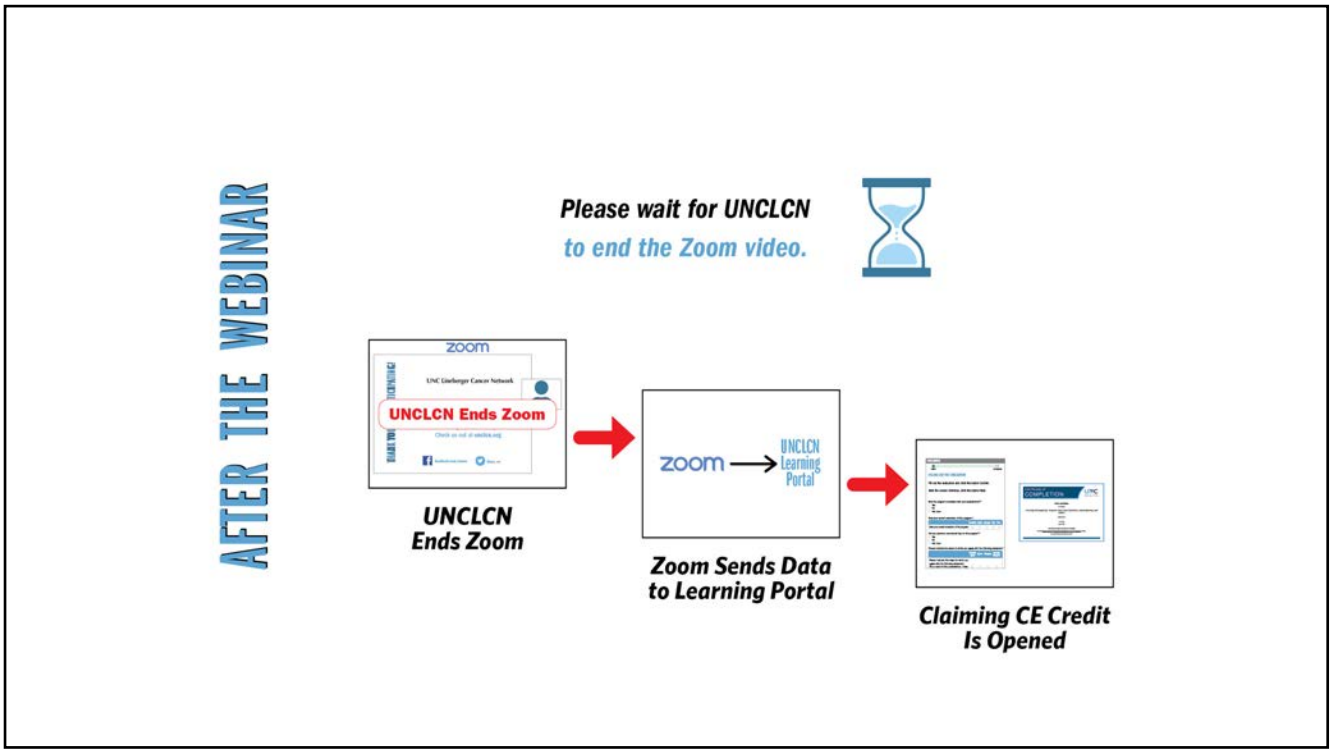
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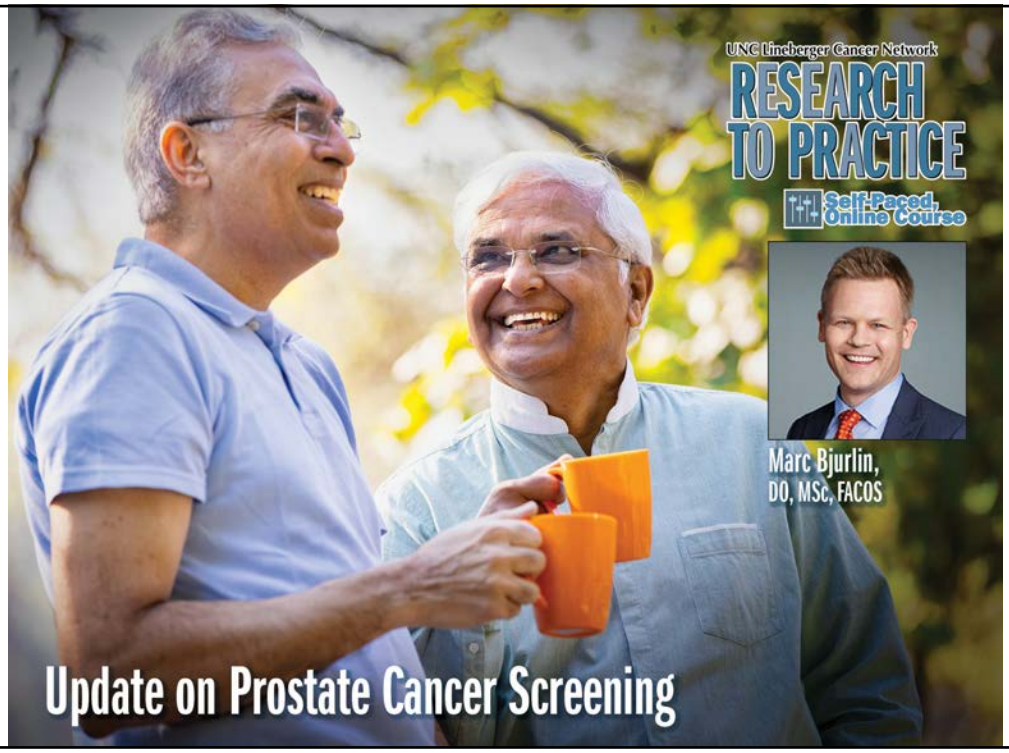

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OUR PRESENTER

Marc Bjurlin,
DO, MSc, FACOS

Marc Bjurlin, DO, MSc, FACOS, is an Associate Professor of Urology, member of the Lineberger Comprehensive Cancer Center, and Director of Clinical Trials at the University of North Carolina at Chapel Hill. He completed his residency at Cook County Hospital in Chicago.

After residency, Dr. Bjurlin completed a fellowship in urologic oncology at New York University along with a Master of Science degree in clinical investigation through the New York University School of Medicine.

Prior to joining UNC, Dr. Bjurlin was Assistant Professor of Urology and Director of Urologic Oncology at NYU Langone Hospital Brooklyn. His research interests include the molecular epidemiology of smoking and e-cigarette use-related bladder cancers.

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OUR PRESENTER

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OUR PRESENTER

5. Marc Bjurlin, DO, MSc, FACOS, is an Associate Professor of Urology.

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OUR PRESENTER

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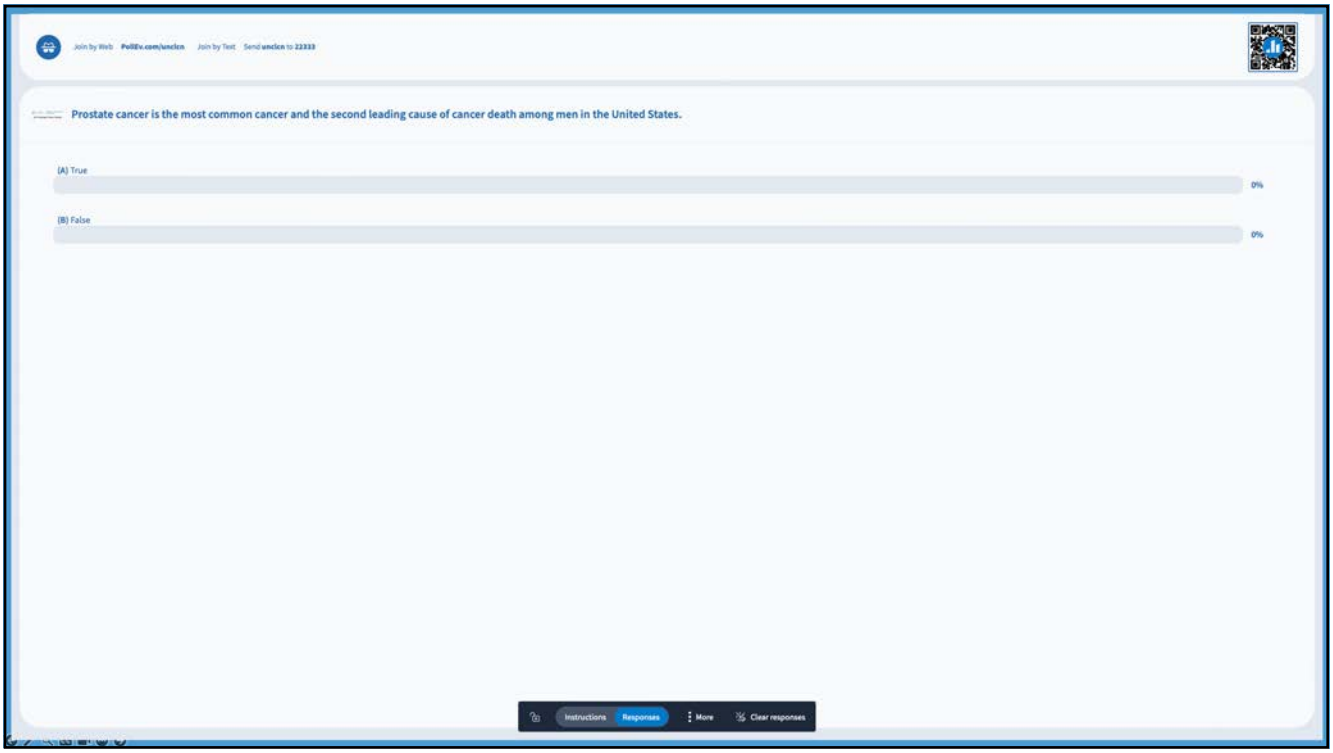

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Marc Bjurlin, DO, MSc, FACOS, receives consulting fees from Urogen and research support from Janssen Pharmaceuticals, ImmunityBio, and Intuitive.

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Criteria for Activity Completion:
Criteria for successful completion requires attendance at the NCPD activity and submission of an evaluation within 30 days.

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Prostate cancer is the most common cancer and the second leading cause of cancer death among men in the United States.

True 0%

False 0%

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Update on Prostate Cancer Screening

Lineberger Comprehensive Cancer Center

Research to Practice

Marc A. Bjurlin, DO, MSc
Associate Professor of Urology
Director of Clinical Trials
Lineberger Comprehensive Cancer Center
University of North Carolina

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Financial Disclosures/Conflict of Interest

- Clinical Investigator: Janssen Pharmaceuticals – high risk prostate cancer trial
- Clinical Investigator: ImmunityBio
- Paid consultant: Urogen
- Surgical Proctor: Intuitive

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Objectives

- Understanding the history of limitations of PSA screening for prostate cancer
- Be familiar with strategies of prostate cancer risk assessment to screen "smarter"
- Understand the role of prostate MRI for cancer risk assessment and localization
- Be familiar with guideline endorsed molecular markers for prostate cancer risk stratification
  - Blood markers - Prostate health index [PHI], IsoPSA, 4K score
  - Urinary markers - Select MDx, ExoDx®, My Prostate Score

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Prostate Cancer in 2023

Estimated New Cases

Males		
Prostate	288,300	29%
Lung & bronchus	117,550	12%
Colon & rectum	81,860	8%
Urinary		
Melanoma of		
Kidney & ren		
Non-Hodgkin ly		
Oral cavity & p		
Le		
P		

Estimated Deaths

Males		
Lung & bronchus	67,160	21%
Prostate	34,700	11%
Colon & rectum	28,470	9%
		8%
		6%
		4%
		4%
		4%
		4%
		3%
All sites	322,000	100%

North Carolina
10,040 New Cases
1,250 Deaths

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Siegel et al. CA Cancer J Clin. 2023

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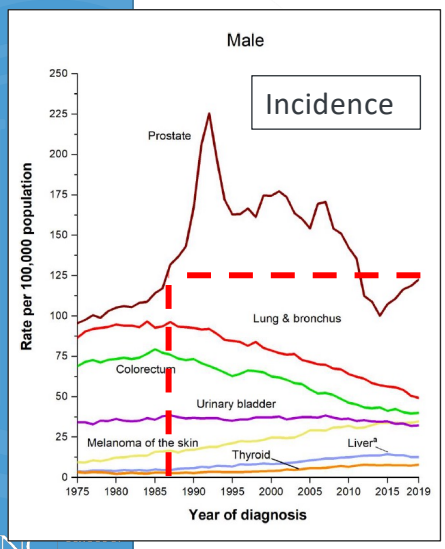
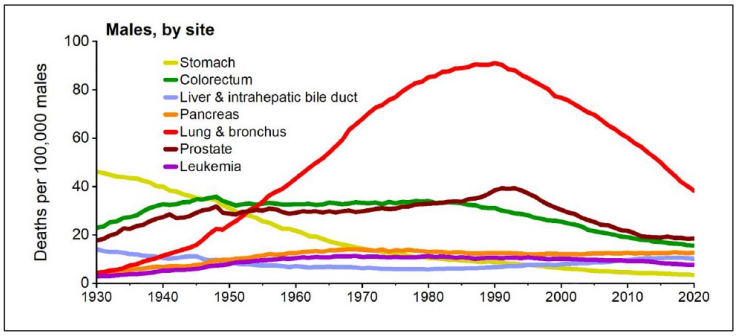
The Impact of Policy Changes on Prostate Cancer Screening



Mortality



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Siegel et al. CA Cancer J Clin. 2023

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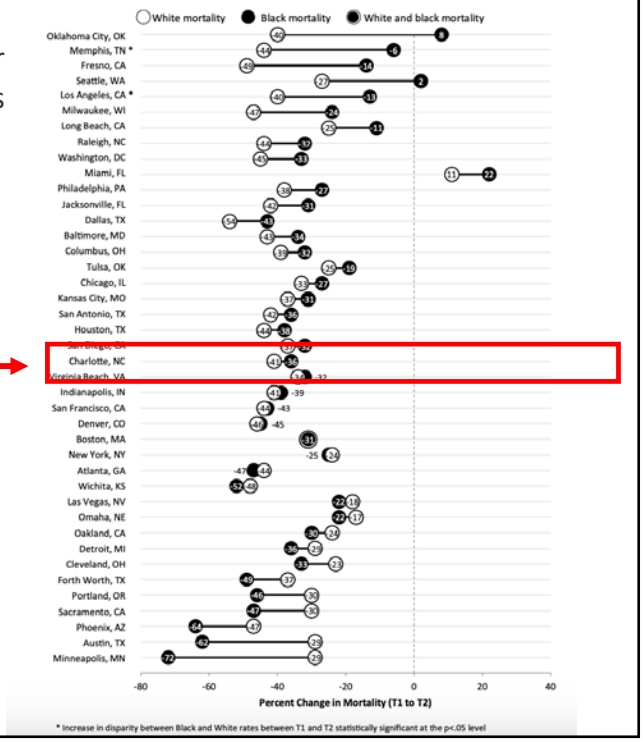
Racial Disparities in Prostate Cancer Mortality in the 50 Largest US Cities

1990-94 to 2005-09

Charlotte, NC

41% mortality reduction for white men
36% mortality reduction for Black men

Benjamins et al. Cancer Epi. 2016



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CANCER

More men diagnosed with advanced prostate cancer as PSA screening declines

After two decades of decline, cases of prostate cancer rose by 3% per year from 2014 to 2019, a new report from the American Cancer Society has found.

U.S.News NEWS » News Best Countries Best States Healthiest Communities Opinion Elections The Racial Divide

Home / News / Health News / U.S. Cancer Deaths Decline Ov...

U.S. Cancer Deaths Decline Overall, But Prostate Cancers Make Rebound

By HealthDay | Jan. 12, 2023, at 12:33 p.m.

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Why did this happen?

Annals of Internal Medicine

U.S. Preventive Services TASK FORCE
www.USPreventiveServicesTaskForce.org

SCREENING FOR PROSTATE CANCER
CLINICAL SUMMARY OF U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATION

Population	Adult Males
Recommendation	Do not use prostate-specific antigen (PSA)–based screening for prostate cancer.
	Grade: D

Do not use prostate-specific antigen (PSA)–based screening for prostate cancer.

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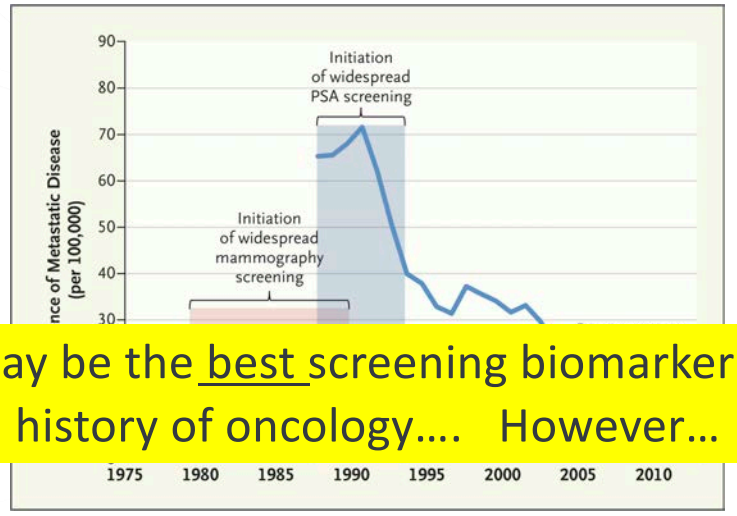
Incidence of M1 Disease at Diagnosis



PSA may be the best screening biomarker in the history of oncology…. However…

Welch et a. Trends in Metastatic Breast and Prostate Cancer — Lessons in Cancer Dynamics. N Engl J Med 2015; Oct, 373:1685-1687

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History of PSA Screening

- 1990-2000: Poorly implemented prostate cancer screening
  - Over screened elder and those with limited longevity
  - Under screened young men
- Drove down mortality >50% but at cost of side effects of treatment
- "screen none" was not the solution, rather "screen smarter"

"4.0 is the worst thing thing that ever happened to PSA"

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PSA guidelines 4.0 focused on inadequate testing and with the wrong population groups.

True 0%

False 0%

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National Comprehensive Cancer Network®

NCCN Guidelines Version 1.2023
Prostate Cancer Early Detection

NCCN Guidelines Index
Table of Contents
Discussion

BASELINE EVALUATION

- History and physical (H&P) including:
  - Family cancer history[a,b,c]
  - Family or personal history of high-risk germline mutations[a,b,c]
  - History of prostate disease and cancer early detection, including prior prostate-specific antigen (PSA) and/or isoforms, exams, and biopsies
  - Black/African American identity[d]
  - Medications[e]
  - Environmental exposure[f]

RISK ASSESSMENT

Start risk and benefit discussion about offering prostate cancer early detection:
- Baseline PSA[g]
- Consider baseline digital rectal examination (DRE)[g]

EARLY DETECTION EVALUATION

Age 45–75 y for patients with average risk

or

Age 40–75 y for patients with high risk:
- Black/African American individuals[d]
- Those with germline mutations that increase the risk for prostate cancer[a,b,c]
- Those with suspicious family history[a,c]

Patients with average risk and PSA <1 ng/mL[e], DRE normal (if done) → Repeat testing at 2- to 4-year intervals[j]

Patients with high risk and PSA ≤3 ng/mL[e], DRE normal (if done) And Patients with average risk and PSA 1–3 ng/mL,[i] DRE normal (if done) → Repeat testing at 1- to 2-year intervals

PSA >3 ng/mL[e,i] and/or very suspicious DRE → See Further Evaluation and Indications for Biopsy (PROSD-3)

Age >75 y, in select patients (category 2B)[h]:
- PSA <4 ng/mL[e], DRE normal (if done), and no other indications for biopsy → Repeat testing at 1- to 2-year intervals[j]
- PSA ≥4 ng/mL[e] or very suspicious DRE → See Further Evaluation and Indications for Biopsy (PROSD-3)
- Not screened[h]

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FURTHER EVALUAT
INDICATIONS FOR

RISK STRATIFICATION FOR CLINICALLY SIGNIFICANT DIEASE

- Repeat PSA
- DRE, if not performed during initial risk assessment
- Workup for benign disease

→

- Multiparametric MRI (mpMRI) is strongly recommended, if available[l,m]
- Consider biomarkers that improve the specificity of screening[n]

MANAGEMENT

- High suspicion for clinically significant cancer → Transrectal ultrasound (TRUS)-guided biopsy[o] via transrectal or transperineal approach with or without MRI targeting[l]
- Low suspicion for clinically significant cancer → Follow-up in 6–12 mo with PSA/DRE[p]

[n] Biomarkers that improve the specificity of detection are not, as yet, mandated as first-line screening tests in conjunction with serum PSA. However, there may be some patients who meet PSA standards for consideration of prostate biopsy, but for whom the patient and/or the physician wish to further define risk. Lower percent-free PSA and/or higher PSA density are associated with a greater risk of high-grade prostate cancer. The probability of high-grade cancer (Gleason score ≥3+4, Grade Group 2 or higher) may be further defined utilizing the Prostate Health Index (PHI), SelectMDx, 4Kscore, ExoDx Prostate Test, MyProstateScore (MPS), and IsoPSA. Extent of validation of these tests across diverse populations is variable. It is not yet known how such tests could be applied in optimal combination with MRI.

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Smarter prostate cancer risk assessment includes which of the following:

MRI and biomarker assessment 0%

MRI and ultrasound 0%

MRI, biomarker assessment, and ultrasound 0%

PSA, MRI, biomarker assessment, and ultrasound 0%

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MRI – Noninvasive Prebiopsy Risk Assessment

Update of the Standard Operating Procedure on the Use of Multiparametric Magnetic Resonance Imaging for the Diagnosis, Staging and Management of Prostate Cancer

CrossMark

Marc A. Bjurlin,* Peter R. Carroll, Scott Eggener, Pat F. Fulgham, Daniel J. Margolis, Peter A. Pinto, Andrew B. Rosenkrantz, Jonathan N. Rubenstein, Daniel B. Rukstalis, Samir S. Taneja and Baris Turkbey

From the University of North Carolina at Chapel Hill (MAB), Chapel Hill and Wake Forest Baptist Medical Center (DBR), Winston-Salem, North Carolina, University of California San Francisco (PRC), San Francisco, California, University of Chicago Medical Center (SE), Chicago, Illinois, Texas Health Presbyterian Hospital of Dallas (PFF), Dallas, Texas, Weill Cornell Medical College (DJM) and NYU Langone Medical Center (ABR, SST), New York, New York, and National Cancer Institute (PAP, BT), National Institutes of Health, Bethesda and Chesapeake Urology Associates (JNR), Baltimore, Maryland

" When quality prostate imaging is obtained, sufficient data now exist to support the recommendation of magnetic resonance imaging before prostate biopsy in *all* men who have no history of biopsy."

- MRI suspicion score – PI-RADS correlates with both overall cancer detection and clinically significant cancer detection
- Allows for pre-biopsy counseling of risk of disease

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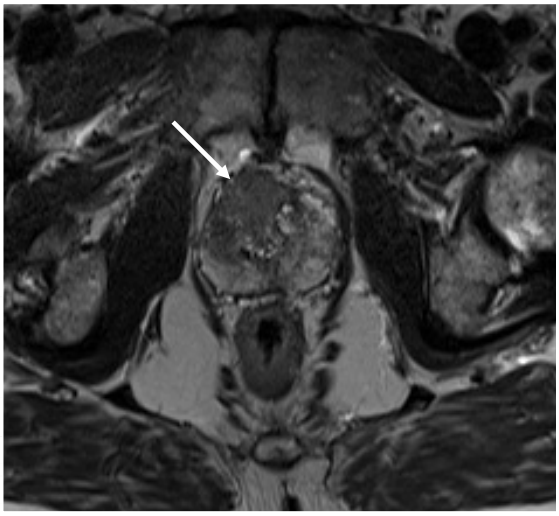
Prostate MRI



Orerther et al. *Prostate Cancer and Prostatic Diseases*. 2022

PI-RADS Scoring System

- PI-RADS 1 – Very low (clinically significant cancer is highly unlikely to be present) [2%]
- PI-RADS 2 – Low (clinically significant cancer is unlikely to be present) [4%]
- PI-RADS 3 – Intermediate (the presence of clinically significant cancer is equivocal) [20%]
- PI-RADS 4 – High (clinically significant cancer is likely to be present) [52%]
- PI-RADS 5 – Very high (clinically significant cancer is highly likely to be present) [89%]

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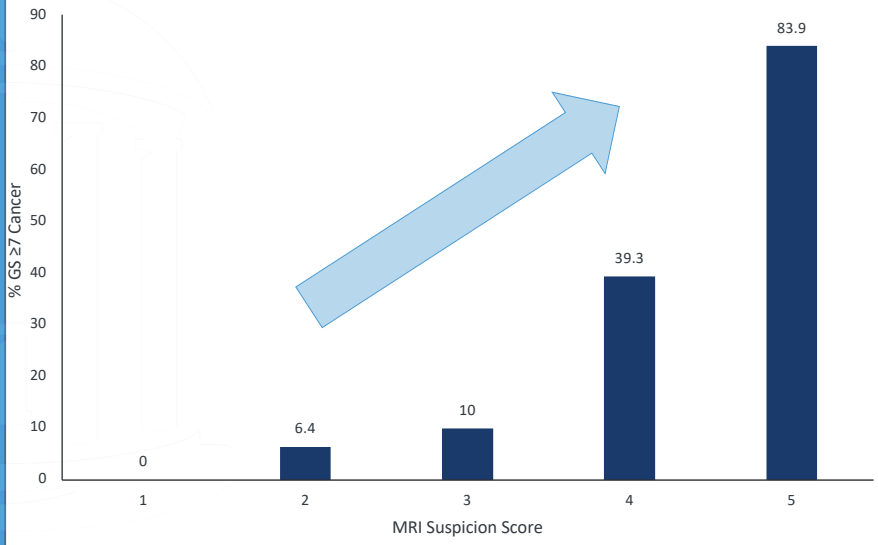
GS ≥ 7 Stratified by MRI Suspicion Score for Targeted Biopsy – Prior Negative Biopsy



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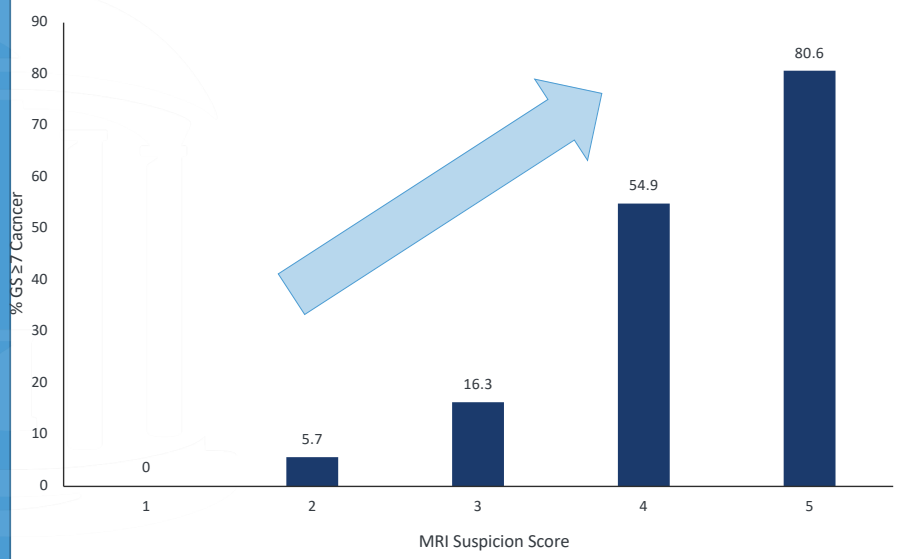
GS ≥ 7 Stratified by MRI Suspicion Score for Targeted Biopsy – No Prior Biopsy



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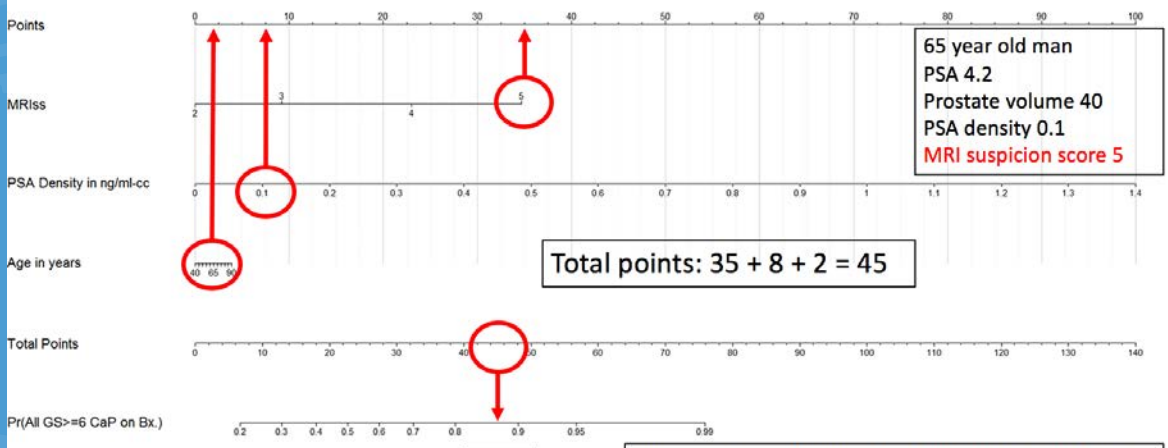
CLINICALY SIGNIFICANT CANCER – IMPACT OF MRIss



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Bjurlin et al. In Press.

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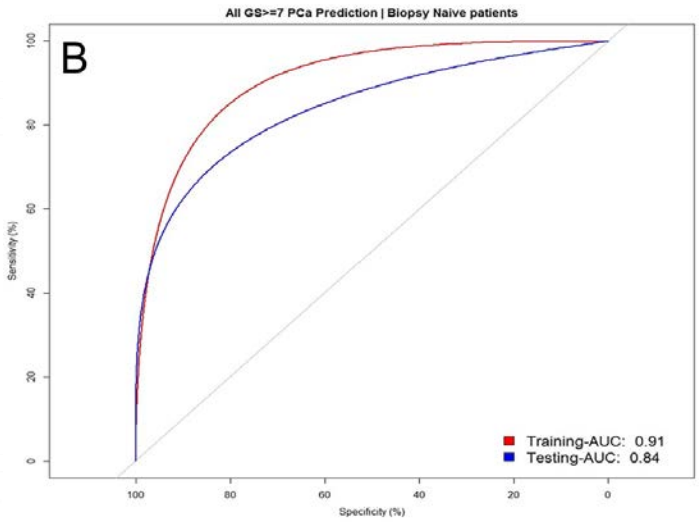
Nomogram Performance Characteristics



Bjurlin et al. In Press.

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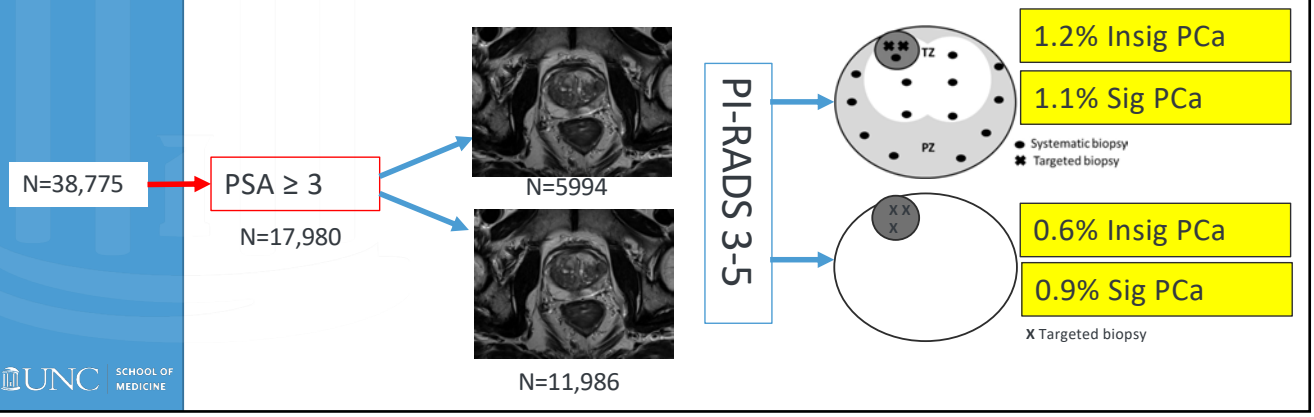
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Prostate Cancer Screening with PSA and MRI Followed by Targeted Biopsy Only

GÖTEBORG-2 Trial Investigators

N ENGL J MED 387;23 NEJM.ORG DECEMBER 8, 2022



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An MRI allows the physician to better assess the likelihood that a patient has prostate cancer before conducting an invasive biopsy.

True 0%

False 0%

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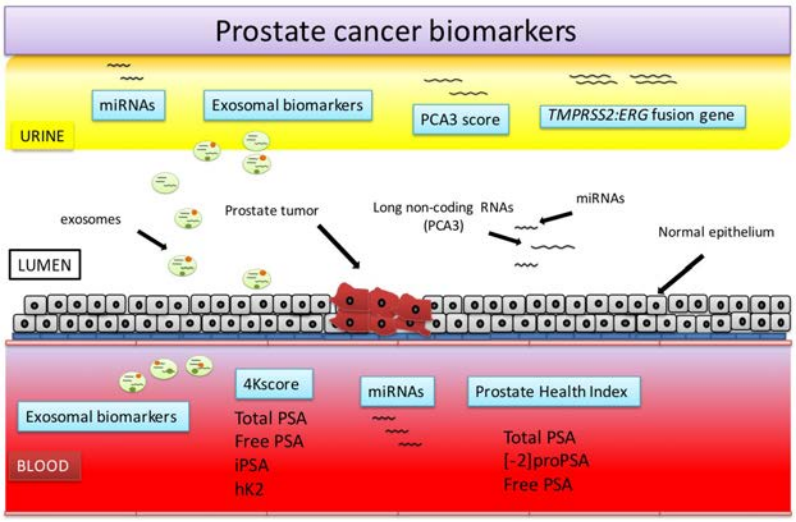
Prostate Cancer Biomarkers



Filella and Foj. Prostate Cancer Detection and Prognosis: From Prostate Specific Antigen (PSA) to Exosomal Biomarkers. *Int. J. Mol. Sci.* 2016, *17*(11), 1784.

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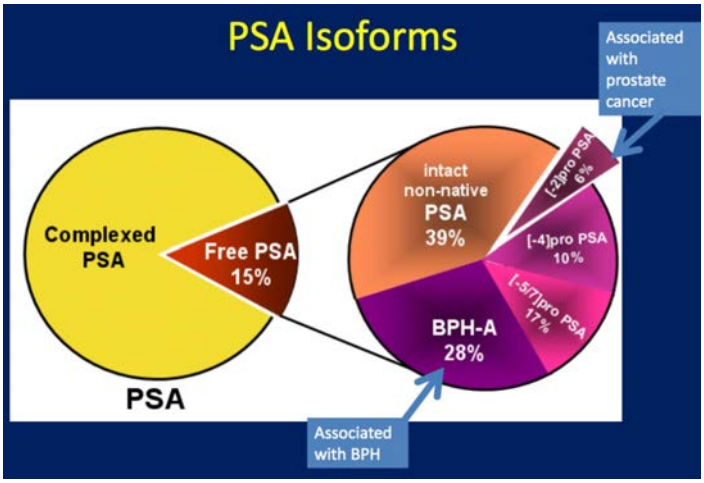
Prostate Health Index - PHI

Side Courtesy of Stacy Loeb, MD

$$PHI = \frac{[-2]\,pro-PSA}{fPSA} * \sqrt{tPSA}$$

The Prostate Health Index (*phi*) is a calculation that uses a combination of three blood tests to produce a "*phi* score"

This score provides more information about what elevated PSA levels might mean and the probability of finding prostate cancer on biopsy



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Loeb S, et al. The prostate health index selectively identifies clinically significant prostate cancer. J Urol. 2015;193(4):1163-9.

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Phi Report

Side Courtesy of Stacy Loeb, MD

PSA =10

p2PSA= 2

%fPSA=10

Phi=6.3

Patient

Name:	Phone #:	Patient ID#:	
Case Study	804-123-1234	10-063-0025	
Fasting Status:	Gender:	Birthdate:	Age:
Unknown	Male	6/15/1957	55
Height:	Weight:	BMI:	Prev. BMI
5 ft. 6 in.	173 pounds	28	

Specimen

Collection Time:	Specimen ID:
9:54 am	10030400027
Collection Date:	Report Type:
1/4/2014	Complete
Received Date:	Report Date:
1/5/2014	1/10/2014

Provider

Requesting Provider: Bob Johnson, MD
123 Broad St. Suite 456
Richmond, VA 12345
Client ID: 11-22222-33-4444444

Tumor Markers	Result	Reference Interval	Probability of Cancer
Total PSA (ng/mL)	10	Normal <2.0 and at risk ≥2.0	
free PSA (ng/mL)	1	See %free PSA	
p2PSA (pg/mL)	2	See *phi*	
%free PSA	10	%free PSA Prostate Cancer Probability by Age %free PSA / <60yr / 60-70yr / >70yr <7 / 85% / 95% / 96% 7-15 / 25% / 50% / 60% 16-25 / 11% / 27% / 35% >25 / 2% / 6% / 10%	
Prostate Health Index (*phi*)	6.3	*phi* (calculated) / Cancer Probability 0-24.9 / 11.0% 25.0-34.9 / 18.1% 35.0-54.9 / 32.7% >55.0 / 52.1%	Probability of CaP 11.0%

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Phi Report

Side Courtesy of Stacy Loeb, MD

PSA =4.4

p2PSA =41.9

%fPSA =21

phi = 97

Patient			
Name: Case Study	Phone #: 804-123-1234	Patient ID#: 10-063-0025	
Fasting Status: Unknown	Gender: Male	Birthdate: 6/15/1957	Age: 55
Height: 5 ft. 6 in.	Weight: 173	BMI:	

Specimen	
Collection Time: 9:54 am	Specimen ID: 10030400027
Collection Date: 1/4/2014	Report Type: Complete
Received Date: 1/5/2014	Report Date: 1/10/2014

Provider	
Requesting Provider: Bob Johnson, MD 123 Broad St. Ste 456 Richmond, VA 12345	
Client ID: 11-22222-33-4444444	

Tumor Markers	Result	Reference Interval	Probability of Cancer
Total PSA (ng/mL)	4.4	Normal <2.0 and at risk ≥2.0	
free PSA (ng/mL)	0.9	See %free PSA	
p2PSA (pg/mL)	41.9	See *phi*	
%free PSA	21%	Prostate Cancer Probability by Age %free PSA / <60yr / 60-70yr / >70yr <7: 85% / 95% / 96% 7-15: 25% / 50% / 60% 16-25: 11% / 27% / 35% 2%: 6% / 10%	
Prostate Health Index *phi*	97	*phi* (calculated) / Cancer Probability 0-24.9 / 11.0% 25.0-34.9 / 18.1% 35.0-54.9 / 32.7% >55.0 / 52.1%	52.1%

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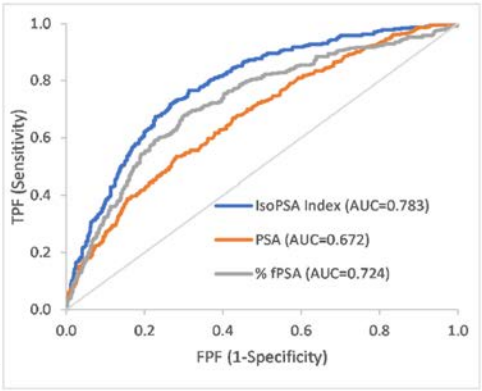
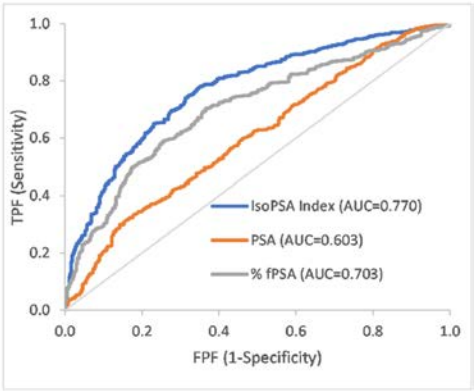
IsoPSA





Klein et Al. Urol Onc. 2022

PSA Isoform that could result in a substantial reduction of unnecessary biopsies

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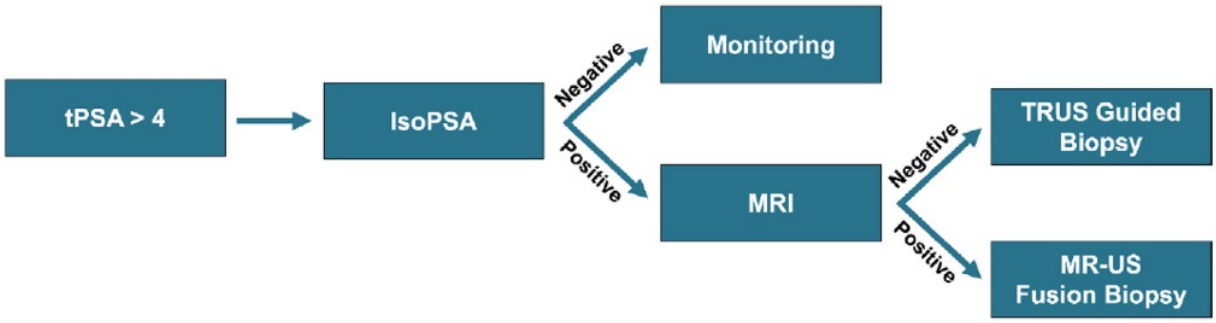
IsoPSA – Proposed Algorithm for Clinical Use



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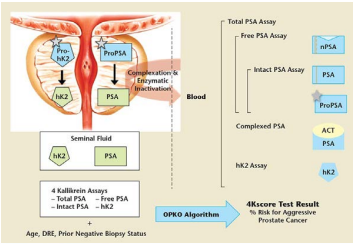
4Kscore – Report



Interpretation

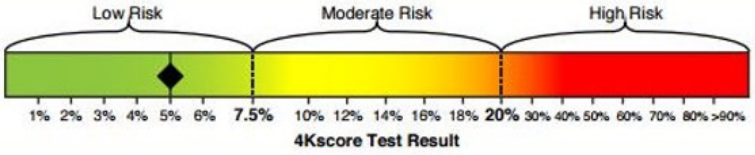
LOW RISK

There is a **95%** probability that the patient will not have aggressive disease on a prostate biopsy.

For a patient aged 60 years or older with a total PSA ≥ 3 ng/mL and a 4Kscore <7.5%, the probability of not developing distant metastases within the next 10 years is **99.8%**.

4Kscore Test Results

4Kscore: **5%**



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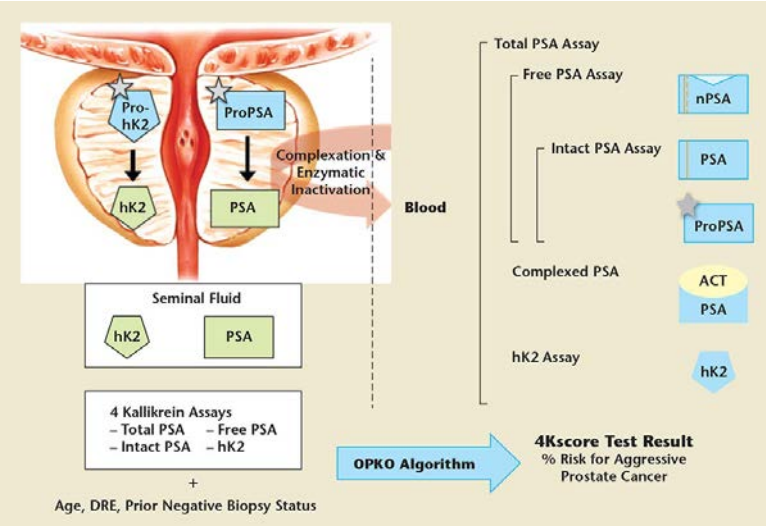
4Kscore

- Panel of kallikrein markers (total PSA, free PSA, intact PSA, and hK2) combined with age, DRE and prior biopsy status using a proprietary algorithm
- Multiple prospective studies in US and Europe show improved prediction of high-grade cancer



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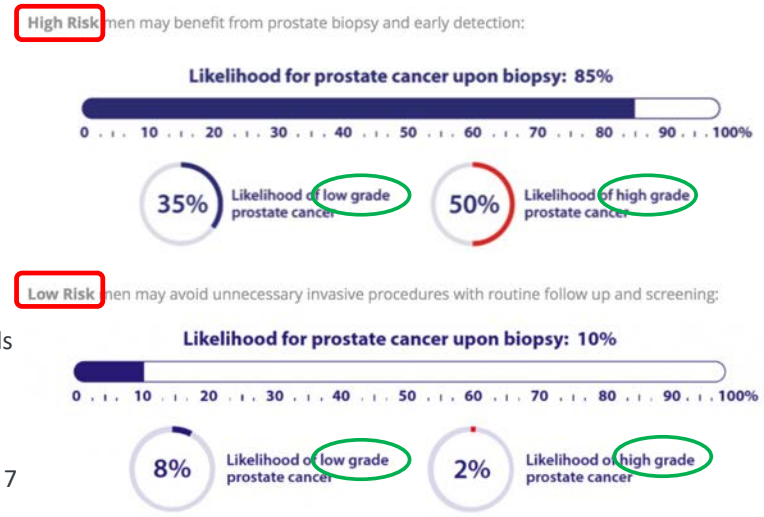
SelectMDx for Prostate Cancer – Liquid Biopsy

- Identify patients at increased risk for aggressive disease, thereby aiding in the selection of men for prostate biopsy
- Measures the mRNA levels of the DLX1 and HOXC6 biomarkers
- Higher expression levels of DLX1 and HOXC6 mRNA are associated with an increased probability for high-grade (Gleason score ≥ 7 prostate cancer



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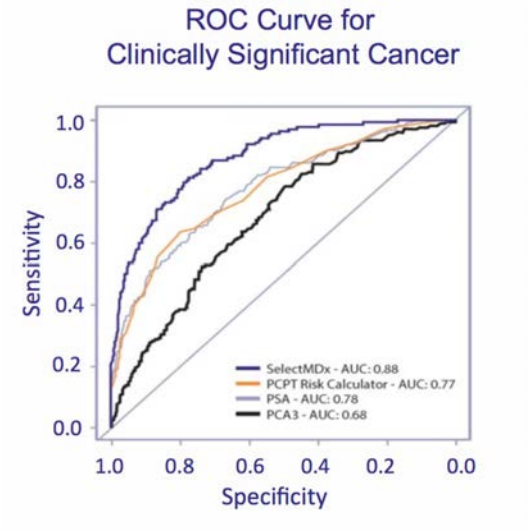
SelectMDx for Prostate Cancer - Liquid Biopsy

- Improved detection of men harboring high-grade disease, with a negative predictive value for significant cancer of 98% and an area under the curve (AUC) of 0.88



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Van Neste et al, Detection of High-Grade Prostate Cancer Using a Urinary Molecular Biomarker-Based Risk Score. European Urology 2016.

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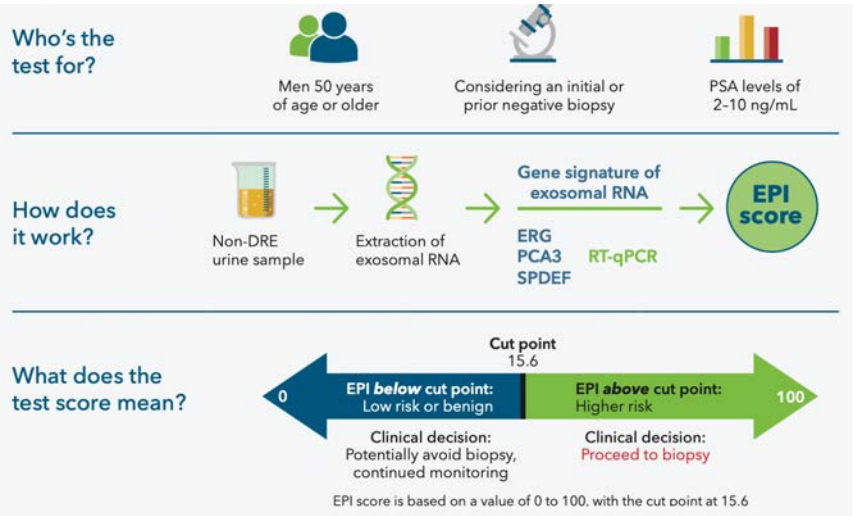
ExoDx™ Prostate(IntelliScore)



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Valentino A, et al. (2017) Exosomal microRNAs in liquid biopsies: future biomarkers for prostate cancer. Clin Transl Oncol

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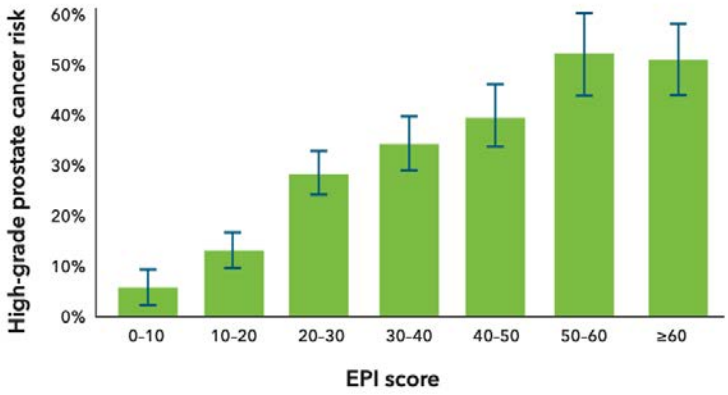
ExoDx® Prostate(IntelliScore)

Figure 1: Likelihood of finding HGPCa on biopsy in intended use population[4,5]



Key Points:

- Every patient in this data is in the intended use population (PSA 2-10ng/mL, presenting with initial biopsy, and 50 years and above)
- Consider age group and other standard of care factors when interpreting the results

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McKiernan J, et al. A Novel Urine Exosome Gene Expression Assay to Predict High-grade Prostate Cancer at Initial Biopsy. JAMA Oncol. 2016 Jul 1;2(7):882-9

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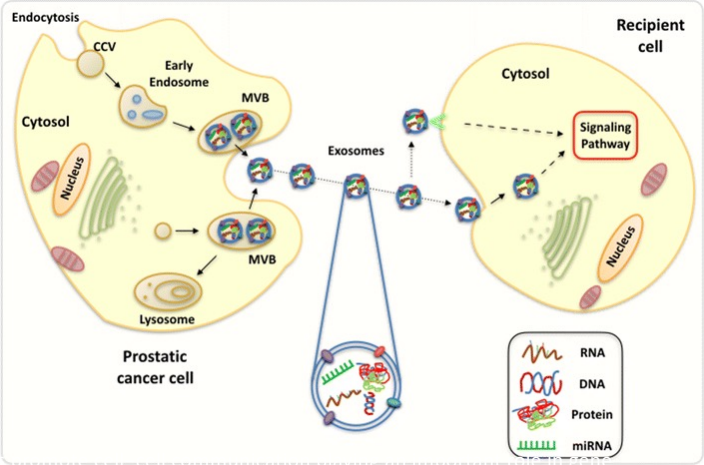
ExoDx™ Prostate(IntelliScore)

- Analyzes exosomal RNA for three biomarkers (PCA3, TMPRSS2:ERG and SAM) known to be expressed in men with high-grade prostate cancer (Gleason Score ≥ 7)
- Men 50 years or older
- PSA: 2-10ng/mL presenting for an initial biopsy
- Urine test – No DRE



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Valentino A, et al. (2017) Exosomal microRNAs in liquid biopsies: future biomarkers for prostate cancer. Clin Transl Oncol

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MY PROSTATE SCORE

Risk category: Low or Elevated

Likelihood of Clinically Significant Cancer Grade Group 2 or higher: 0-100%

Easy-to-Interpret Results

MPS2 results are available within 5-7 days and report the percent likelihood that clinically significant prostate cancer would be detected on biopsy. The cutoff for low risk is dependent on prior biopsy status.

7.5% Threshold for biopsy naïve patients

5.4% Threshold for prior negative patients

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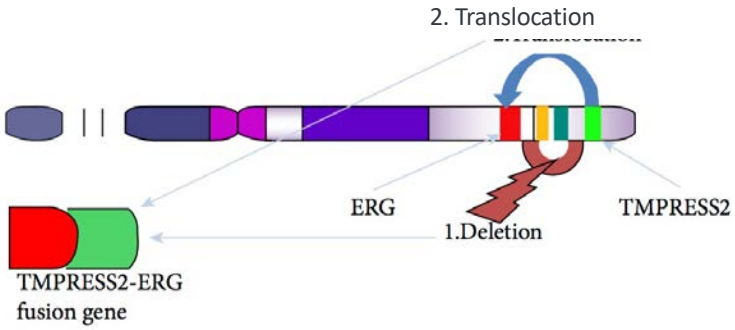
TMPRSS2:ERG gene fusion

- Loss of genetic material between two genes on chromosome 21
- Limited exclusively to prostate cancer
- Performance may be improved through combination with other urinary markers (ex: Mi-Ps combines PCA3 + TMPRSS2:ERG)

Fig. 1 Mechanism of TMPRESS2-ERG fusion (chromosome 21). 1. Large deletion of intervening genetic region between ERG and TMPRESS2 genes (most common). 2. Translocation of TMPRESS2 and ERG genes.



Hossain et al 2013 BJU International 111, 834–835

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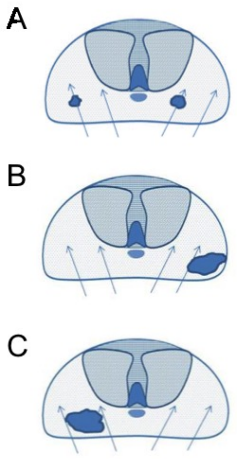
Limitations of All Molecular Markers

- **None** of the prostate cancer molecular risk assessment biomarkers assist in tumor localization for biopsy
- Can not guide where to biopsy



(Bjurlin, et al, J Urol, 2014; adapted from H Ahmed, UCL)

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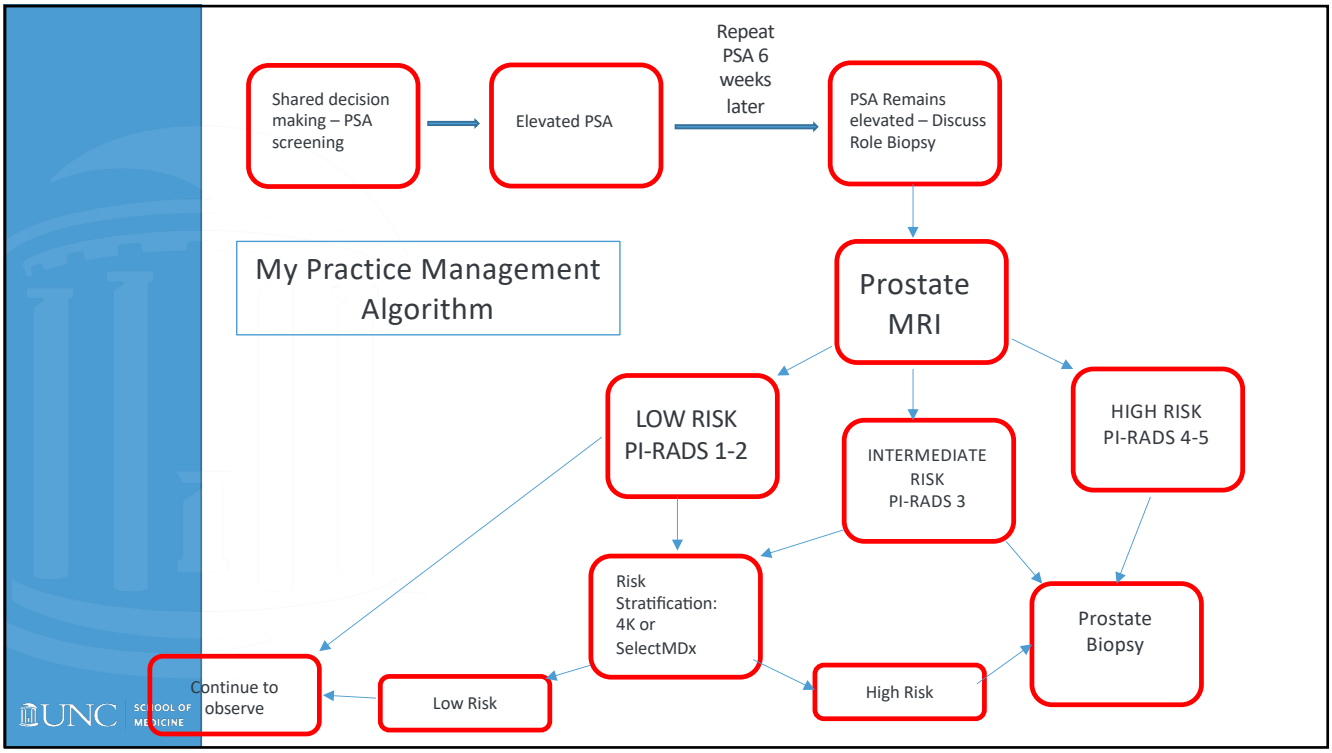

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Molecular markers permit a physician to analyze a prostate biopsy to gauge the likelihood of aggressive cancer.

True 0%

False 0%

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Additional Considerations

- African American men remain underrepresented in most validation studies to date – despite the fact that they have a higher incidence of prostate cancer and death rates more than 2.4-fold higher than whites
- Unclear how initial test results can change with repeat assessments
- As prostate cancer as a disease evolves in an individual, an assessment using one of these tests only represents a snapshot of the disease state at the time tested
- Further research into how the information from these tests changes with repeat measurements is required

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Conclusions

- Screening for Prostate cancer needs to be smarter
- Incorporation of secondary risks assessment tools will help make this possible
- Including MRI and blood/urine biomarkers
- Goal is to detect lethal disease in men who would benefit from treatment

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