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PSA Screening: What's new in 2025?

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Disclosures

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Prostate Cancer Screening

Goals:

- Detect early stage, clinically significant prostate cancer (PCa)
- Provide localized treatment with fewer side effects and reduced need for systemic treatments
- Prevent metastatic PCa and death from PCa

Limitations/Harms:

- Anxiety regarding potential PCa & living with PCa (overtreatment of low risk cancer)
- Risks of prostate biopsy
- Treatment side effects (urinary, bowel and sexual side effects)
- Will result in over treatment of men who would otherwise not develop metastatic disease or death from CaP

What is acceptable number needed to screen (NNS) and treat (NNT)?

Prostate Cancer Screening

Localized treatment Side Effects:

- Biopsy: Bleeding, pain, risk of infection
- Surgery: Stress urinary incontinence, erectile dysfunction (ED), surgical recovery
- Radiation: irritative GI and GU symptoms, hematuria, secondary malignancy, ED
- Androgen Deprivation Therapy (ADT) 4-36 months: fatigue, weight gain, ED/low libido, CV events, osteoporosis, hot flashes

Locally Advanced & Metastatic Prostate Cancer:

- Urinary retention→ catheter/SPT, TURP
- Ureteral obstruction→ nephrostomy tubes
- ADT 24 months-Indefinite: greater CV events, osteoporosis, “brain fog”/cognitive effects
- Bone pain, malignant fracture, spinal cord compression

PSA Screening Guidelines

USPTF[1]:

- Grade C for men aged 55-69 to encompass shared decision making.
- Grade D (do not screen) for men aged >70

AUA[2]

- Shared decision making for PSA screening
- Begin at age 45-50 for average risk men
- Begin at age 40 for high risk men (black ancestry, known genetic mutations, strong fhx prostate cancer)
- Individualize cessation of PSA screening at age 75

ACS[3]

- Informed decision making for prostate cancer screening
- Begin at age 50 for average risk men
- Begin at age 45 for high risk men (black, 1st degree relative w prostate cancer at age <65)
- Begin at age 40 for highest risk men (2+ 1st degree relative w prostate cancer at young age)

1. USPTF. Screening for Prostate Cancer US Preventive Services Task Force Recommendation Statement. JAMA. 2018;319(18):1901-1913
2. Wei, et al. Early Detection of Prostate Cancer: AUA/SUO Guideline Part I: Prostate Cancer Screening. J Urol. 2023 July ; 210(1): 46–53.
3. https://www.cancer.org/cancer/types/prostate-cancer/detection-diagnosis-staging/acs-recommendations.html

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Prostate Cancer Statistics

- Prostate cancer is the 2nd leading cause of cancer death in men in the United States.

Estimated New Cases

Male		
Prostate	299,010	29%
Lung & bronchus	116,310	11%
Colon & rectum	81,540	8%
Urinary bladder	63,070	6%
Melanoma of the skin	59,170	6%
Kidney & renal pelvis	52,380	5%
Non-Hodgkin lymphoma	44,590	4%
Oral cavity & pharynx	41,510	4%
Leukemia	36,450	4%
Pancreas	34,530	3%
All sites	**1,029,080**	

Estimated Deaths

Male		
Lung & bronchus	65,790	20%
Prostate	35,250	11%
Colon & rectum	28,700	9%
Pancreas	27,270	8%
Liver & intrahepatic bile duct	19,120	6%
Leukemia	13,640	4%
Esophagus	12,880	4%
Urinary bladder	12,290	4%
Non-Hodgkin lymphoma	11,780	4%
Brain & other nervous system	10,690	3%
All sites	**322,800**	

ACS, Siegel, et all. CA Cancer J Clin. 2024;74:12–49

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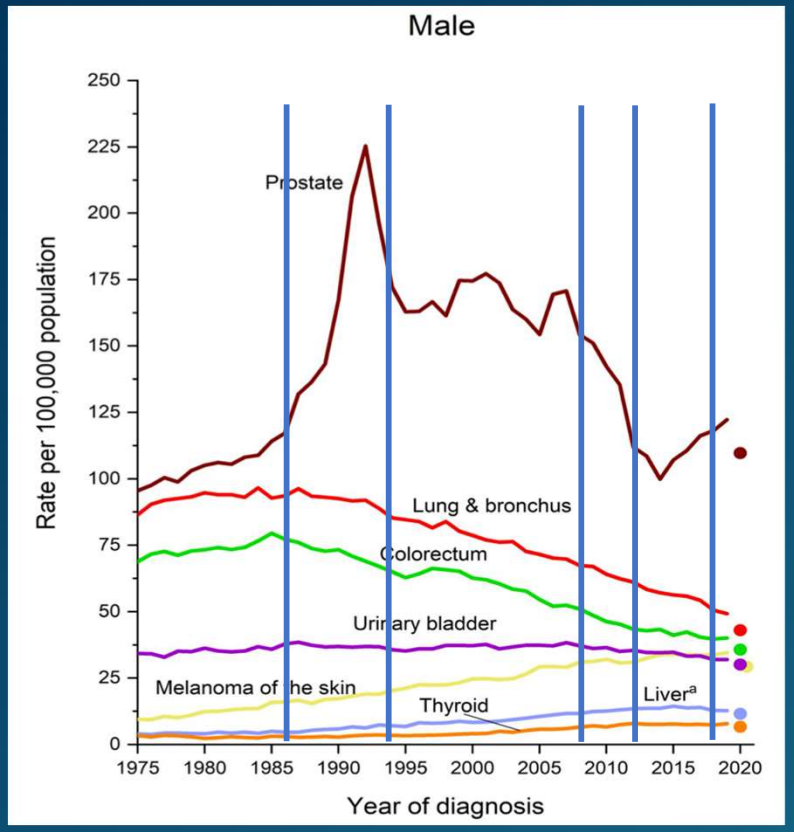
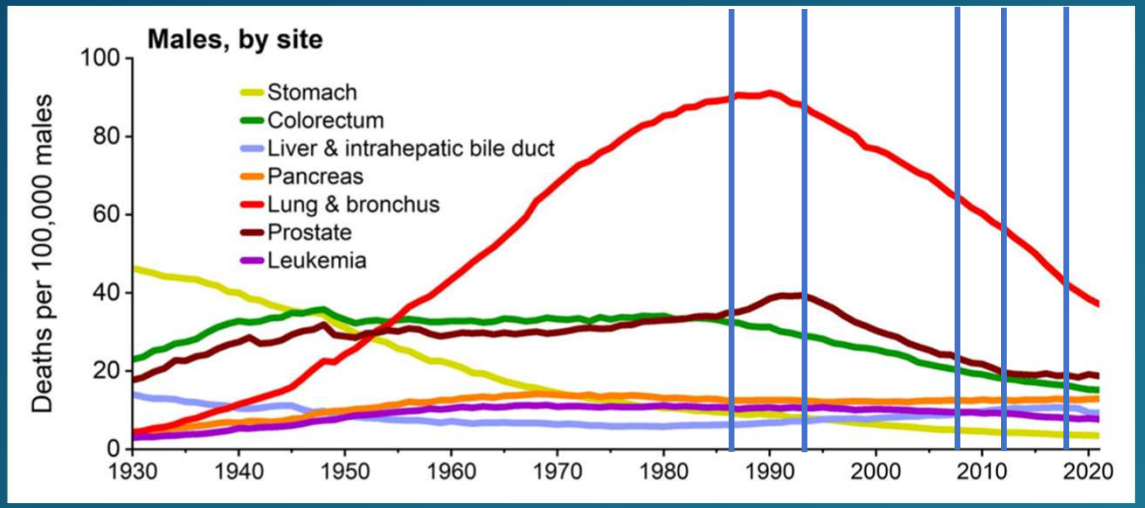
Prostate Cancer Statistics

- 1986 FDA approves PSA to monitor recurrence of PCa
- 1994 FDA approves PSA to screen for PCa (1990s widespread PSA screening had begun)
- 2008 USPTF gives grade D recommendation for PSA screening in men aged >75 years old
- 2012 USPTF gives grade D recommendation routine PSA screening in all men
- 2018 USPTF gives grade C recommendation for men aged 55-69 years old





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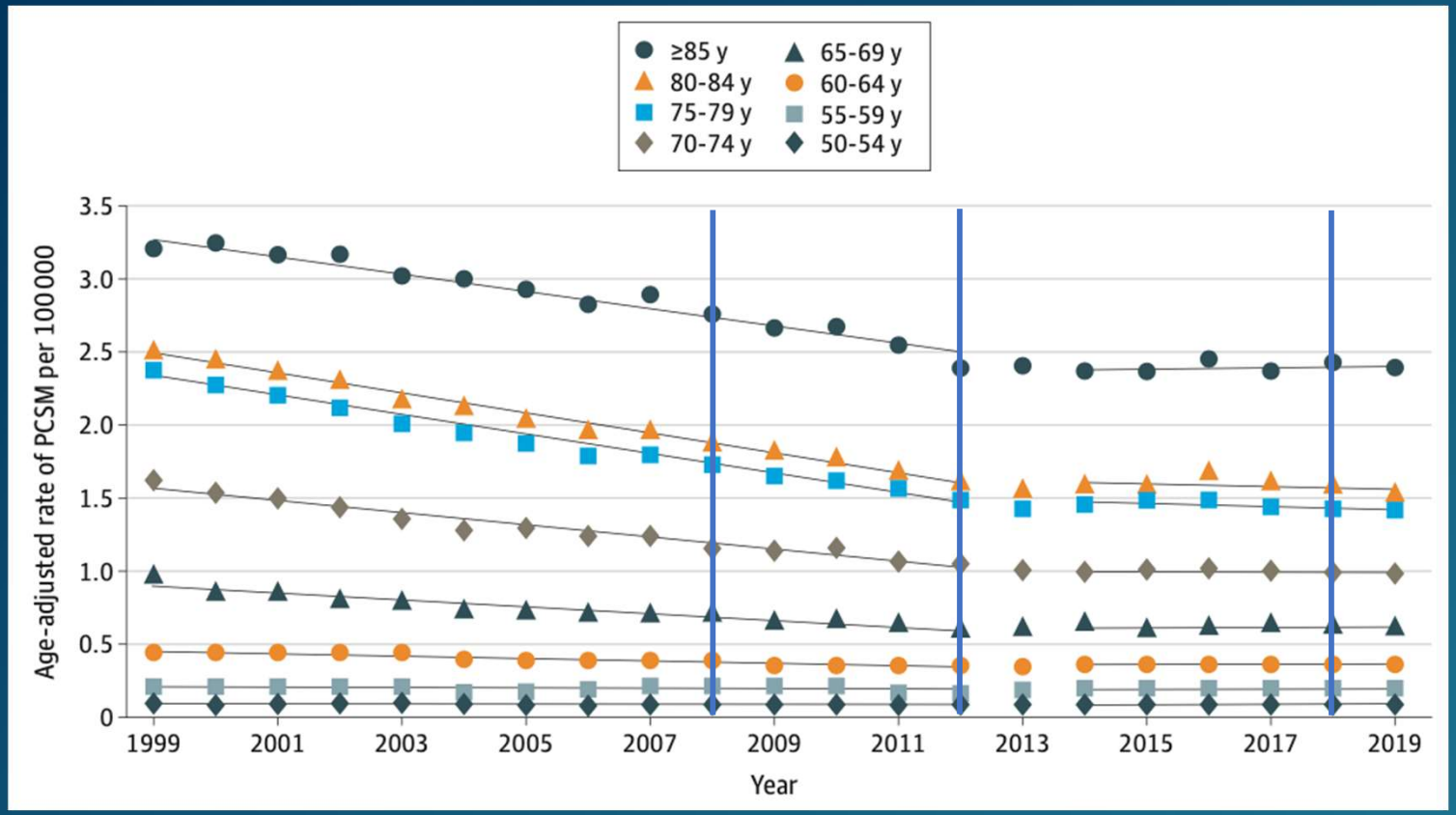
ACS, Siegel, et all. CA Cancer J Clin. 2024;74:12–49

Prostate Cancer Statistics

- Prostate cancer mortality rates stopped decreasing from 2014 onward



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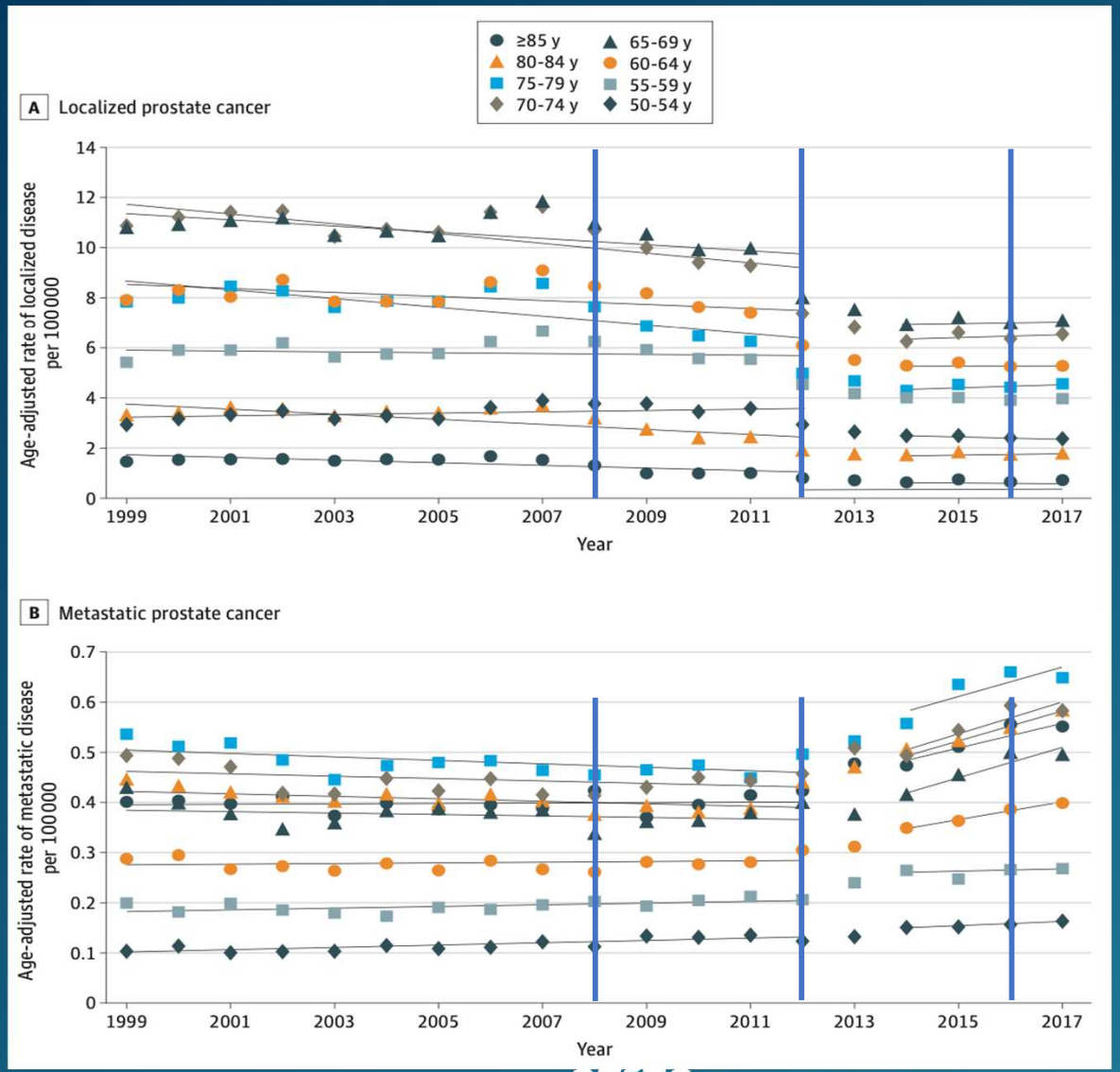
Burgess, et al Association of the USPSTF Grade D Recommendation Against Prostate-Specific Antigen Screening With Prostate Cancer–Specific Mortality. JAMA Network Open. 2022;5(5):e2211869

Prostate Cancer Statistics

- Localized PCa diagnosis decreased
- Metastatic PCa diagnosis increased



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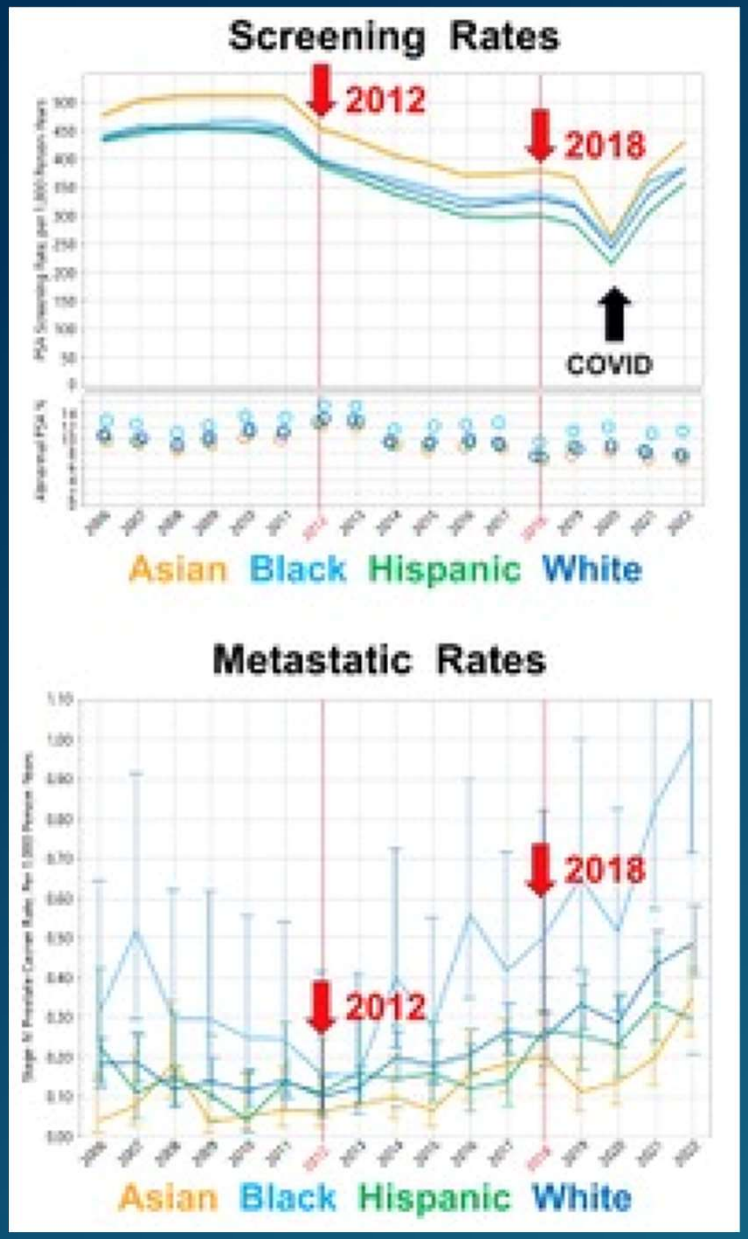

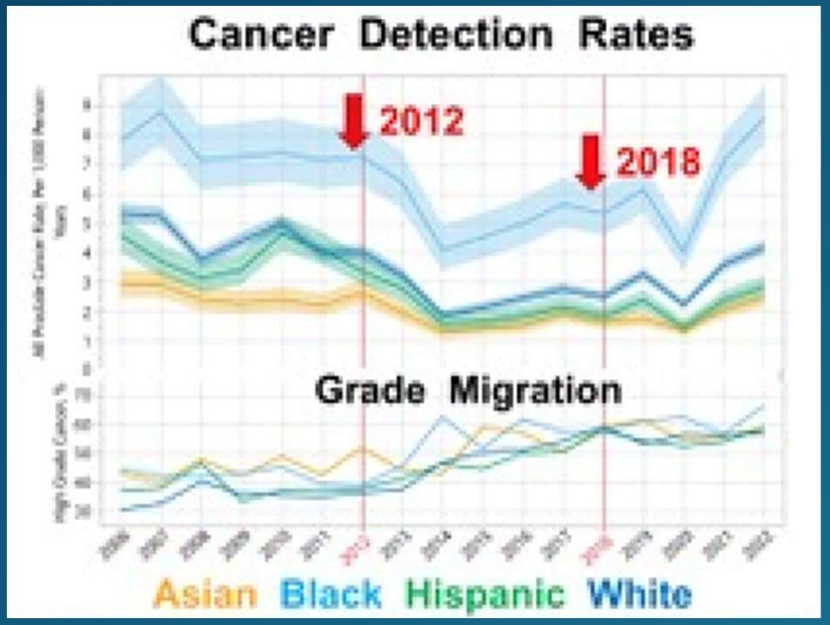

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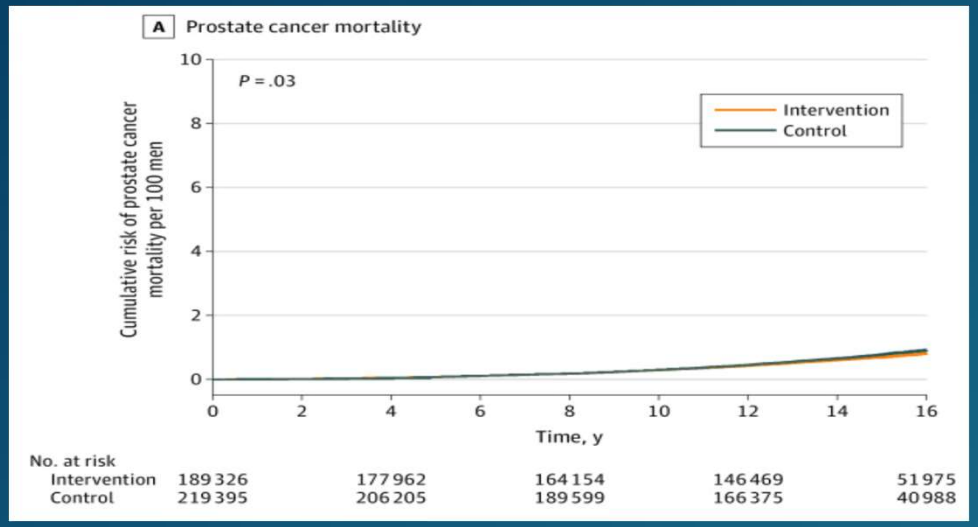
Horton, et al. Impact of the 2012 and 2018 USPTF Statements on Prostate Cancer Screening and Metastatic Rates in Kaiser Permanente Northern California. GU ASCO 2025.

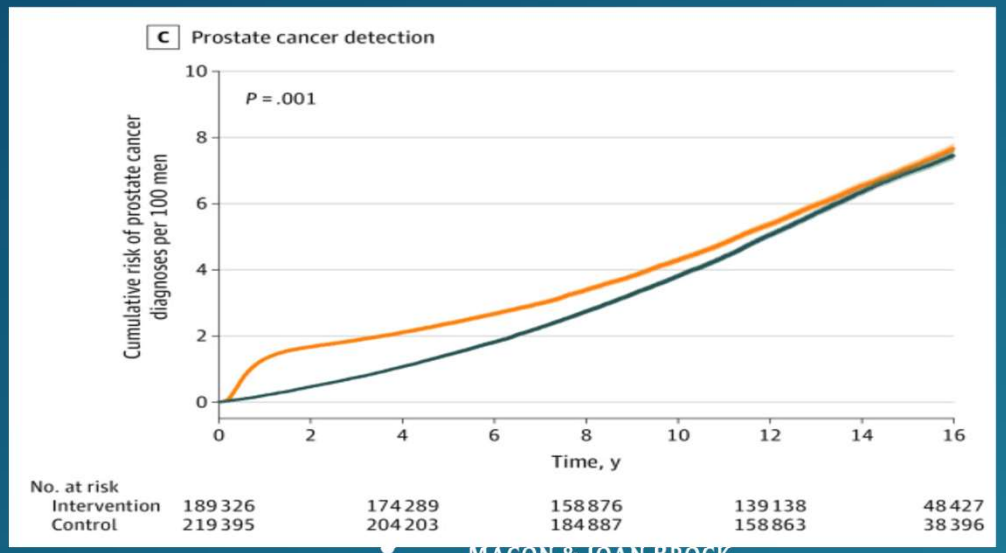
Population Based PSA Screening Trials

- Cluster Randomized Trial for PSA Testing for Prostate Cancer (CAP)
- Prostate Lung Colon Ovarian Cancer Screening Trial (PLCO)
- European Randomized Study of Screening for Prostate Cancer (ERSPC)
  - Rotterdam Section
  - Göteborg Randomized Screening Trial
- 44-61% of positive biopsies in population screening studies for elevated PSA are Grade Group (GG) 1
  - Initially managed with AS
  - Contributes to overdiagnosis and overtreatment
  - Lead to USPTF Grade D and C recommendation

CAP Trial

- UK; 415,357 men 50-69 year old
- Single PSA screening test. Biopsy if PSA ≥ 3.0 ng/mL
- 15 year follow up RR 0.92 PCa death
- Single test increased detection of low grade and localized PCa
- No difference in metastatic, locally advanced or high grade PCa
- <u>One time screening not beneficial</u>





Martin, et al. Prostate-Specific Antigen Screening and 15-Year Prostate Cancer Mortality: A Secondary Analysis of the CAP Randomized Clinical Trial. JAMA. 2024, Apr 6;331(17):1460–1470.

PLCO Trial

- USA, 1993-2001
- 76,683 men randomized to PSA screening for 6 years and DRE for 4 years
- 15 year follow up
- No difference in PCa survival
- At 15 years, 86% of control arm (non-screening) received a PSA test

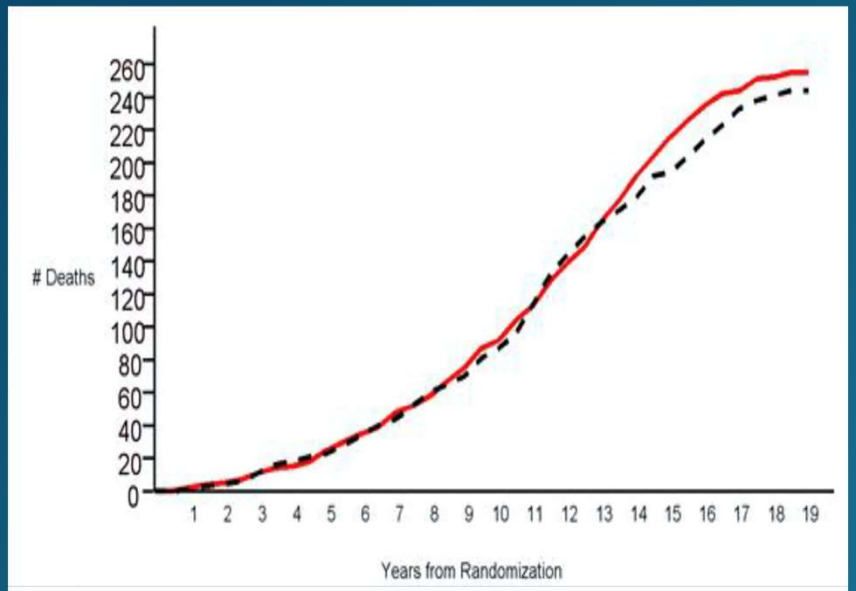


Figure 1.
Deaths from prostate cancer by arm and years from randomization. Red solid line is intervention arm, black dotted line is control arm. Numbers still at risk at selected time points are listed below the graph.

Pinsky, et al. Extended Mortality Results for Prostate Cancer Screening in the PLCO Trial with Median 15 Years Follow-up. Cancer. 2017 February 15; 123(4): 592–599.

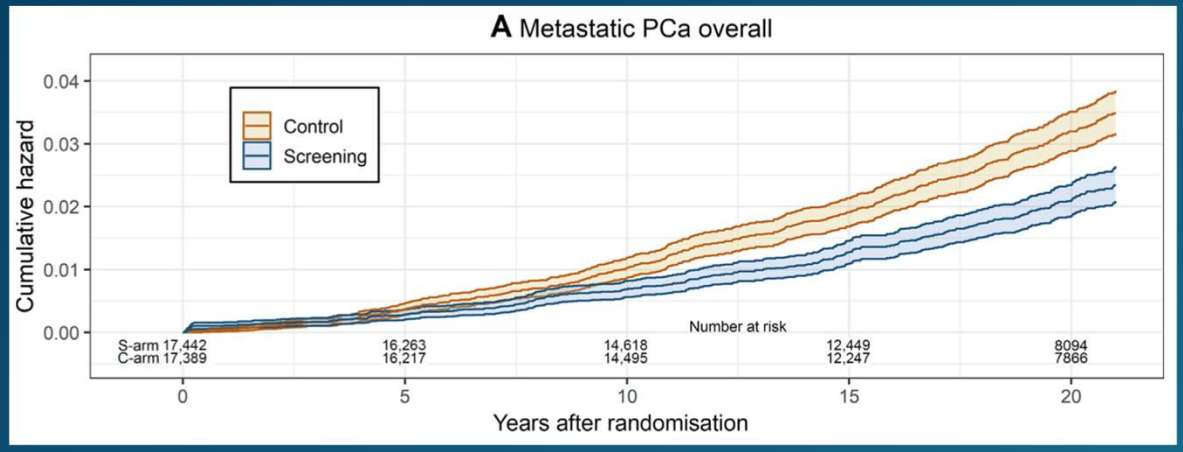
ERSPC

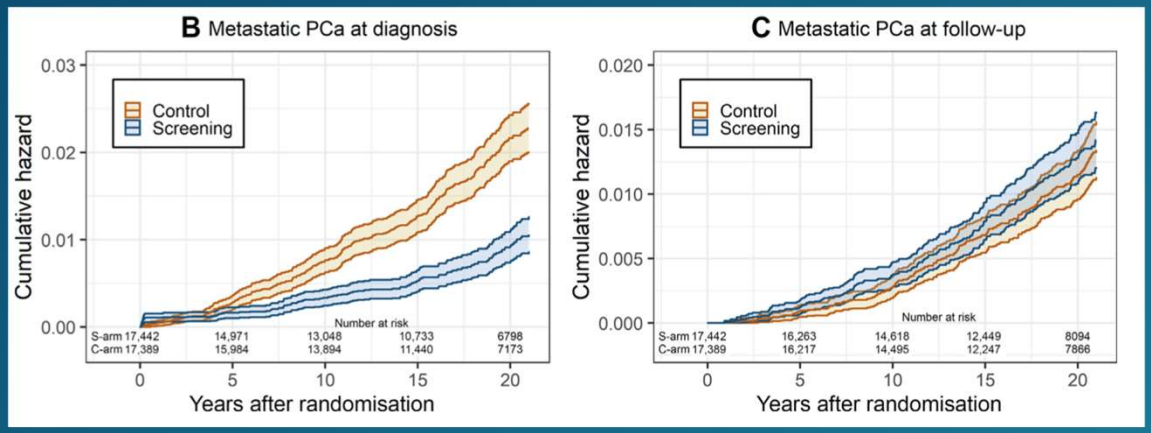
- 8 European countries, q2-7yr screening (largely 2-4yr)
- 182,160 men randomized to PSA screening vs no screening
- PSA ≥ 3.0 lead to biopsy. Initially 6 core, then 10-12 core
- 16 year follow up: 20% reduction in PCa mortality
- NNS 570 | NNT 18
- Limited use of Active Surveillance
- Significant concern about over-treatment

Hugosson, et al. A 16-yr Follow-up of the European Randomized study of Screening for Prostate Cancer . Eur Urol. 2019 July ; 76(1): 43–51

ERSPC Rotterdam Section

- Q4 year PSA; 42,376 men; 21 year follow up; 54-74 y/o
- 21 year follow-up
- 33% RR reduction metastatic PCa
- NNS 212; NNT 7 to prevent metastatic PCa
- M+ disease increases where screening stopped at age 74.
- M+ protective affect fades after ~10 years





De vos, et al. A Detailed Evaluation of the Effect of Prostate-specific Antigen–based Screening on Morbidity and Mortality of Prostate Cancer: 21-year Follow-up Results of the Rotterdam Section of the European Randomised Study of Screening for Prostate Cancer. Eur Urol. 84 (2023): 426-434

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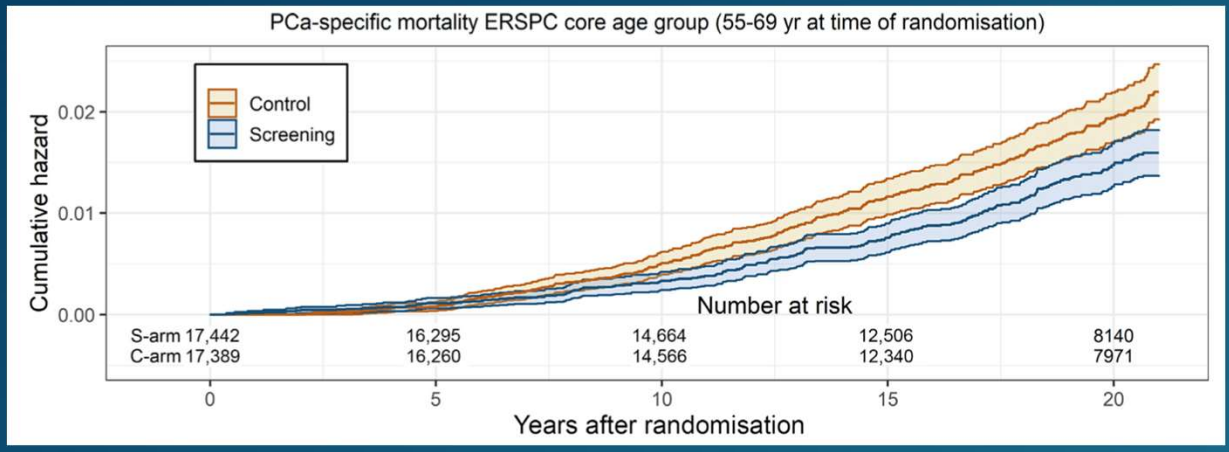
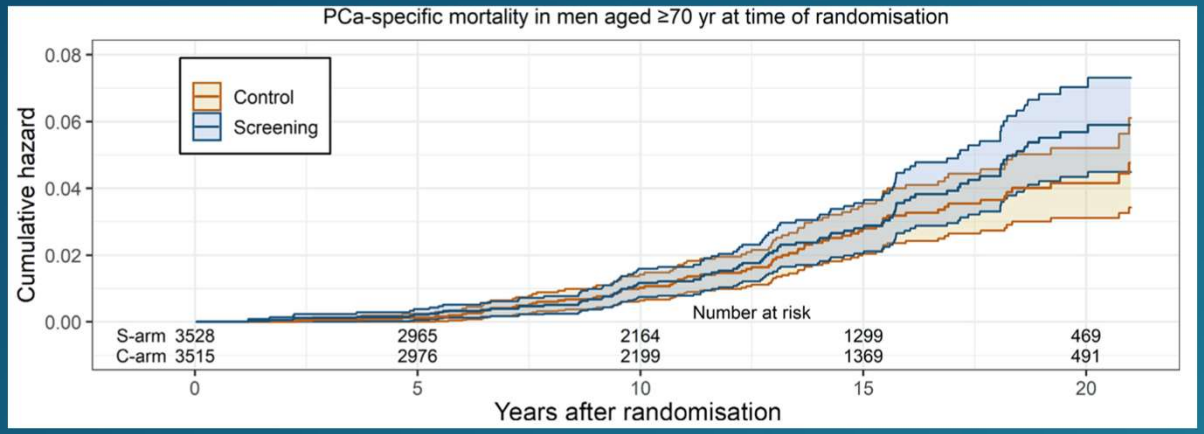
ERSPC Rotterdam Section

- 27% RR PCa death reduction
- NNS 246; NNT 14 to prevent PCa death
- Benefit in men 55-69 when screening began.
- No benefit in men screening began ≥ 70 (trial stopped screening at 74)





De vos, et al. A Detailed Evaluation of the Effect of Prostate-specific Antigen–based Screening on Morbidity and Mortality of Prostate Cancer: 21-year Follow-up Results of the Rotterdam Section of the European Randomised Study of Screening for Prostate Cancer. Eur Urol. 84 (2023): 426-434

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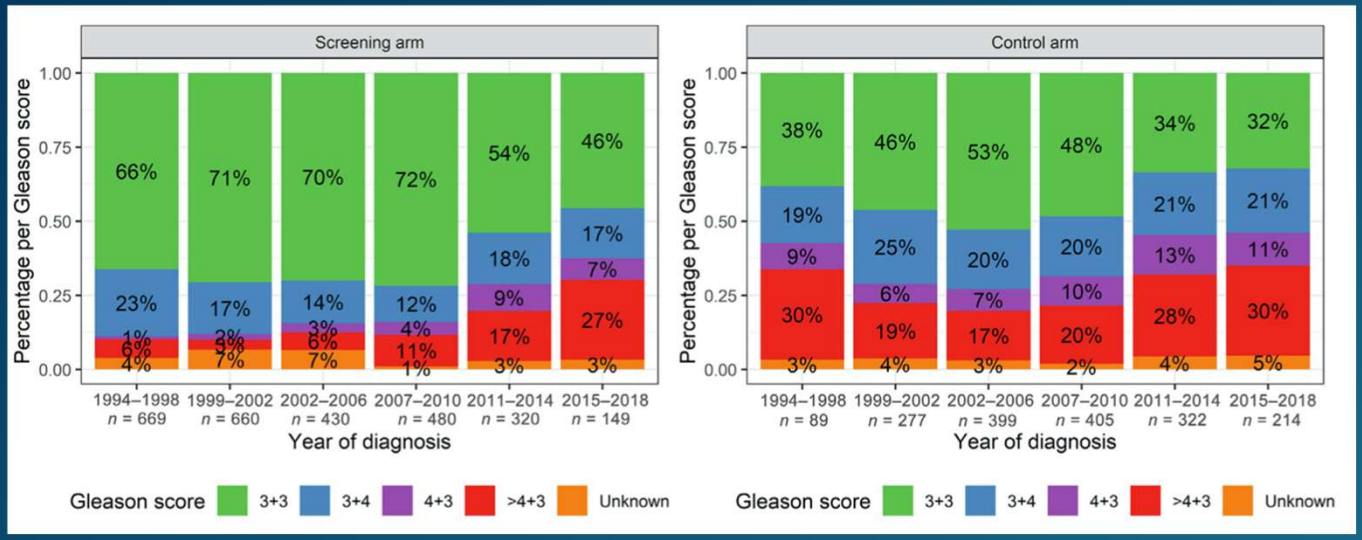
ERSPC Rotterdam Section

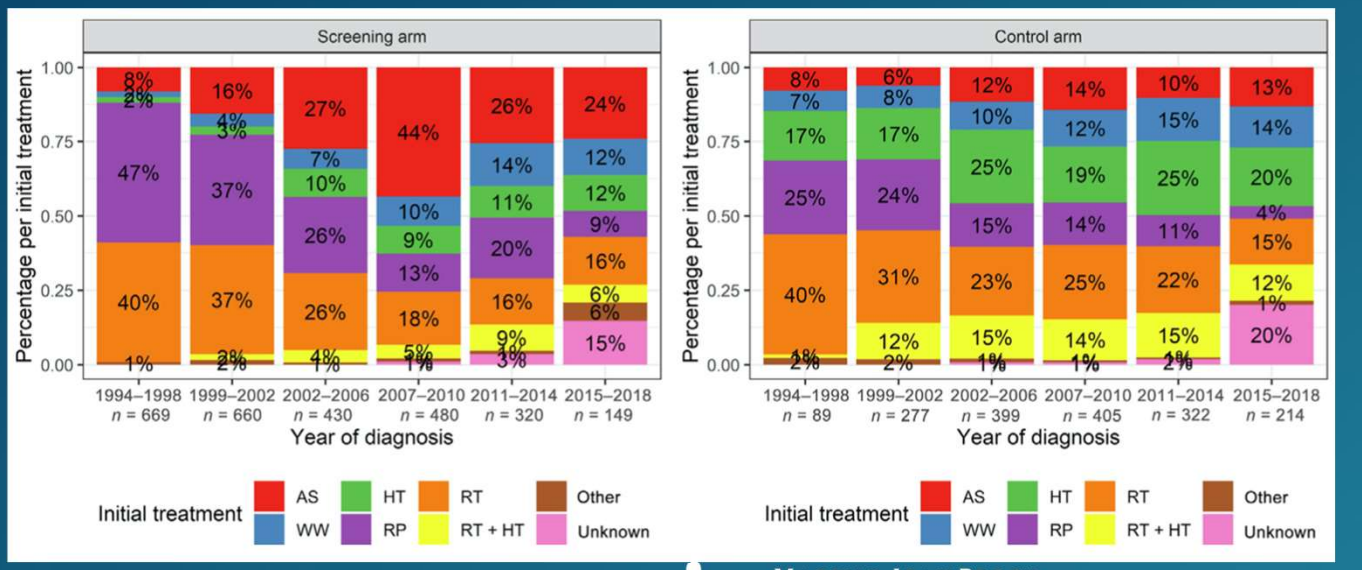
- 64% deaths in screening, only screened 1x[1]
- 71% of screening deaths diagnosis in 1st round[1]
- 26% of screening deaths occurred with diagnosis after last screening cycle[1]
  - 43% of those had elevated PSA at last screen
  - 38% refused biopsy
- 51% decreased risk death from prostate cancer when controlling for those who did not get screened in screening arm and those screened in the control arm[2]

1. De vos, et al. A Detailed Evaluation of the Effect of Prostate-specific Antigen–based Screening on Morbidity and Mortality of Prostate Cancer: 21-year Follow-up Results of the Rotterdam Section of the European Randomised Study of Screening for Prostate Cancer. Eur Urol. 84 (2023): 426-434
2. Bokhorst, et al. Prostate-specific antigen-based prostate cancer screening: reduction of prostate cancer mortality after correction for nonattendance and contamination in the Rotterdam section of the European Randomized Study of Screening for Prostate Cancer. Eur Urol. 2014 Feb;65(2):329-36

ERSPC Rotterdam Section

- Active Surveillance introduced ~2006 after 3 screening cycles
- RR 0.38 Systemic palliative treatment
- RR 0.28 Radiation + hormonal therapy
- RR 0.61 secondary treatment
- RR 2.0 for surgery
- QALY Model adjustment (MISCAN)
  - 23% decrease QALY for side effects resulting in 56 QALYs gained by screening (61.7 QALYs for breast ca screening)
  - NNT 5 to prevent 1 death





Hogenhout, et al. From Screening to Mortality Reduction: An Overview of Empirical Data on the Patient Journey in European Randomized Study of Screening for Prostate Cancer Rotterdam After 21 Years of Follow-up and a Reflection on Quality of Life. Eur Urol. 7 (2024): 713-720

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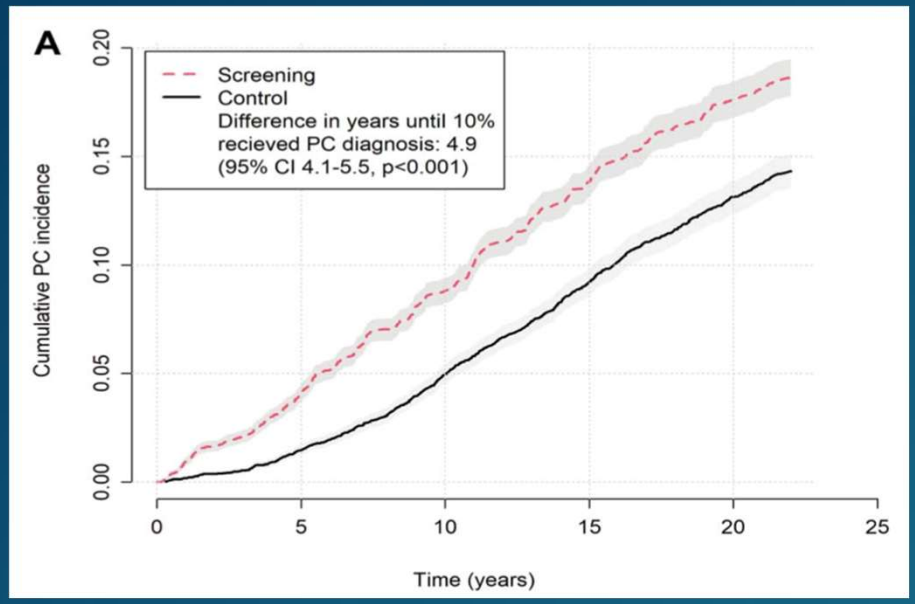
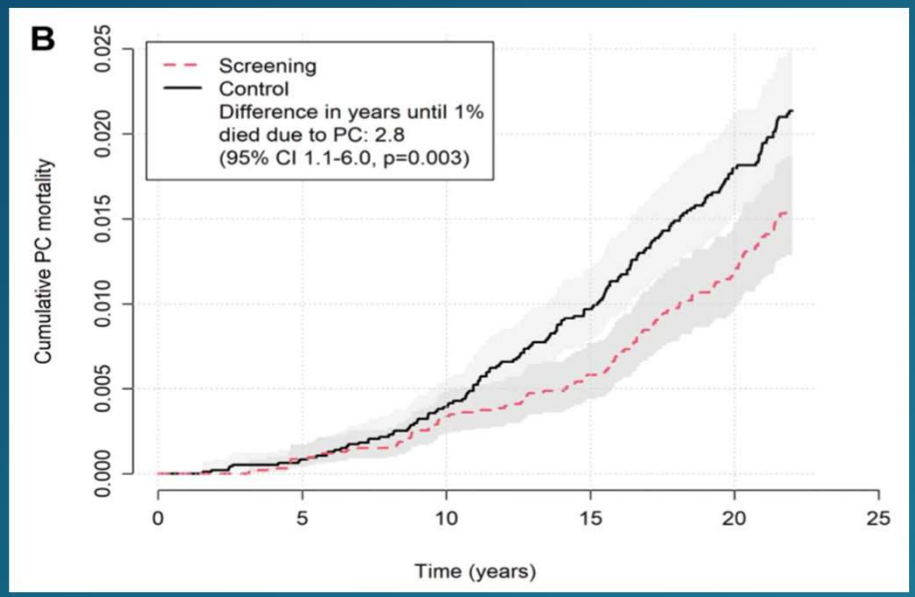
Göteborg-1 Study

- Sweden, 20,000 men age 55-69, q2yr PSA, 77% participation
- 3.4 ng/ml in 1995-1998, 2.9 ng/ml 1999-2004 and 2.5 ng/ml after 2004 for prostate biopsy
- 22 year follow up
- 18.6% vs 14.3% incidence PCa in screening vs control
- RR 0.71 PCa death
- RR 0.59 PCa death for those who participated
- NNS 217; NNT 9 to prevent 1 PCa death





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Franlug, et al. Results from 22 years of Follow up in the Goteborg Randomized Population-Based Prostate Cancer Screening Trial. J Urol. 208 (2022): 292-300

When to stop PSA screening?

- 50% of men in Western world die of PCa >80 years old
- Goteborg-1[1]
  - 9 years post screening, PCa diagnosis and death equivalent in screening and non-screening arms
- Roterdam[2]
  - No difference in PCSM 12 years after last screen, regardless of # screens
  - 7 years Median time between time of last screen to diagnosis in men who died from disease after completed screening
- PSA screening protection fades after about 10 years[1,2]
- Baltimore Longitudinal Aging Study
  - 849 men (122 w/o; 727 w prostate cancer)
  - No men >75 with PSA <3.0 died from prostate cancer

1. Bergdahl, et al. Incidence of prostate cancer after termination of screening in a population-based randomised screening trial. Eur Urol. 2013 Nov;64(5):703-9.
2. De vos, et al. A Detailed Evaluation of the Effect of Prostate-specific Antigen–based Screening on Morbidity and Mortality of Prostate Cancer: 21-year Follow-up Results of the Rotterdam Section of the European Randomised Study of Screening for Prostate Cancer. Eur Urol. 84 (2023): 426-434
3. Schaeffer, et al. Prostate Specific Antigen Testing Among the Elderly—When To Stop?. J Urol. 2009 April ; 181(4): 1606–1614

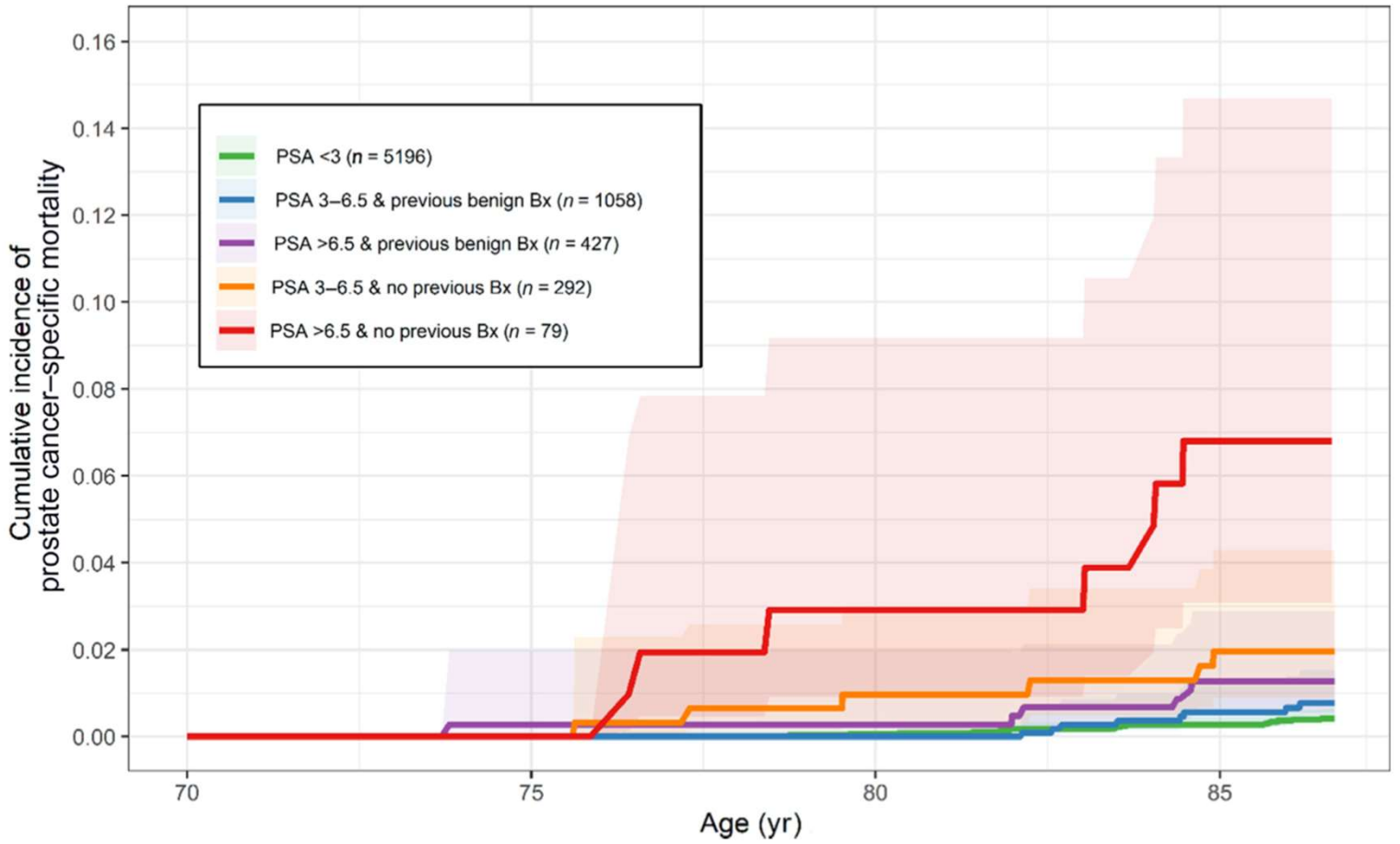


Fig. 3 – Cumulative incidence of prostate cancer–specific mortality stratified by PSA level and presence of previous benign biopsies at the time of last screening. Bx = prostate biopsy; PSA = prostate-specific antigen.

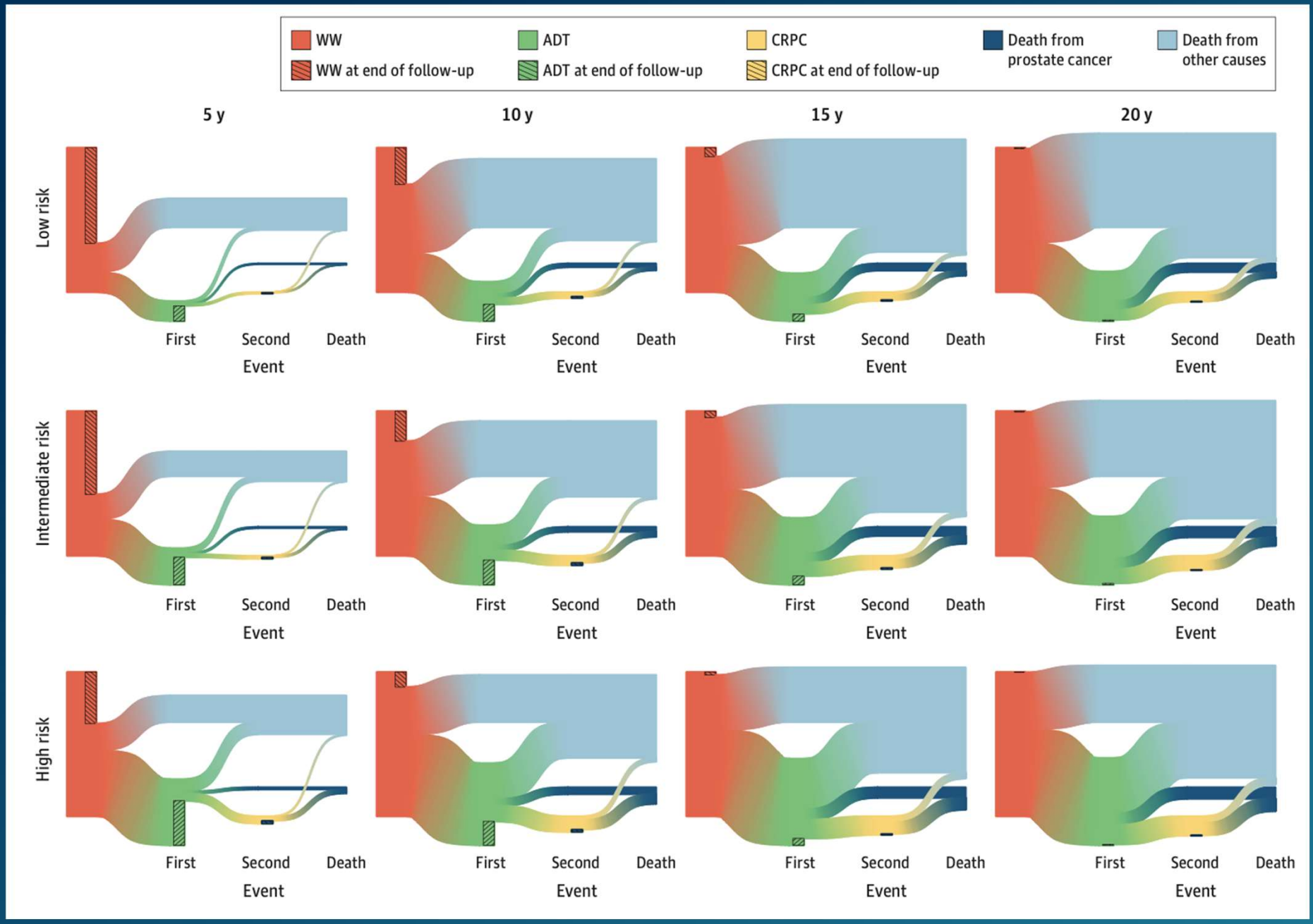
- ERSPC Rotterdam mortality in men aged 70-74 with last screening PSA value

De Vos, et al. Prostate Cancer Mortality Among Elderly Men After Discontinuing Organised Screening: Long-term Results from the European Randomized Study of Screening for Prostate Cancer Rotterdam. Eur Urol. 85 (2024): 74-81

Natural History of Watchful Waiting

- Swedish prostate cancer registry (98% PCa dx)
- Dx 2007-2019 with cT1-3N0M0 PSA<100 PCa in men with life expectancy <10 years
- Life expectancy based on age, Charleson Comorbidity Index and Drug Comorbidity Index
- 5234 men, median age 81, life expectancy <6 years in 23%, 39.2% high risk PCa
- 5 years
  - 66.2% low risk, 36.1% high risk alive, not on ADT
- 10 years
  - 25.5% low risk, 10.4% high risk alive, not on ADT
  - 10% low risk, 20% high risk developed CRPC
  - 7.5% low risk, 21.8% high risk died from PCa

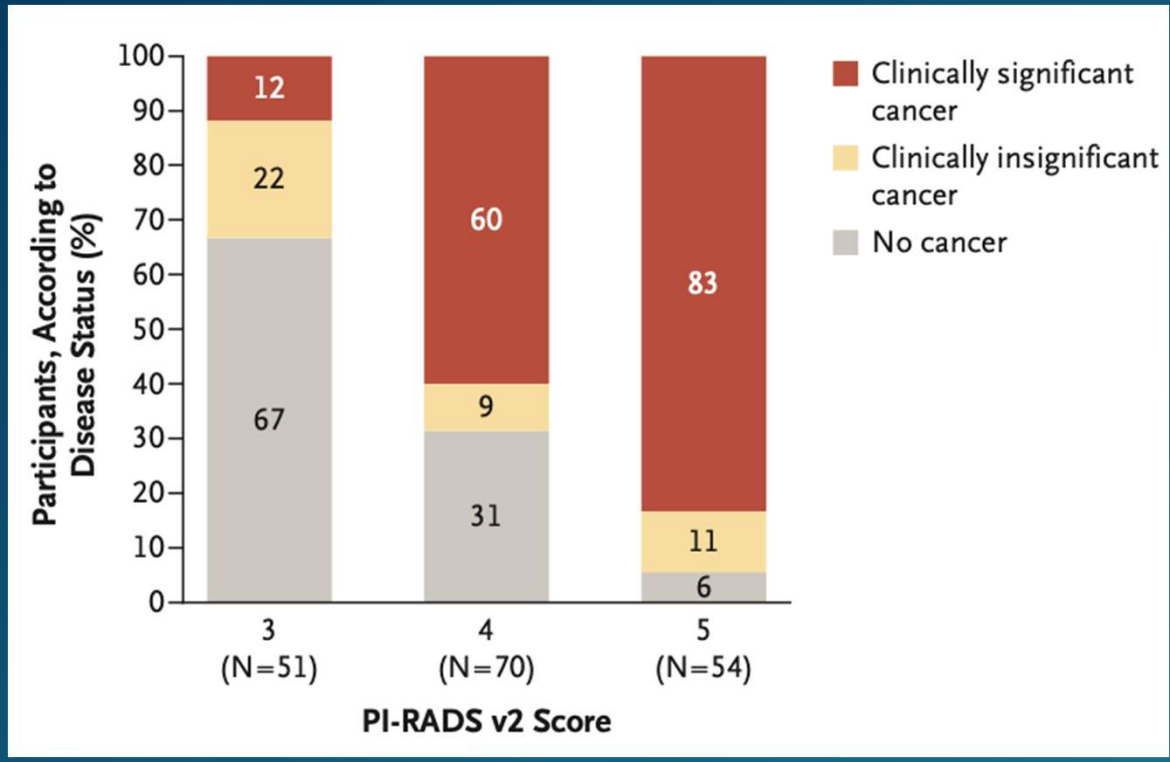
Ventimiglia, et al. Natural History of Nonmetastatic Prostate Cancer Managed With Watchful Waiting. JAMA Network Open. 2024;7(6)



Ventimiglia, et al. Natural History of Nonmetastatic Prostate Cancer Managed With Watchful Waiting. JAMA Network Open. 2024;7(6)

PRECISION Trial

- Multicenter, international, randomized, noninferiority trial in 500 men recommended to undergo prostate biopsy (PSA <20)
  - Randomized to MRI or standard 10-12 core TRUS biopsy
  - If MRI with PIRADS ≥3 → MRI fusion biopsy only. Otherwise, no biopsy



- 28% avoided biopsy by utilizing MRI
- 22% vs 9% GG1 in Standard vs MRI fusion
- 39% vs 27% ≥ GG2 in MRI fusion vs Standard

Kasivisvanathan, et al. MRI-Targeted or Standard Biopsy for Prostate-Cancer Diagnosis, NEJM (2021): 378(19): 1767-1777

Göteborg-2 Study[1]

- 17980 men 50-60 years old underwent PSA measurement
- PSA ≥ 3.0 underwent MRI
- 1/3 underwent systematic biopsy + targeted biopsy
- 2/3 underwent targeted biopsy only if MRI PIRADS 3-5
  - 489/796 men with PSA ≥ 3 avoided biopsy
  - 51% of men in systematic biopsy dx with GG1 PCa
  - 38% of men in targeted biopsy dx with GG1 PCa
- RR 0.46 of GG1 PCa in targeted biopsy only
  - Prior study has shown HR 2.85 for GG1 PCa on visible on MRI for clinical progression on future biopsy[2]
- 10 cases (15%) of GG2 PCa diagnosed on systematic biopsy only. 6 cases initially managed with AS. No GG3-5 PCa

1. Hugosson, et al. Prostate Cancer Screening with PSA and MRI Followed by Targeted Biopsy Only. NEJM 2022;387:2126-37.
2. Olivier, et al. Prostate Cancer Patients Under Active Surveillance with a Suspicious Magnetic Resonance Imaging Finding Are at Increased Risk of Needing Treatment: Results of the Movember Foundation's Global Action Plan Prostate Cancer Active Surveillance (GAP3) Consortium. Eur Urol Open Sci. 2022 Jan 3;35:59–67.

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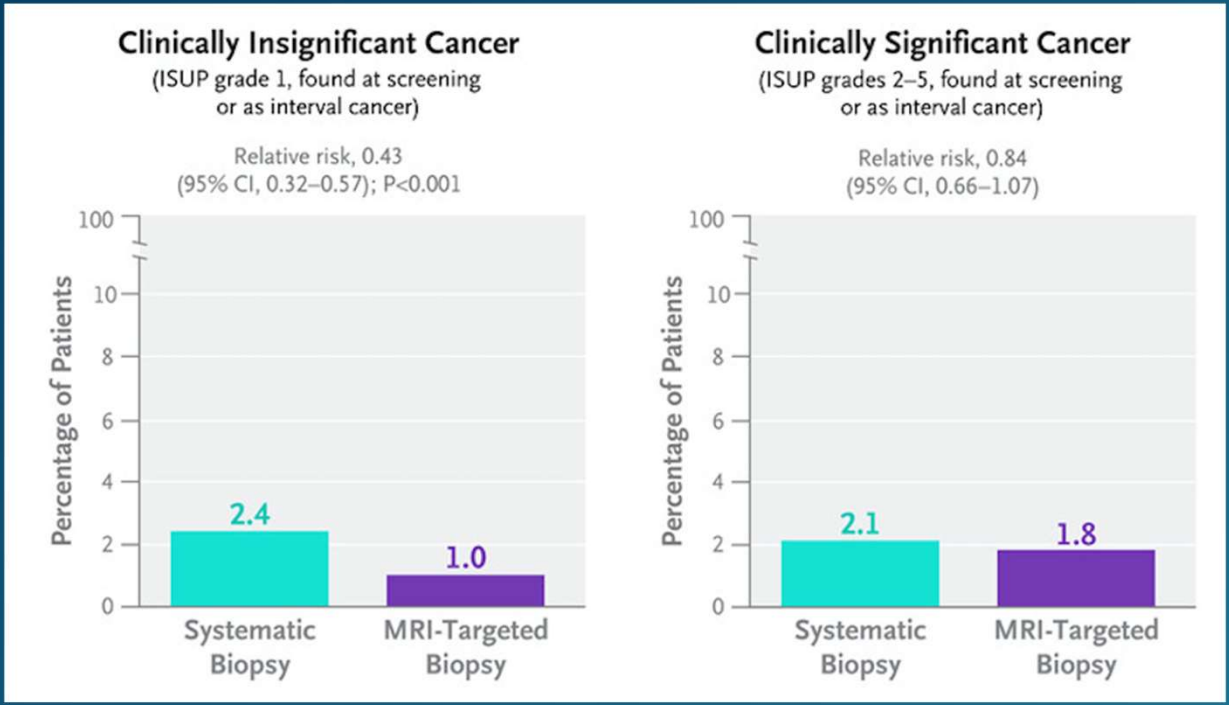
Göteborg-2 Study

- 4 year follow up (median 3.9 years)
- Continued reduction in GG1 PCa detection
- No significant difference in GG2 prostate cancer



Hugosson, et al. Results after four years of screening for prostate cancer with PSA and MRI. NEJM. 391 (2024): 1083-1095

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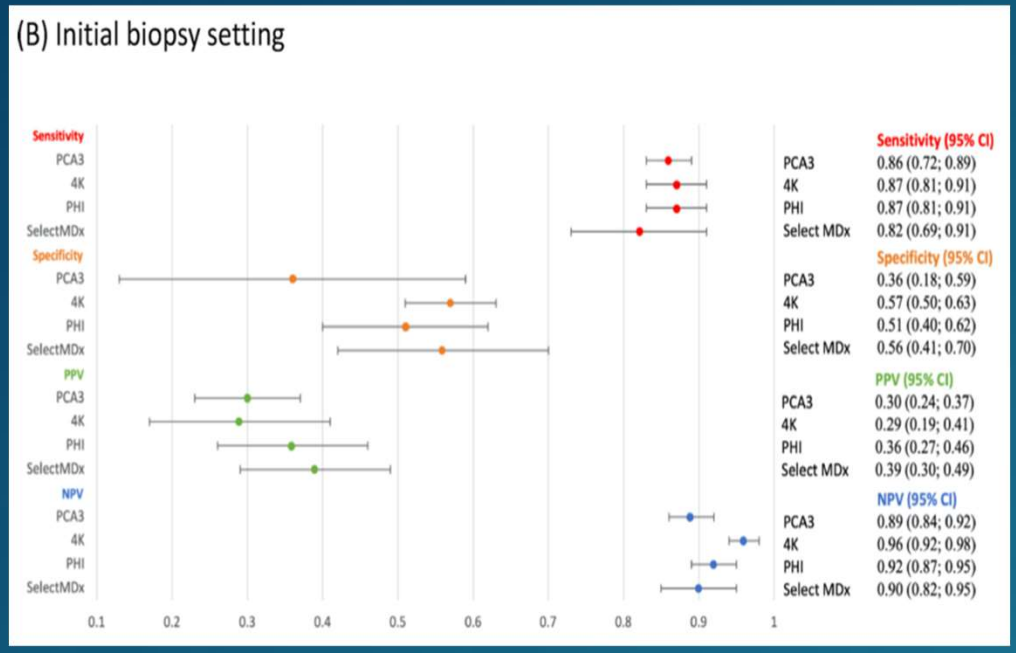
MRI

- Systematic review and meta-analysis
- 80,114 men from 12 studies.
- Compared with standard PSA-based screening, the MRI pathway (sequential screening, PI-RADS score ≥3 cutoff for biopsy)
  - Higher odds of csPCa (OR, 4.15; 95% CI, 2.93-5.88; $P \leq .001$),
  - Decreased odds of biopsies (OR, 0.28; 95% CI, 0.22-0.36; $P \leq .001$),
  - Decreased insignificant cancers detected (OR, 0.34; 95% CI, 0.23-0.49; $P = .002$)
  - No significant differences in the detection of csPCa (OR, 1.02; 95% CI, 0.75-1.37; $P = .86$).
- PI-RADS score ≥ 4 threshold for biopsy
  - Decreased detecting insignificant PCa detected (OR, 0.23; 95% CI, 0.05-0.97; $P = .048$)
  - Decreased odds of biopsies performed (OR, 0.19; 95% CI, 0.09-0.38; $P = .01$)
  - No differences in PCa detection (OR, 0.85; 95% CI, 0.49-1.45; $P = .22$).

Fazekas, et al. Magnetic Resonance Imaging in Prostate Cancer Screening: A Systematic Review and Meta-Analysis. JAMA Oncol. 2024;10(6):745-754

New Biomarkers

- Blood
  - PSA Density[1]: 0.15 ng/mL[2] | 14xPSAD + # lesions >4.25 → AUC 0.87
  - 4K score[2]: AUC 0.83 csPCa, sens 0.87, spec 0.58, PPV 0.28, NPV 0.96
  - IsoPSA[3]: AUC 0.78 csPCa, sens 0.90, spec 0.46, PPV 0.48, NPV 0.89
  - Proclarix[4]: Sens 0.91, spec 22%,
  - PHI (Prostate Health Index)[2]: AUC 0.78 csPCa, sens 0.85, spec 0.52, PPV 0.38, NPV 0.91
  - STHLM3
- Post DRE Urine
  - PCA3[2]: AUC 0.73 csPCa, sens 0.85, spec 0.37, PPV 0.31, NPV 0.89
  - MPS[2]: Sens 0.82, spec 0.59, PPV 0.36, NPV 0.92
  - SelectMDx[2]: AUC 0.76 csPCa, sens 0.82, spec 0.56, PPV 0.39, NPV 0.90
  - TMPRSS2:ERG
- Urine
  - ExoDx Prostate Intelliscore[2]: Sens 0.85, spec 0.54, PPV 0.37, NPV 0.90
  - miR Stentinel[5]: Sens 0.91, spec 0.94, PPV 0.867, NPV 0.99



1. Rais-Bahrami, et al. Diagnostic value of biparametric magnetic resonance imaging (MRI) as an adjunct to prostate-specific antigen (PSA)-based detection of prostate cancer in men without prior biopsies. BJUI (2015); 115(3): 381–388
2. Kawada, et al. Diagnostic Accuracy of Liquid Biomarkers for Clinically Significant Prostate Cancer Detection: A Systematic Review and Diagnostic Meta-analysis of Multiple Thresholds. Eur Urol Onc 7(2024): 649-662
3. Klein, et al. Clinical validation of IsoPSA, a single parameter, structure-focused assay for improved detection of prostate cancer: A prospective, multicenter study. Uro Onc. 40 (2022) 408.e9–408.e18
4. Steuber, et al. PROPOSe: A Real-life Prospective Study of Proclarix, a Novel Blood-based Test to Support Challenging Biopsy Decision-making in Prostate Cancer. European Urol Onc. 5:3 (2022): 321-327
5. Wang, et al. Expression of Small Noncoding RNAs in Urinary Exosomes Classifies Prostate Cancer into Indolent and Aggressive Disease. J Urol 204 (2020): 466-475

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Ongoing Trials

- Closed Recruitment, long term data pending
  - PROBASE (Germany) Baseline PSA at young age
  - ReIMAGINE (UK) MRI as screening tool
  - STHLM-3 (Sweden) Biomarker vs PSA + MRI screening
- Open Recruitment
  - BARCODE1 (UK) Genetic Screening
  - GOTEBORG-2 (Sweden) MRI
  - ProScreen (Finland) 4K score, MRI Targeted biopsy

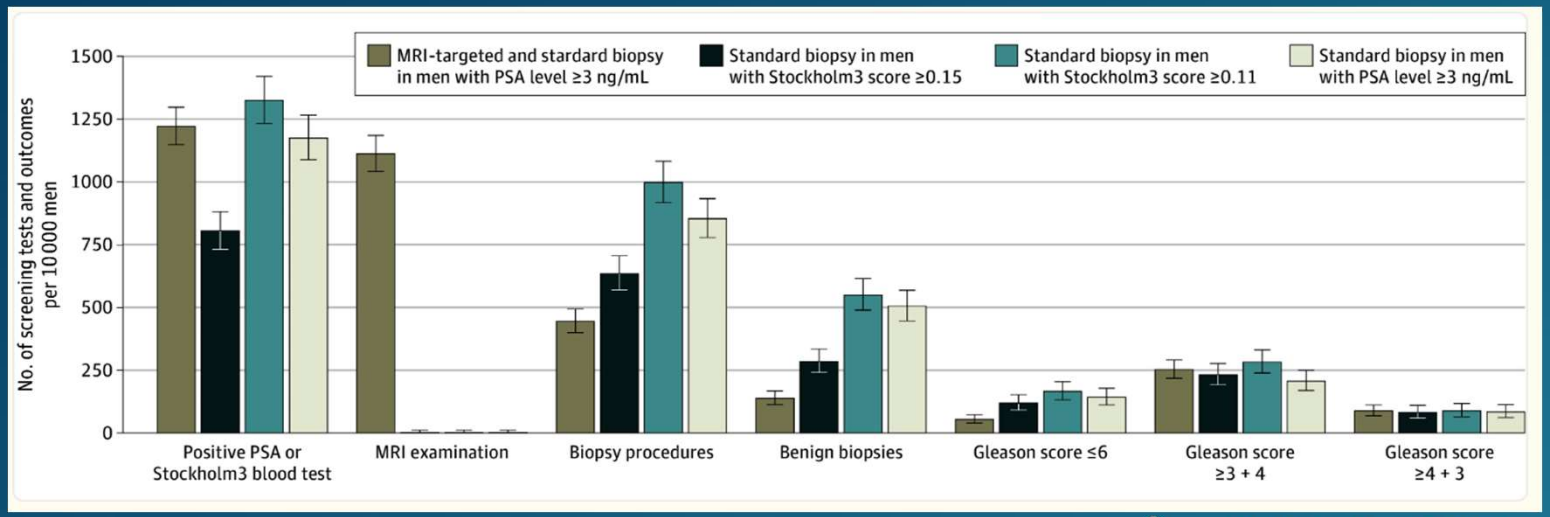
ProScreen Trial

- Finland; 61,193 men 50-63 years old randomized 1:3 to be invited or not invited to single PCa screening from 2018-2020
- PSA ≥ 3.0 → 4-kallikrein (4K) score. If 4K score ≥ 7.5%→ MRI prostate→ targeted biopsies if MRI ≥ PIRADS 3 (Standard biopsy also performed if PSA density ≥ 0.15ng/mL^2)
- 1.5 biopsies needed to detect PCa
  - 84% ≥ GG2, 16% GG1
- 47% of systematic biopsies positive for PSAD ≥ 0.15
  - 60% ≥ GG2, 40% GG1
- Compared to control group
  - 0.27% absolute increase in GG1 PCa
  - 1.03% absolute increase in ≥ GG2 PCa

Auvinen, et al. Prostate Cancer Screening With PSA, Kallikrein Panel, and MRI The ProScreen Randomized Trial. JAMA. 2024 Apr 6;331(17):1452–1459.

STHLM-3

- Sweden; men 50-74 years old provided PSA and Stockholm3 samples.
- If PSA ≥ 3.0 or Stockholm3 ≥ 0.11, then randomized 2:3 to undergo PSA + MRI vs Stockholm3 only screening
  - Standard biopsy if Stockholm3 ≥ 0.15
  - MRI if PSA ≥ 3 with standard and targeted biopsy ONLY if MRI positive
- If PSA <1.5, repeat screening in 6 years. If PSA 1.5-3 and Stockholm3 <11%, repeat screening in 2 years
- No difference in csPCa detection rates (2.3% vs 2.5%)
- More biopsies in biomarker group (6.3% vs 4.4%)
- More GG1 PCa in biomarker group (1.2% vs 0.4%)



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Bjornebo, et al. Biomarker vs MRI-Enhanced Strategies for Prostate Cancer Screening: The STHLM3-MRI Randomized Clinical Trial. JAMA Netw Open. 2024 Apr 22;7(4):e247131

Next Steps After an Elevated PSA

- Do not empirically treat with antibiotics
- Repeat PSA about 8 weeks apart
  - 25-40% will normalize on repeat[1]
  - If PSA >10, repeat in shorter window (~2 weeks)
- DRE (Should not be used as primary screening)
- Adjust (double) PSA value if on 5ARI (after ~1 year duration)
- Consider MRI and/or supplemental biomarkers
- Refer to Urology
  - PSA persistently elevated
    - Age adjusted (>2.5, >3, >4, >6)
  - Nodular/firm DRE in setting of elevated PSA
  - Abnormal MRI or other abnormal biomarker

Eastham JA, Riedel E, Scardino PT et al. Variation of serum prostate-specific antigen levels: An evaluation of year-to-year fluctuations. JAMA 2003; 289: 2695

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Take-Home Messages

- PSA screening saves lives and reduces metastatic PCa
  - Active Surveillance has reduced previous over treatment
  - USPTF recommendations have stopped reduction of prostate cancer mortality & increased diagnosis of metastatic disease
- MRI and newer biomarkers reduce need for biopsy and overdiagnosis of PCa
- Individualized, shared decision making for PSA screening
  - Risk of over diagnosis and over treatment of PCa
  - Life expectancy
  - Patient desires
- Screening should be repeated
  - q2-4yr in average risk patient
  - q1yr in high risk patient
- Cessation of screening
  - age 75 PSA if <3.0
  - Life expectancy <10 years
- Continued work to best identify those with csPCa under study

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Q&A – Discussion

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