

Technological Advances in Prostate Cancer Screening

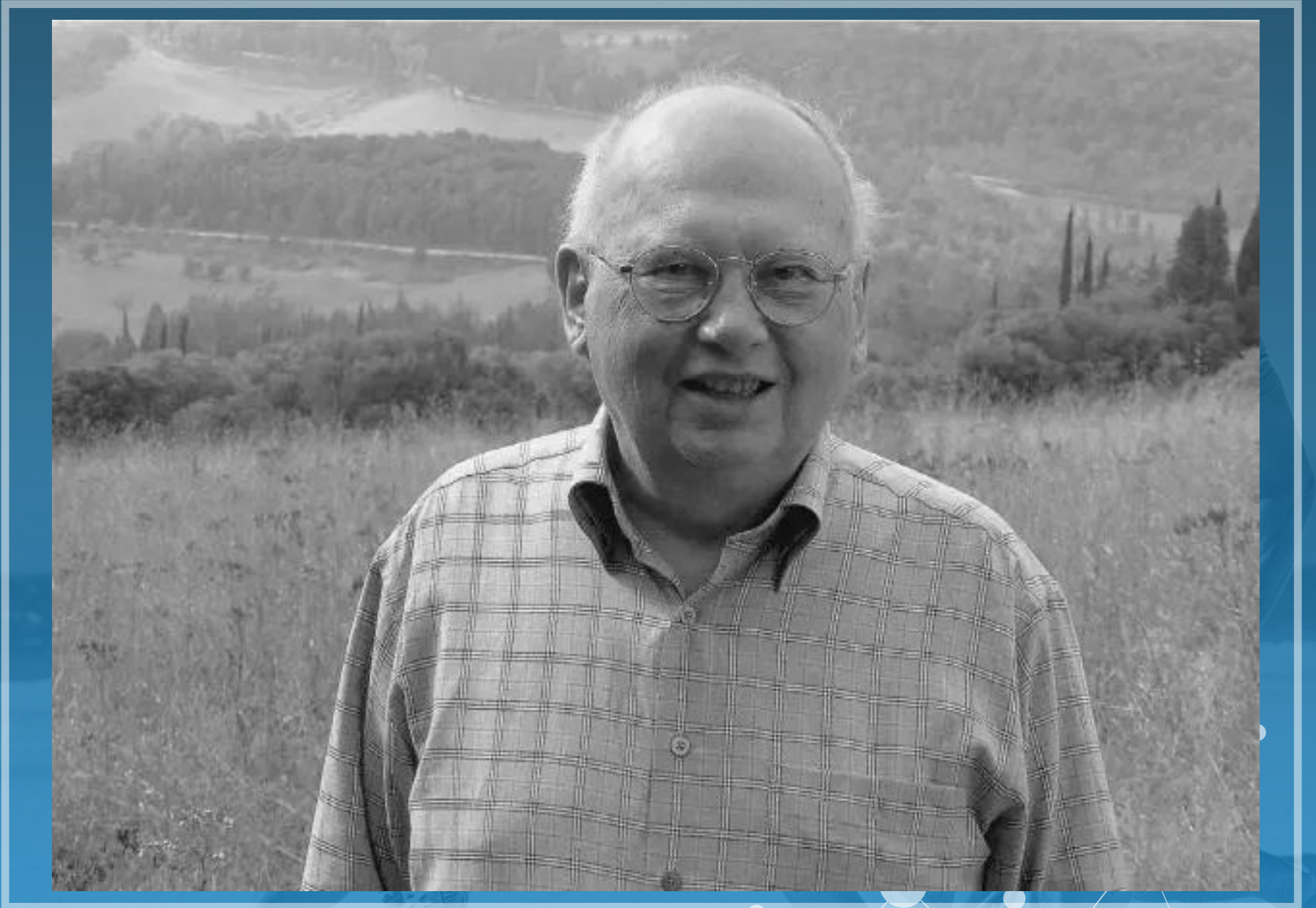


NANOSTICS
PRECISION HEALTH



Frank Sojonky

Oct. 4, 1928 –
Oct. 15, 2012





ALBERTA
PROSTATE CANCER
RESEARCH INITIATIVE

knowledge | action | impact

The **development of biomarkers** to predict the outcome of prostate cancer is our **greatest unmet clinical need**.

John D. Lewis Research Group

Bird Dogs Chair in Translational Oncology

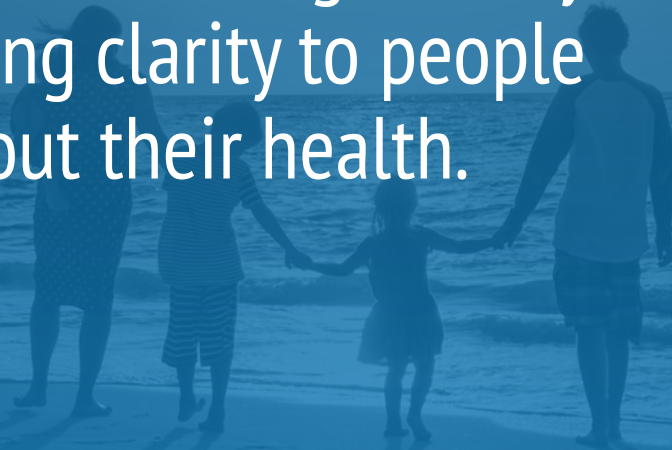
Professor, Department of Oncology
University of Alberta



NANOSTICS
PRECISION HEALTH

Nanostics is a precision health company with a mission to enable better diagnosis by providing clarity to people about their health.

Collaboration
Learning
Accuracy
Reliability
Innovation
QualiTY



Prostate cancer is the most diagnosed cancer and the second leading cause of cancer-related death in men



27,900 new diagnoses

Prostate Cancer accounted for 20% of cancers in men in 2024.



Canadian
Cancer
Society

Prostate Cancer accounted for 10% of cancer-related deaths in men in 2024.

5000 deaths



Detecting and treating PCa early improves outcomes by 3X

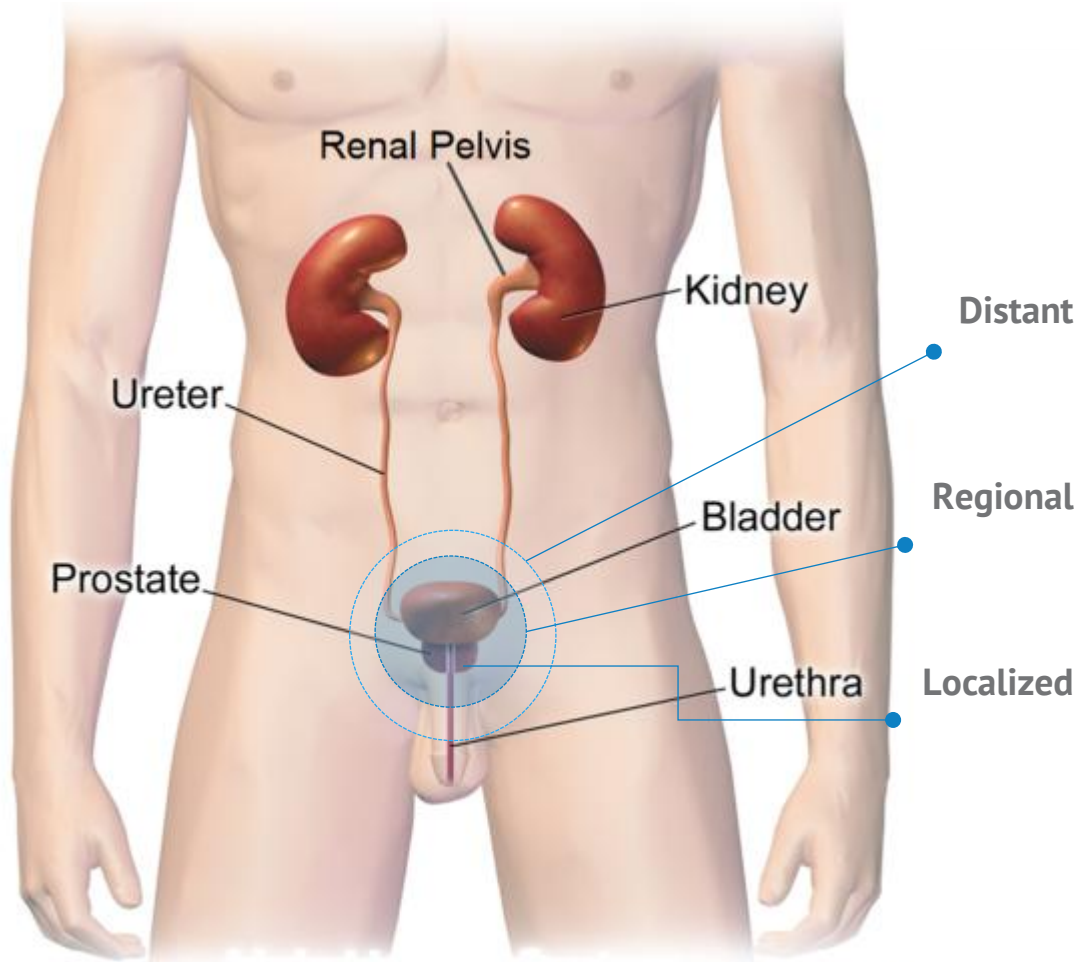
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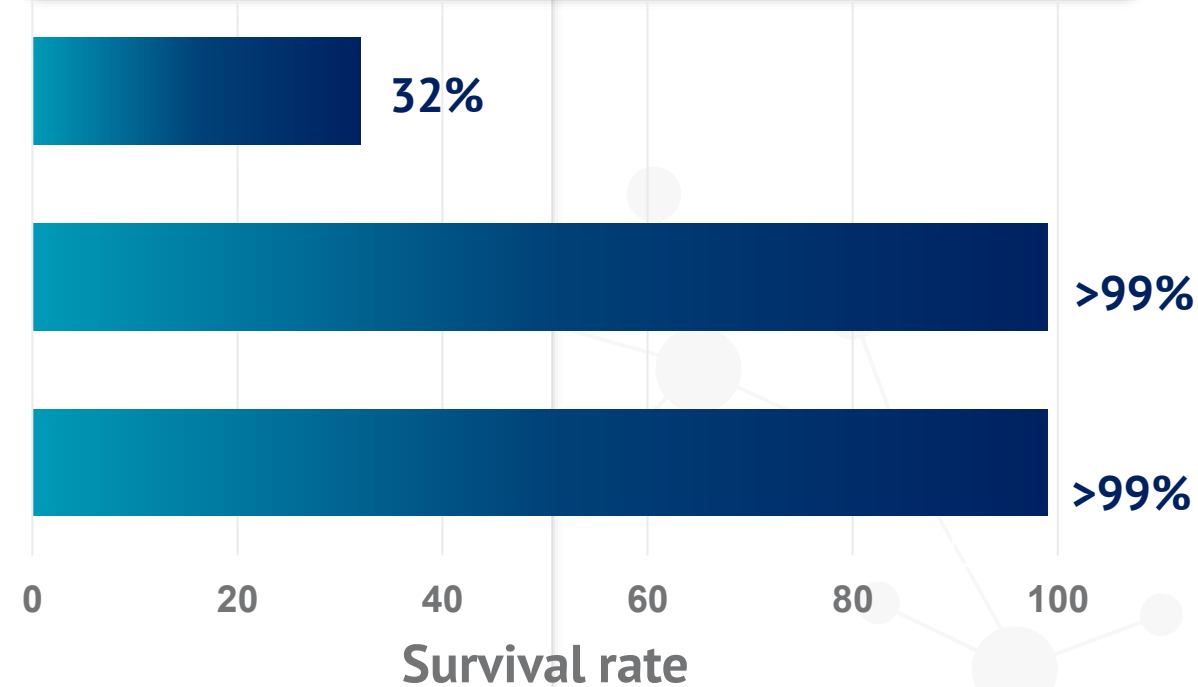
[ARTICLE](#)

Cancer statistics, 2023

Rebecca L. Siegel MPH  | Kimberly D. Miller MPH  |
Nikita Sandeep Wagle MBBS, MHA, PhD  | Ahmedin Jemal DVM, PhD



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*Race does not alter survival rates.

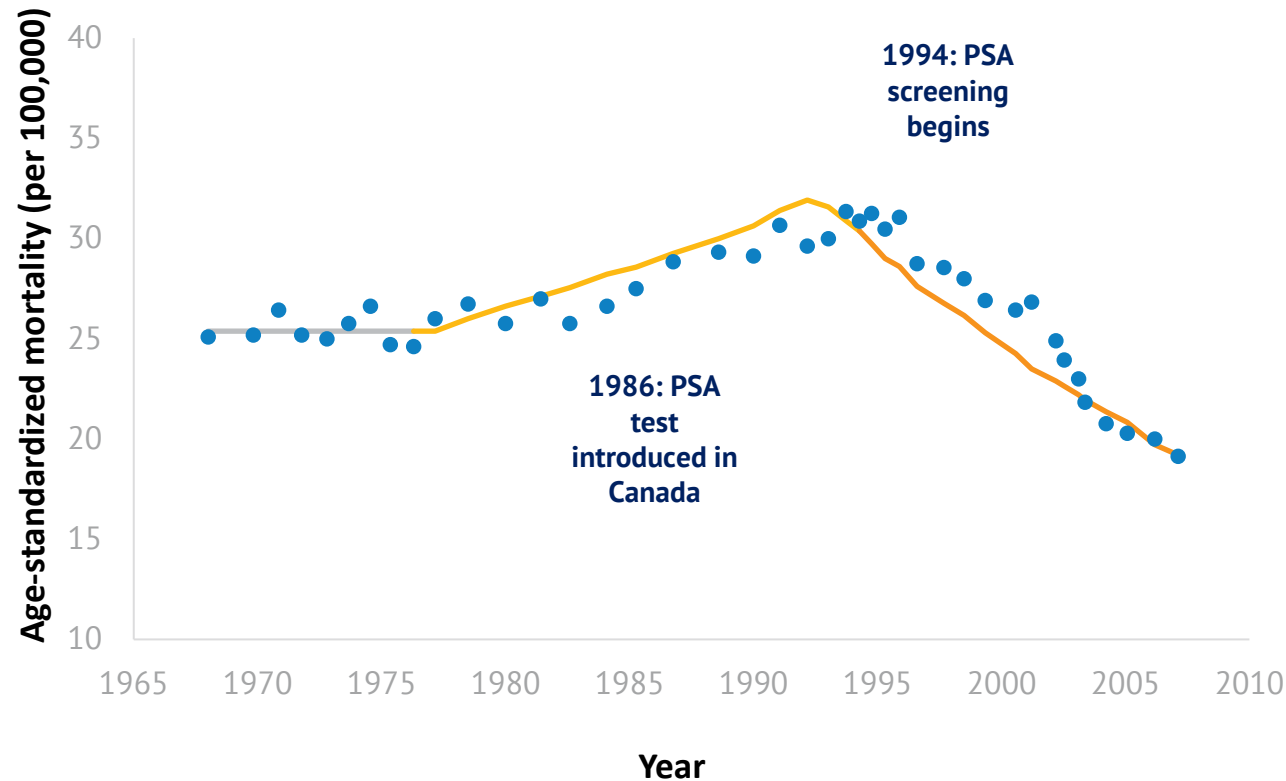
Increased screening for PCa reduced related mortality rates in Canada

CMAJ OPEN

Research

Trends in prostate cancer incidence and mortality in Canada during the era of prostate-specific antigen screening

James Dickinson MBBS PhD, Amanda Shane MSc, Marcello Tonelli MD SM, Sarah Connor Gorber PhD, Michel Joffres MD PhD, Harminster Singh MD MPH, Neil Bell MD SM



Age-standardized mortality (per 100,000) & annual percent change (APC) of prostate cancer mortality, 1969-2009, Canada. Dickinson et al. (2016)

PSA performs as well or better than nearly all widely used cancer screening tests

Lifetime lost Lifetime gained

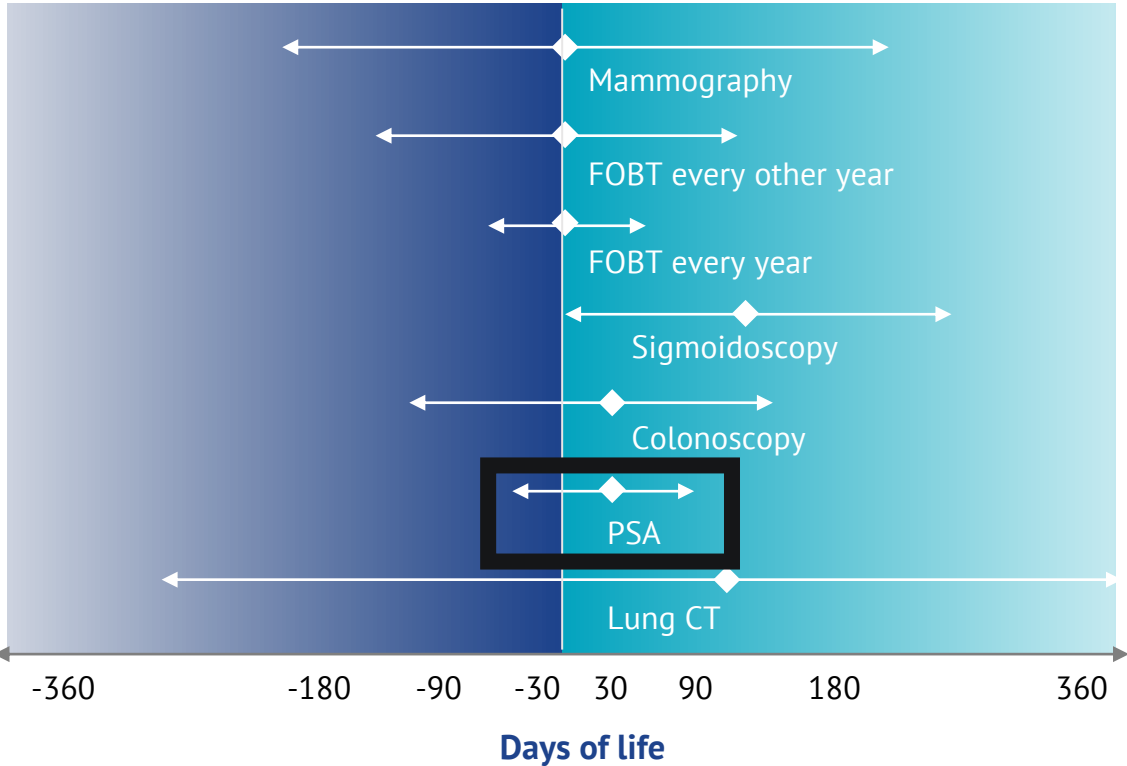


Figure 2: Lifetime Gained With Commonly Used Cancer Screening Tests

JAMA Internal Medicine | Original Investigation

Estimated Lifetime Gained With Cancer Screening Tests A Meta-Analysis of Randomized Clinical Trials

Michael Bretthauer, MD, PhD; Paulina Wieszczyn, MSc, PhD; Magnus Løberg, MD, PhD;
Michal F. Kaminski, MD, PhD; Tarjei Fiskergård Werner, MSc; Lise M. Helsing, MD, PhD; Yuichi Mori, MD, PhD;
Øyvind Holme, MD, PhD; Hans-Olov Adami, MD, PhD; Mette Kalager, MD, PhD

01

Absolute survival benefits are absent for most cancer screening tests

02

PSA performs as well or better than nearly all widely used cancer screening tests

If prostate cancer screening with PSA testing reduces prostate cancer-related mortality, why has it not been more strongly recommended?



Elevated PSA levels were associated with an increase in expensive, risky and invasive procedures

Next steps in Diagnosis

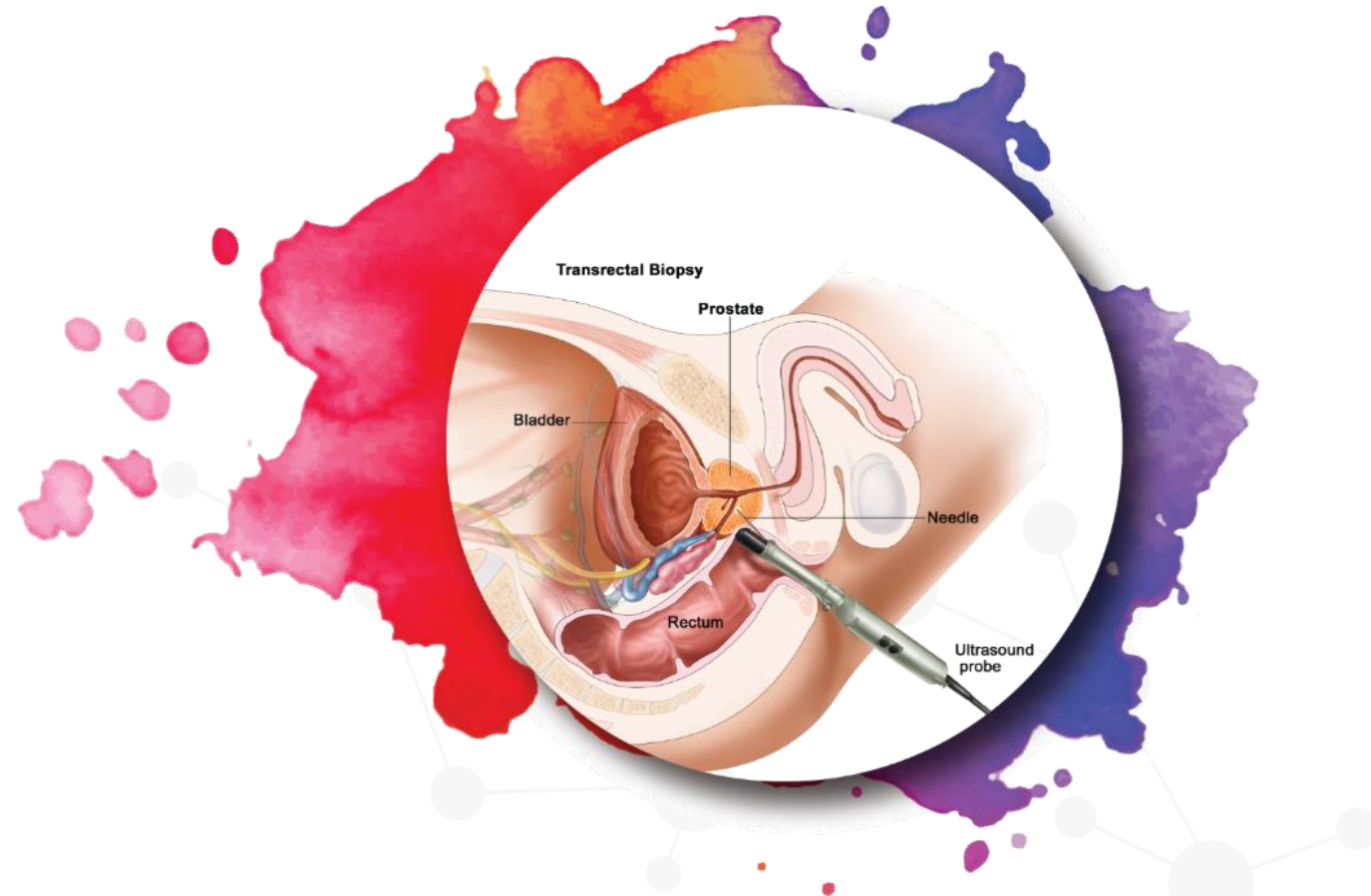
MRI

- Variable access
- Competing demands

Biopsy

- Transrectal or transperitoneal approach
 - Invasive
 - Uncomfortable
 - Associated risks of bleeding, infection, urinary retention, etc.

Results often show absent or indolent prostate cancer



Concerns regarding PSA screening



Lack of specificity of PSA → high burden of investigation

Overdiagnosis of clinically indolent disease → overtreatment



Updated in 2018 & currently under revision



Updates planned for 2026, but then Task Force put on “pause”

Reduced screening led to an increase in late-stage diagnosis: a “reverse stage migration”.

OXFORD

JNCI J Natl Cancer Inst (2021) 113(1): djaa068

doi: 10.1093/jnci/djaa068

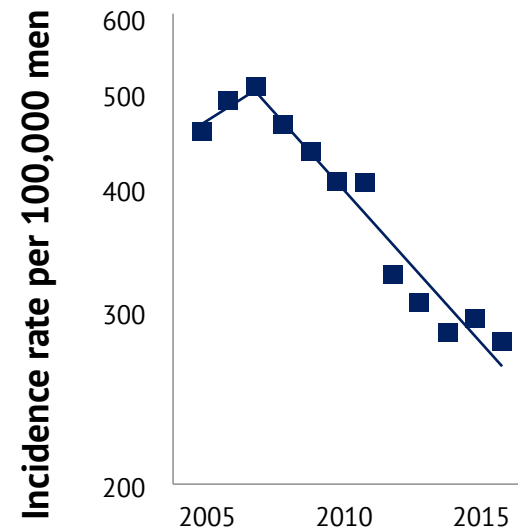
First published online May 20, 2020

Article

Prostate Cancer Incidence 5 Years After US Preventive Services Task Force Recommendations Against Screening

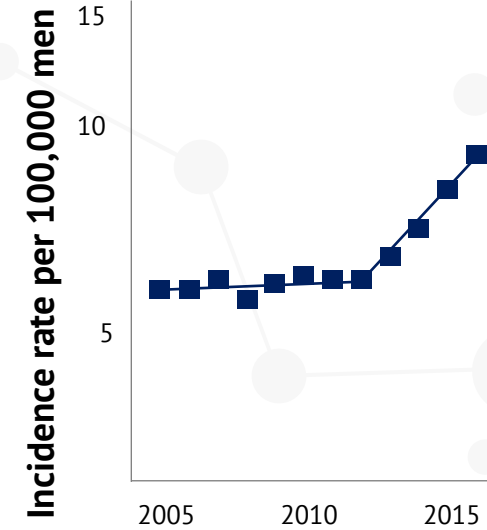
Ahmedin Jemal, DVM, PhD*, MaryBeth B. Culp, MPH , Jiemin Ma, PhD , Farhad Islami, MD, PhD, Stacey A. Fedewa, PhD

Local



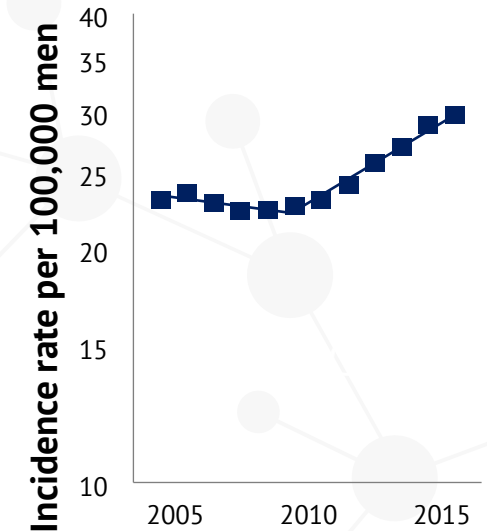
Year of diagnosis

Regional



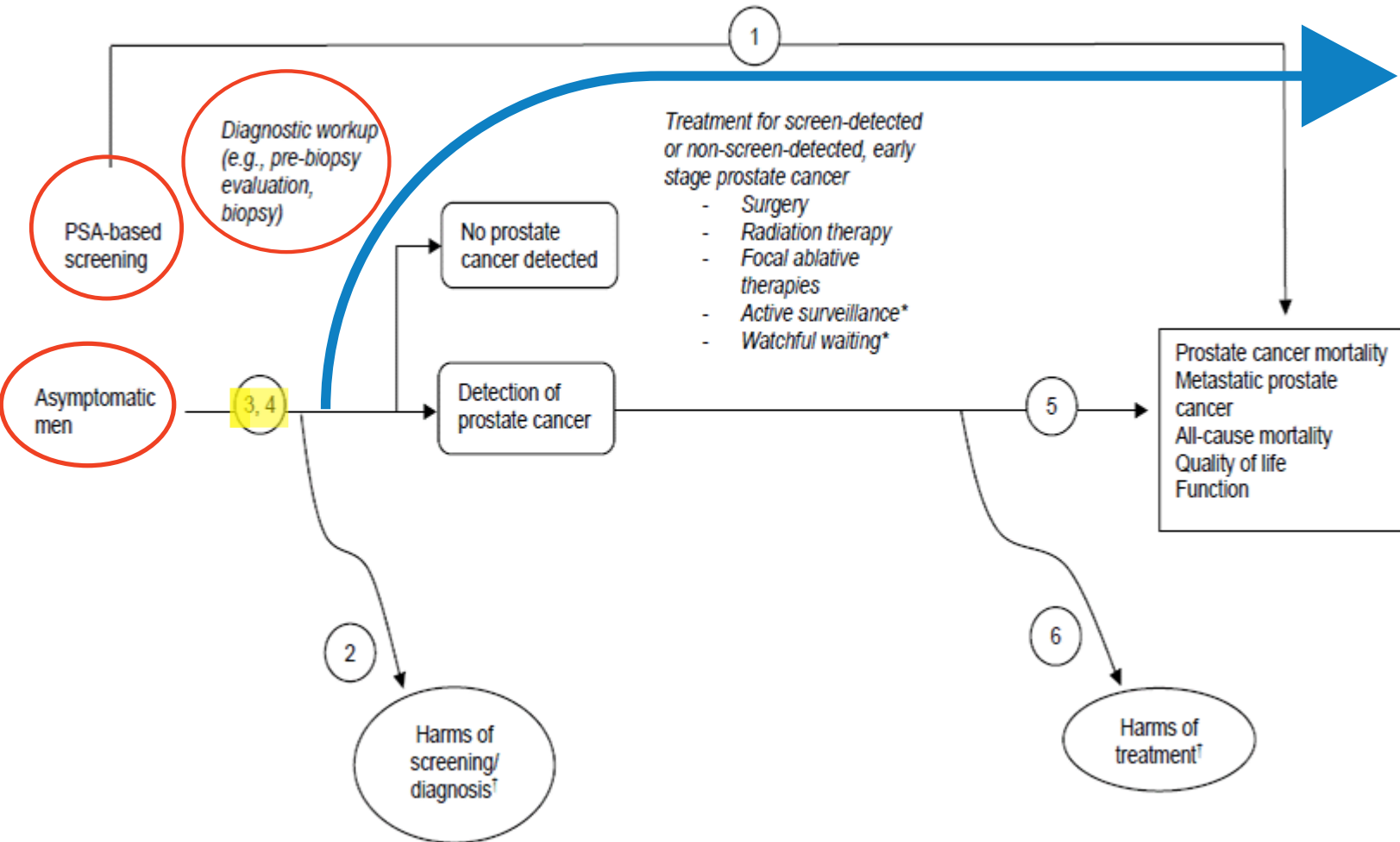
Year of diagnosis

Distant



Year of diagnosis

US Preventive Services Task Force review process



4. **What is the accuracy** of a *pre-biopsy prostate cancer risk calculator* or MRI in combination with a positive PSA-based screening test for identification of men with clinically significant prostate cancer?

4a. **What is the effect** of using a *pre-biopsy prostate cancer risk calculator* or MRI on prostate cancer biopsy rates compared to PSA-based screening alone?

4b. **What is the effect** of using a *pre-biopsy prostate cancer risk calculator* or MRI on prostate cancer morbidity and mortality, quality of life, and function compared to PSA-based screening alone?

<https://www.uspreventiveservicestaskforce.org/uspstf/document/draft-research-plan/prostate-cancer-screening-adults>

- PSA screening should not be avoided.
- The use of adjunctive tests provides the benefits of screening while avoiding the harms of unnecessary transrectal prostate biopsies.

“...we suggest starting PSA testing at age 50 in most men and at age 45 in men at an increased risk of prostate cancer”

“For men with PSA >3 ng/ml, consider more frequent PSA testing intervals or **adjunctive testing strategies**”

CUA GUIDELINE

UPDATE — 2022 Canadian Urological Association recommendations on prostate cancer screening and early diagnosis



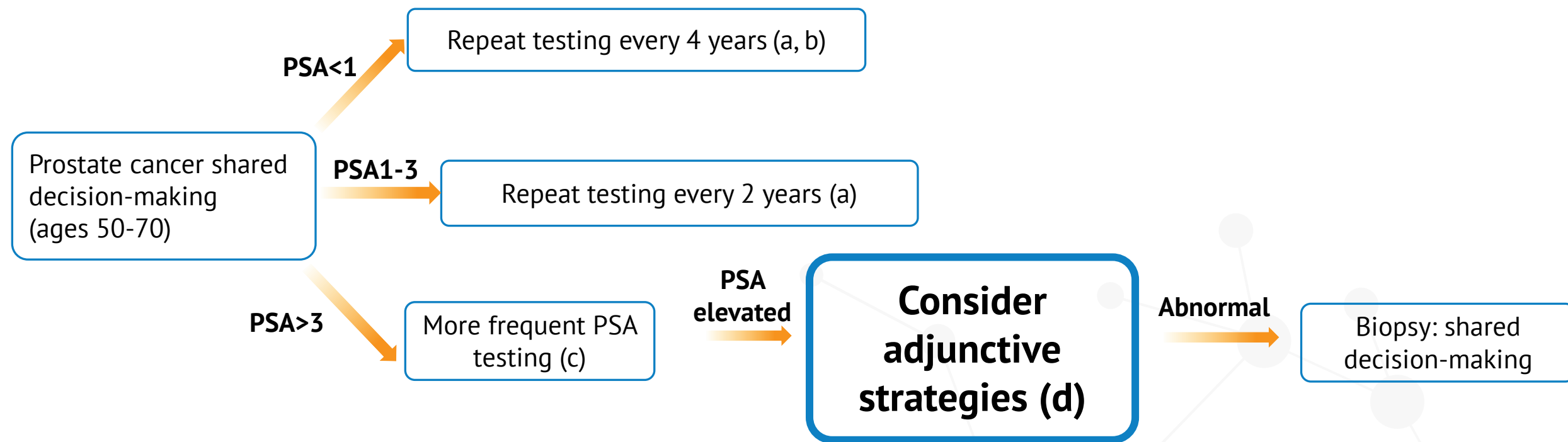
Endorsement of the 2021 Cancer Care Ontario guidelines on prostate multiparametric magnetic resonance imaging

Ross J. Mason¹; Karim Marzouk²; Antonio Finelli³; Fred Saad⁴; Alan I. So⁵; Philippe D. Violette^{6,7}; Rodney H. Breau⁸; Ricardo A. Rendon¹;

¹Department of Urology, Dalhousie University, Halifax, NS, Canada; ²Windsor General Hospital, Windsor, ON; and Western University, London, ON, Canada; ³Division of Urology, University of Toronto, Toronto, ON, Canada; ⁴Department of Surgery (Urology), University of Montreal, Montreal, QC, Canada; ⁵Department of Urologic Sciences, University of British Columbia, Vancouver, BC, Canada; ⁶Department of Surgery, Western University, London, ON, Canada; ⁷Departments of Surgery and Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, ON, Canada; ⁸Division of Urology, University of Ottawa, Ottawa, ON, Canada

Reducing prostate biopsies:

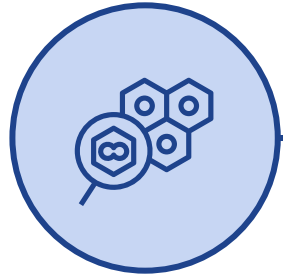
What if we could improve the accuracy of the PSA test to only biopsy those men who really need it?



Prostate cancer screening pathway. (a) Discontinue screening if life expectancy <10 years; (b) consider discontinuation of screening if age >60 and PSA <1 ng/ml; (c) more frequent testing interval can be considered; the optimal frequency is unknown; (d) for example risk calculators, %free PSA, etc.

2022 Canadian Urological Association recommendations on prostate cancer screening and early diagnosis.

What are the goals of the ideal prostate cancer screening approach?



#1

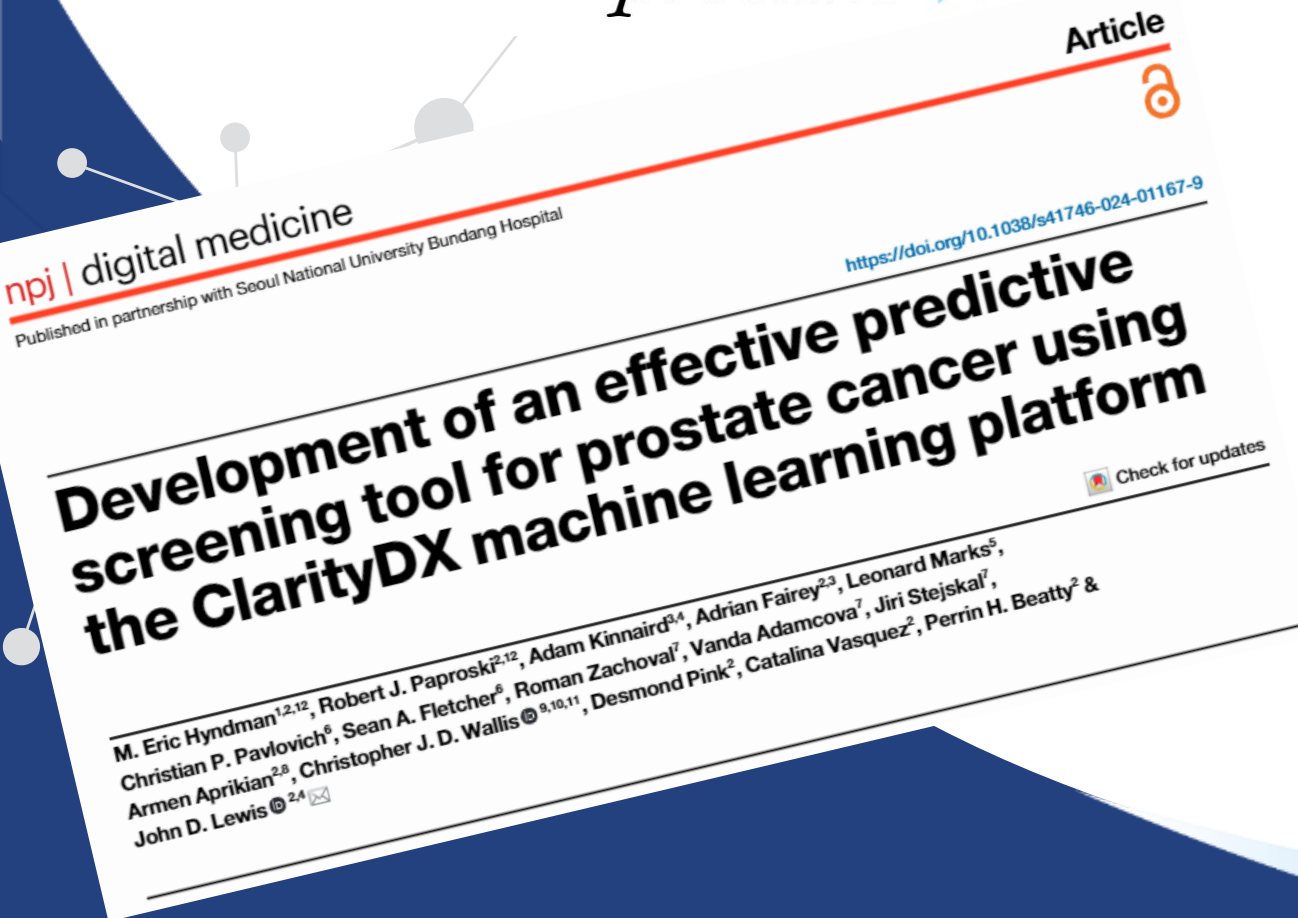
Preserve the mortality benefits of prostate cancer screening and catch prostate cancer early when the treatment options are most effective.



Reduce overdiagnosis and overtreatment by not exposing low risk cases to invasive diagnostic procedures while prioritizing high risk cases for Urological assessment without delay.

#2





- 3-4x more accurate than PSA alone
- Validated using Real-World Evidence
- Can reduce costs to the healthcare system and individuals
- Can help prioritize and reduce wait times for MRI and biopsy

ClarityDX Prostate was developed and validated in a study that included 3,488 patients from across the world



Kipnes Urology Centre
Edmonton, AB, CANADA



Prostate Cancer Centre
Calgary, AB, CANADA



Baltimore, ML, USA



Los Angeles, CA, USA

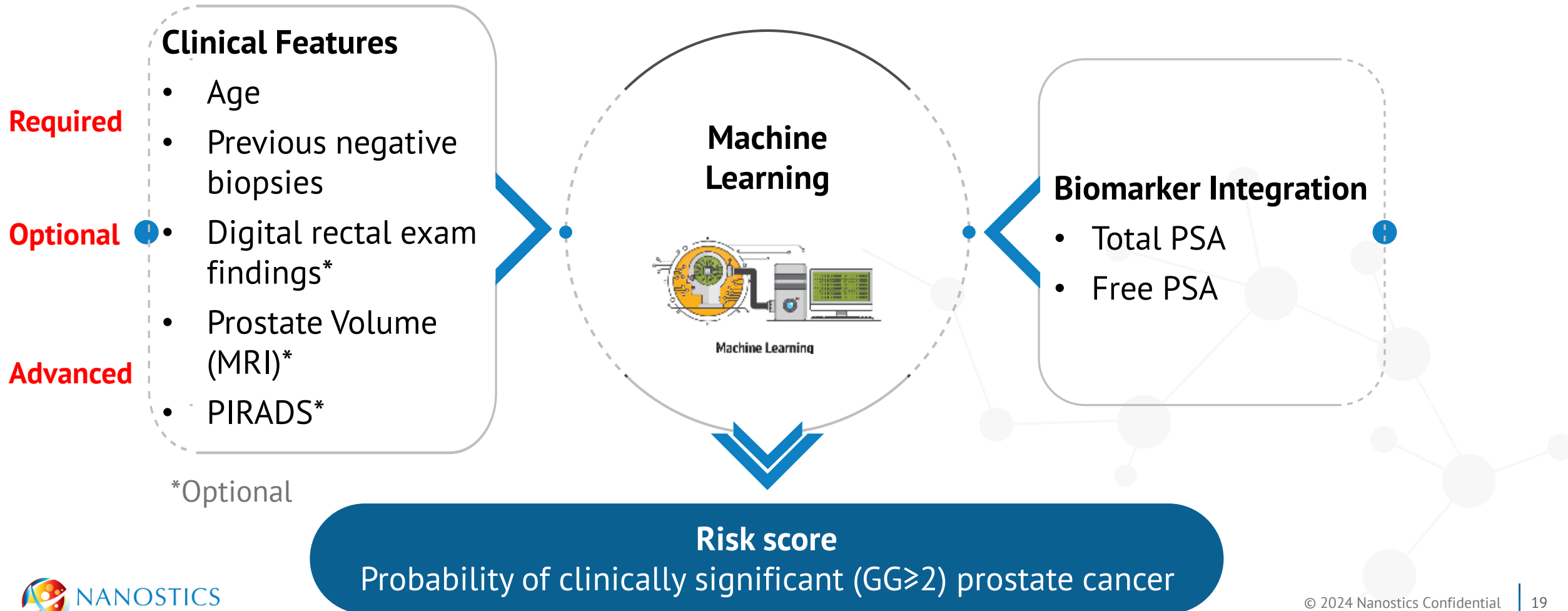


Thomayer University Hospital
Prague, Czech Republic

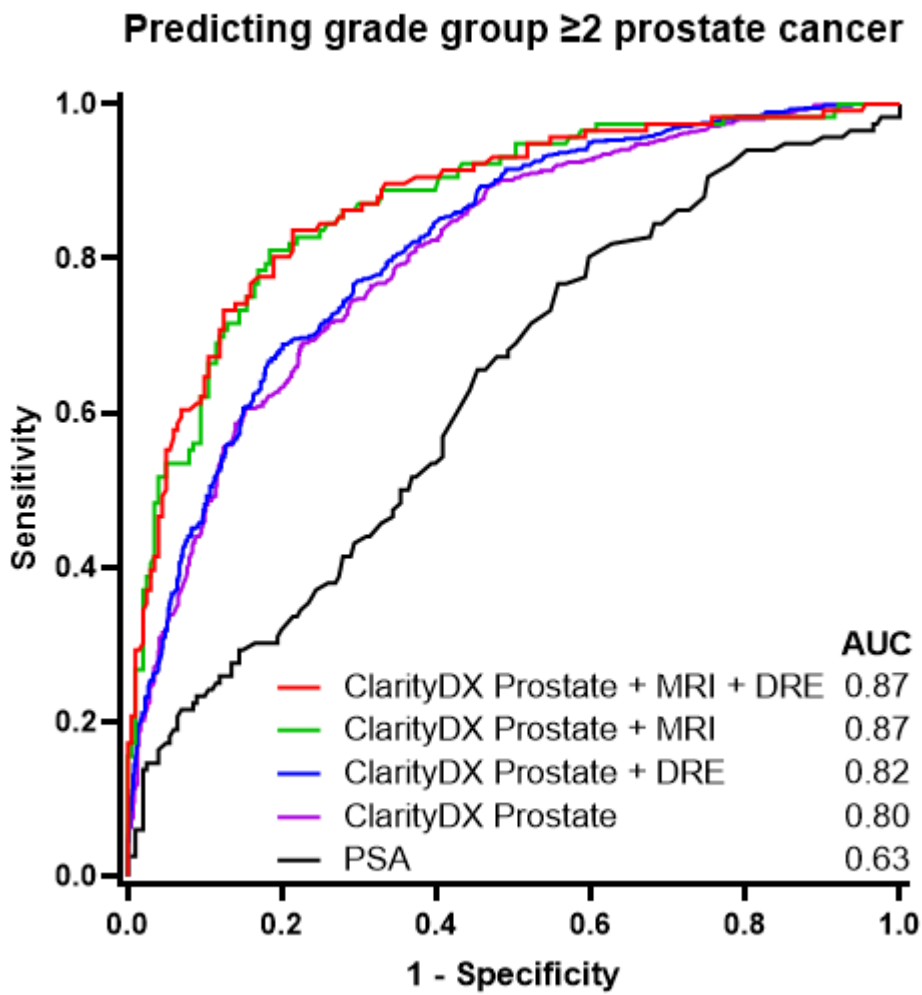


ClarityDX Prostate uses an optimized machine learning model to accurately predict clinically significant prostate cancer

Our Machine Learning Pipeline Significantly Improves Predictive Power



In a 3,448-patient clinical study, we found that ClarityDX Prostate is **3-4X** more accurate than PSA alone

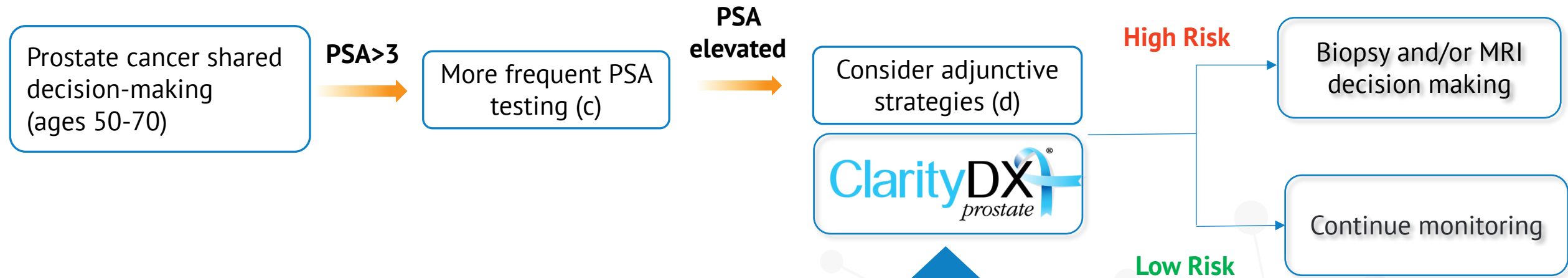


Algorithm	AUC	Sens	Spec	PPV	NPV
ClarityDX Prostate +DRE+MRI	0.87	95	47	51	94
ClarityDX Prostate + MRI	0.87	95	45	50	94
ClarityDX Prostate + DRE	0.82	95	35	54	94
ClarityDX Prostate	0.80	95	32	52	89
PSA	0.63	95	12	38	80

Using ClarityDX Prostate will reduce the number of unnecessary prostate biopsies by up to **47%**

Integrating ClarityDX Prostate into the care path:

ClarityDX Prostate fits perfectly within the CUA and NCCN guidelines as an adjunctive testing strategy to be performed with a PSA >3 and before decisions about an MRI and/or biopsy



2022 Canadian Urological Association recommendations on prostate cancer screening and early diagnosis.

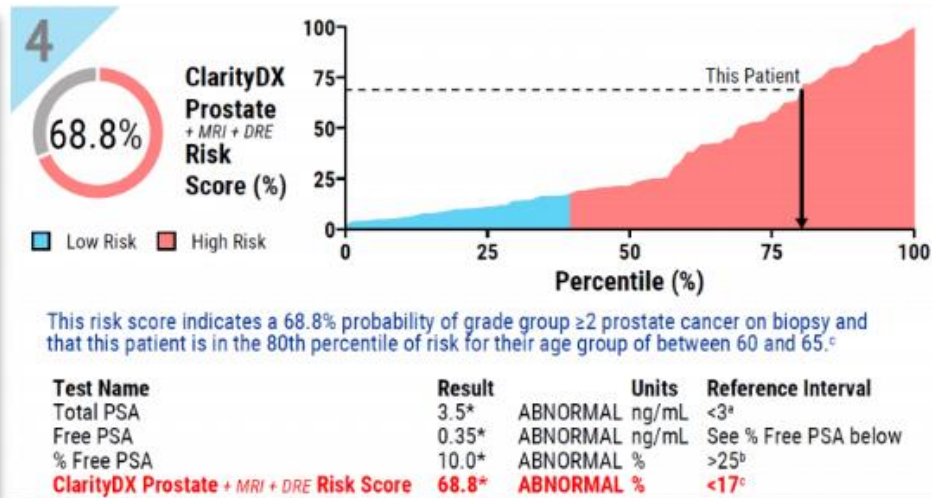
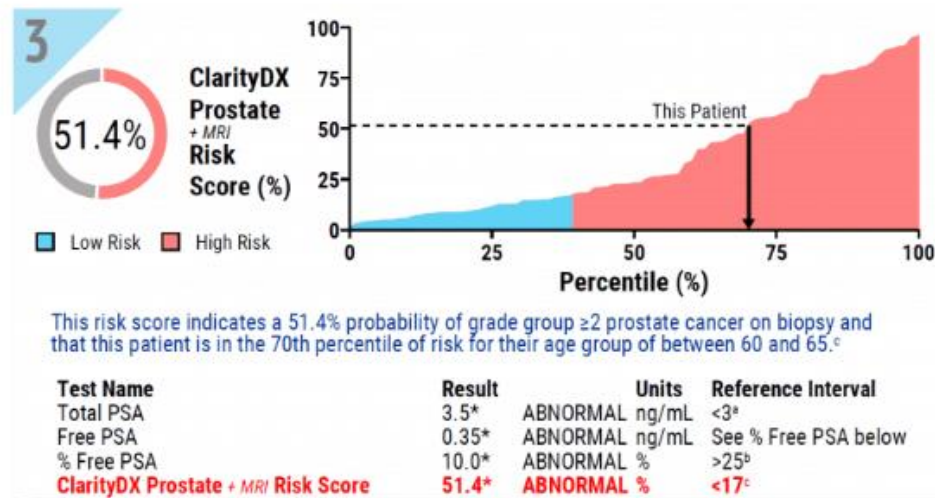
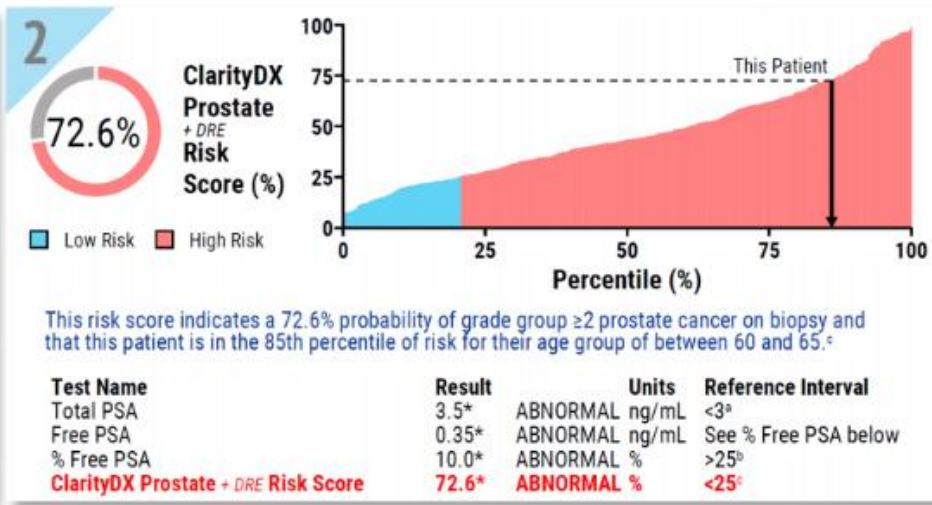
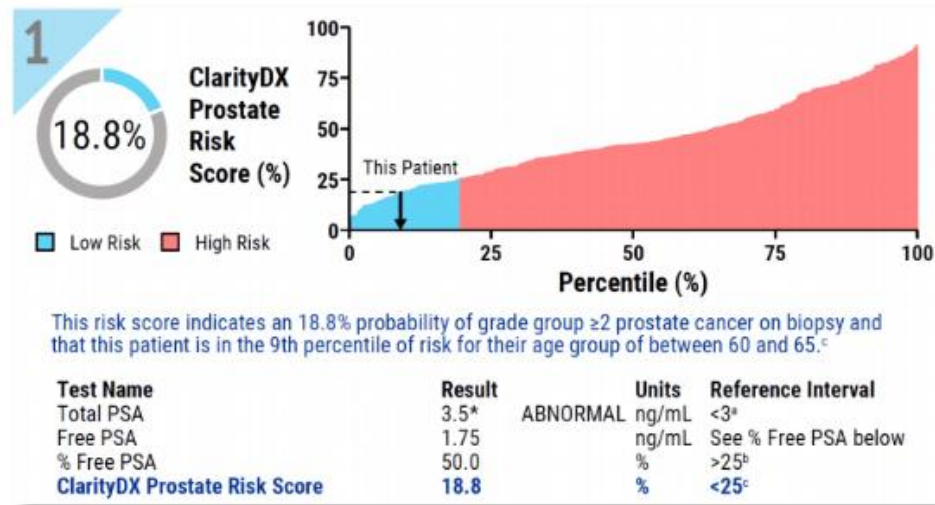


- Avoid **32% - 47%** of biopsies
- Prioritization of high-risk cases

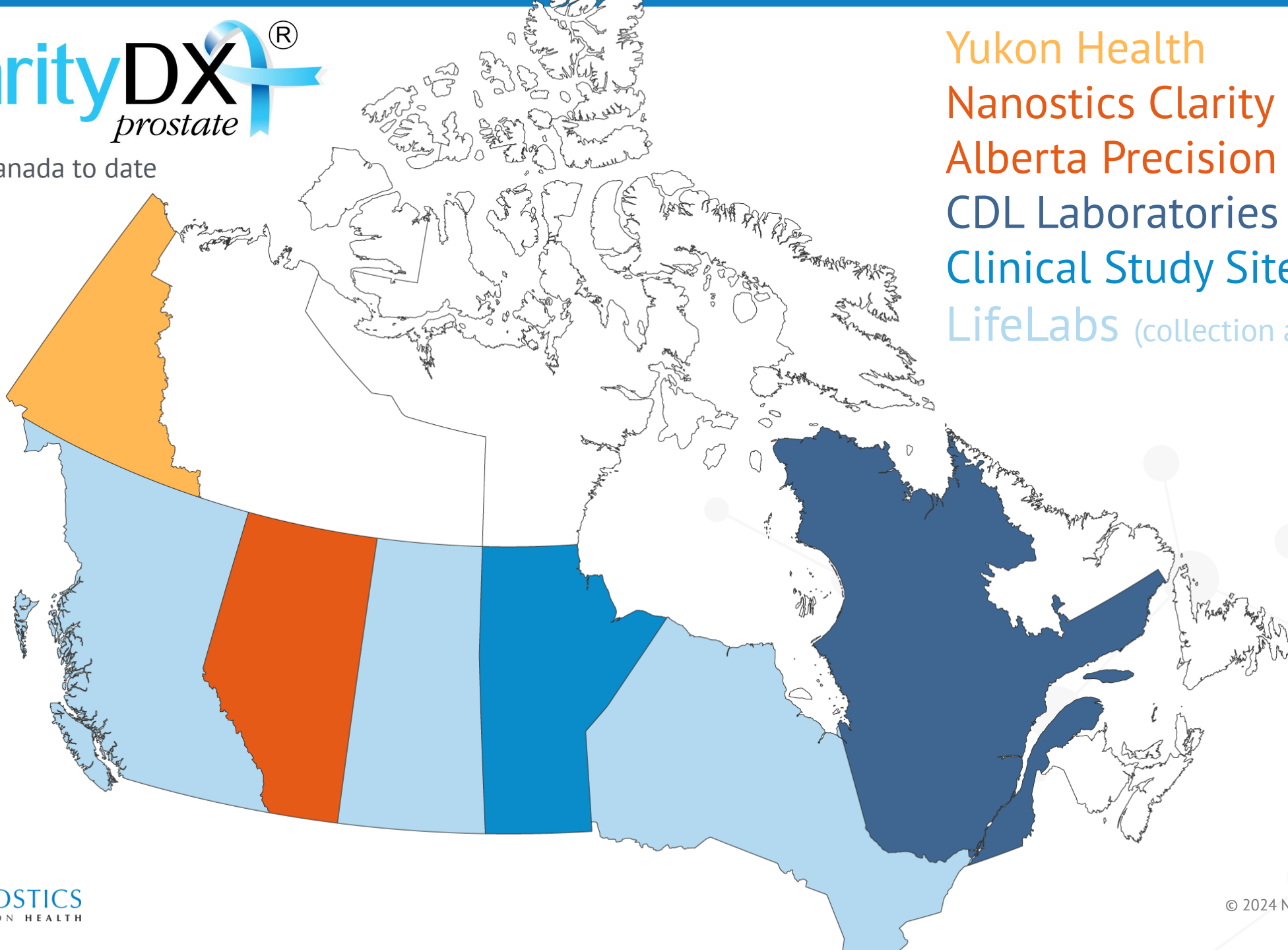
M. Eric Hyndman et al. (2023)
Lock & Yan (2023)

Interpreting the results of the ClarityDX Prostate test

- The ClarityDX Prostate Test Report provides the patient's total PSA, % free PSA, and the ClarityDX Prostate Risk Score calculated by the machine learning algorithm.
- The risk score is provided as a percent probability of GG 2 and above prostate cancer and is reported with the patient's risk associated with their age group.
- A risk score of 25% or below (within the blue section) indicates a low risk for clinically significant prostate cancer.



Across Canada to date



Yukon Health
Nanostics Clarity Core Lab or
Alberta Precision Labs
CDL Laboratories
Clinical Study Site (RFD)
LifeLabs (collection agreement)

Barriers to full adoption and integration of ClarityDX Prostate

- Awareness
 - ❖ By patients, providers, health systems
- Integration into guidelines
 - ❖ Overly complex in Canada. USA is much further ahead
- Cost coverage
 - ❖ Universal healthcare, benefits, seamlessness



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Thank You!

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