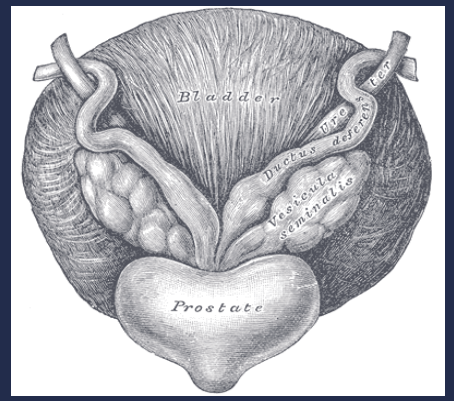
IS THERE ANYTHING NEW IN PROSTATE CANCER SCREENING?



ANDREW M.D. WOLF, MD, FACP
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No financial disclosures

Case Presentation

62 yo white man without significant past medical history presents for annual preventive visit. He has no family history of prostate cancer. He has mild urinary hesitancy and his prostate is mildly enlarged without induration or nodules. His PSA has been gradually rising:

- 2011: 2.35
- 2013: 2.17
- 2017: 3.75
- 2019: 4.51

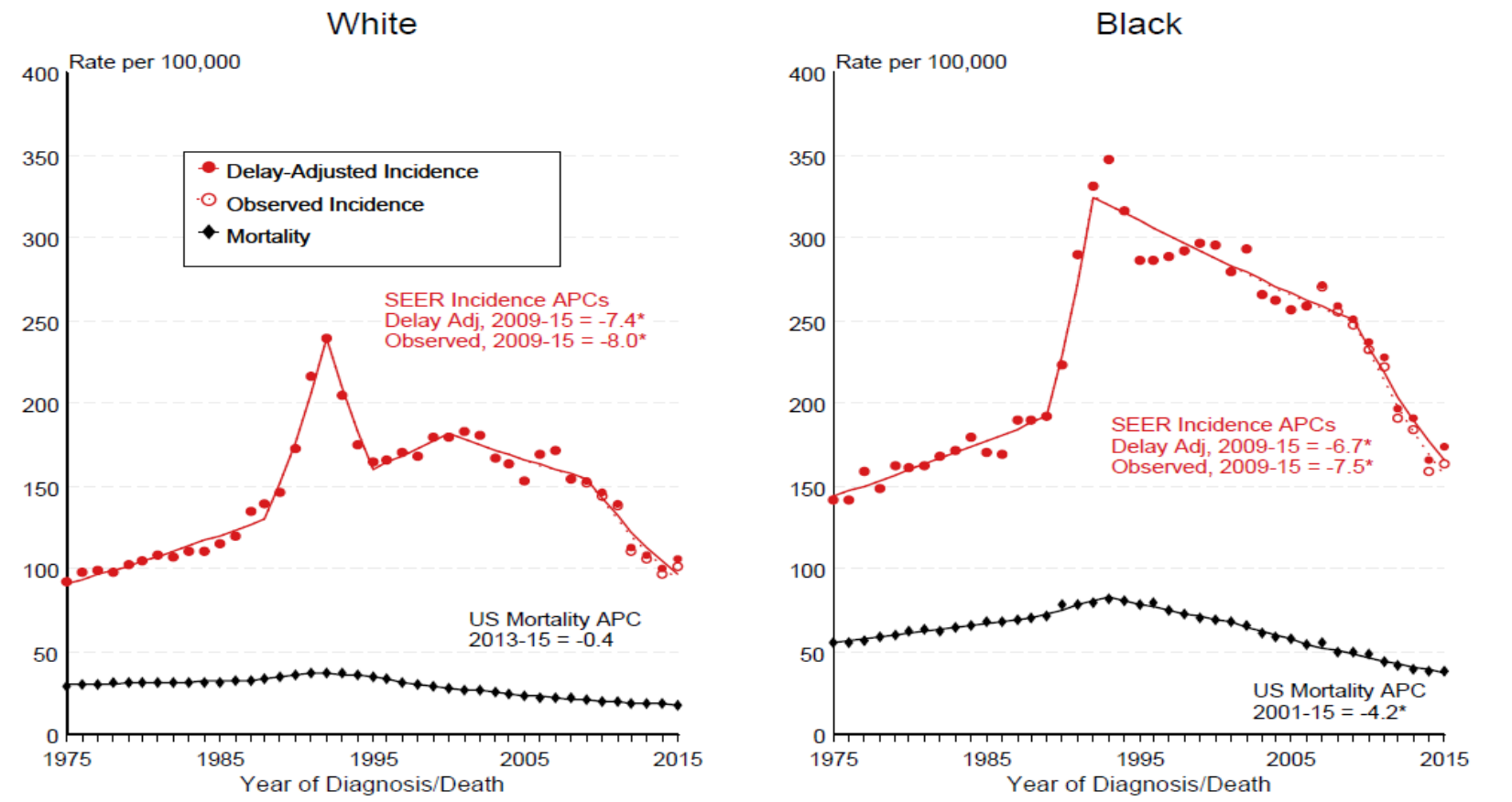
Where do we go from here?

What's New in Prostate Cancer Screening?

Key Questions

- Do we have any new evidence for or against screening?
- Do we have anything better than the PSA?
- What about the good old digital rectal exam?
- Are we doing any better identifying who needs to be treated?
- What do the experts recommend?

Prostate Cancer Incidence & Mortality Over the Decades



Source: Seer 9 areas & US Mortality Files (National Center for Health Statistics, CDC, Feb 2018

Estimated New Cases

Males			Females		
Prostate	174,650	20%	Breast	268,600	30%
Lung & bronchus	116,440	13%	Lung & bronchus	111,710	13%
Colon & rectum	78,500	9%	Colon & rectum	67,100	8%
Urinary bladder	61,700	7%	Uterine corpus	61,880	7%
Melanoma of the skin	57,220	7%	Melanoma of the skin	39,260	4%
Kidney & renal pelvis	44,120	5%	Thyroid	37,810	4%
Non-Hodgkin lymphoma	41,090	5%	Non-Hodgkin lymphoma	33,110	4%
Oral cavity & pharynx	38,140	4%	Kidney & renal pelvis	29,700	3%
Leukemia	35,920	4%	Pancreas	26,830	3%
Pancreas	29,940	3%	Leukemia	25,860	3%
All Sites	**870,970**	**100%**	**All Sites**	**891,480**	**100%**

Estimated Deaths

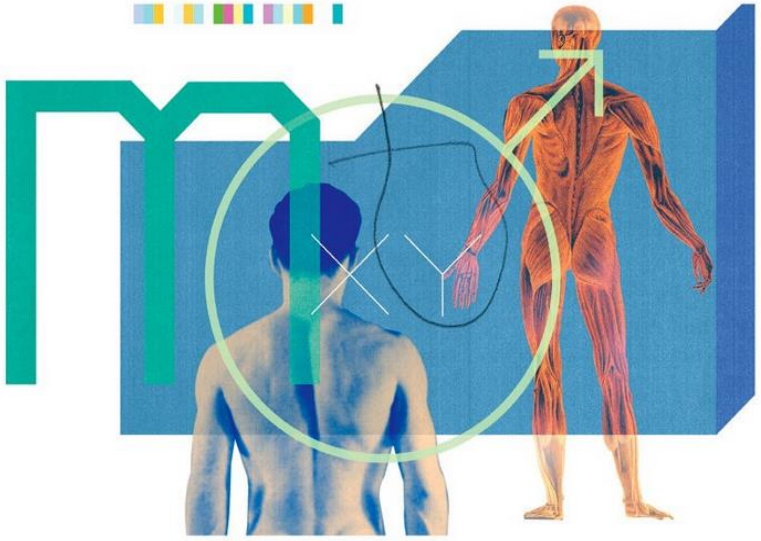
Males			Females		
Lung & bronchus	76,650	24%	Lung & bronchus	66,020	23%
Prostate	31,620	10%	Breast	41,760	15%
Colon & rectum	27,640	9%	Colon & rectum	23,380	8%
Pancreas	23,800	7%	Pancreas	21,950	8%
Liver & intrahepatic bile duct	21,600	7%	Ovary	13,980	5%
Leukemia	13,150	4%	Uterine corpus	12,160	4%
Esophagus	13,020	4%	Liver & intrahepatic bile duct	10,180	4%
Urinary bladder	12,870	4%	Leukemia	9,690	3%
Non-Hodgkin lymphoma	11,510	4%	Non-Hodgkin lymphoma	8,460	3%
Brain & other nervous system	9,910	3%	Brain & other nervous system	7,850	3%
All Sites	**321,670**	**100%**	**All Sites**	**285,210**	**100%**

CA Cancer J Clin 2019;69:7-34.

Do we have any new evidence for or against prostate cancer screening?

Is Prostate Screening *Still* Controversial?

New Study Offers Support for Prostate Testing



Stuart Bradford

By Roni Caryn Rabin

Sept. 4, 2017

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Home » Harvard Health Blog » New study once again casts doubt on PSA screening - Harvard Health Blog

New study once again casts doubt on PSA screening

POSTED APRIL 06, 2018, 6:30 AM , UPDATED APRIL 18, 2018, 9:11 AM

ORIGINAL ARTICLE

Mortality Results from a Randomized Prostate-Cancer Screening Trial

Gerald L. Andriole, M.D., Robert L. Grubb III, M.D., Saundra S. Buys, M.D.,

N ENGL J MED 360;13 NEJM.ORG MARCH 26, 2009

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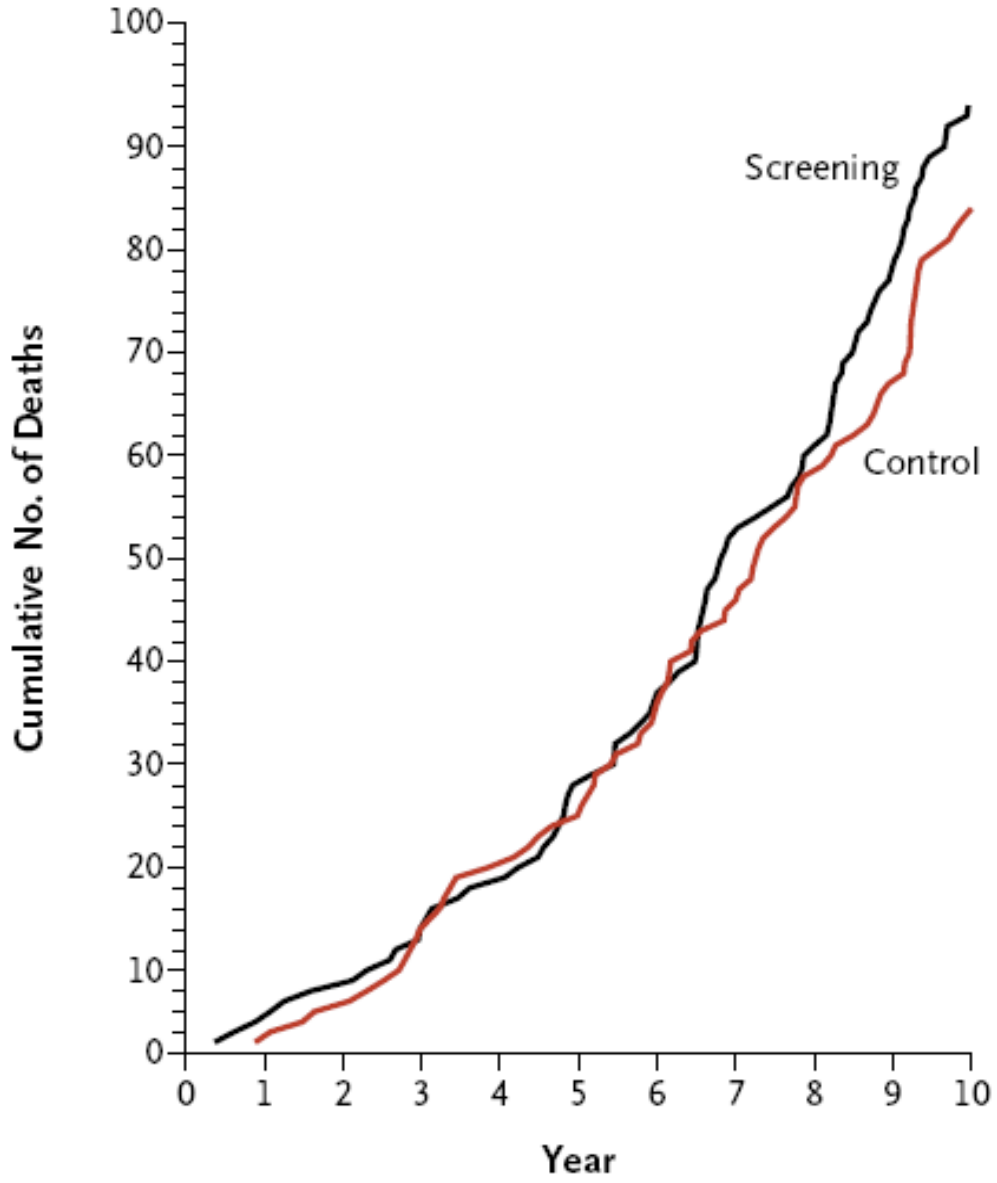
B Prostate-Cancer Deaths



ORIGINAL ARTICLE

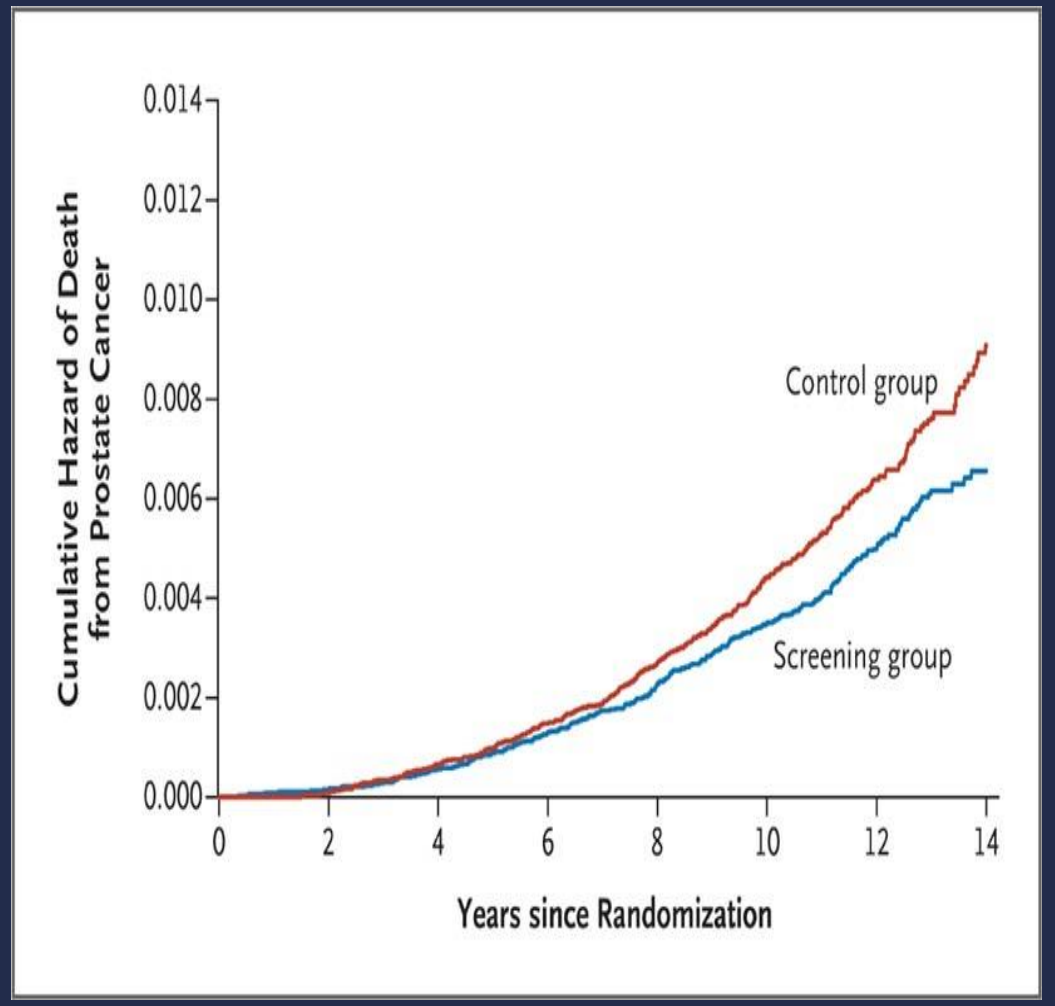
Screening and Prostate-Cancer Mortality in a Randomized European Study

Fritz H. Schröder, M.D., Jonas Hugosson, M.D., Monique J. Roobol, Ph.D.,

N ENGL J MED 360;13 NEJM.ORG MARCH 26, 2009

ERSPC Results

- Prostate cancer death rate 27% lower in screened group (p = 0.0001) at 13 yrs
- Number needed to screen to save 1 life: 781
- NNS to prevent 1 case of metastatic cancer: ~350
- Number needed to diagnose to save 1 life: 27
  - Major issue of over-diagnosis & over-treatment



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Schroder FH, et al. *Lancet* 2014;384: 2027–2035

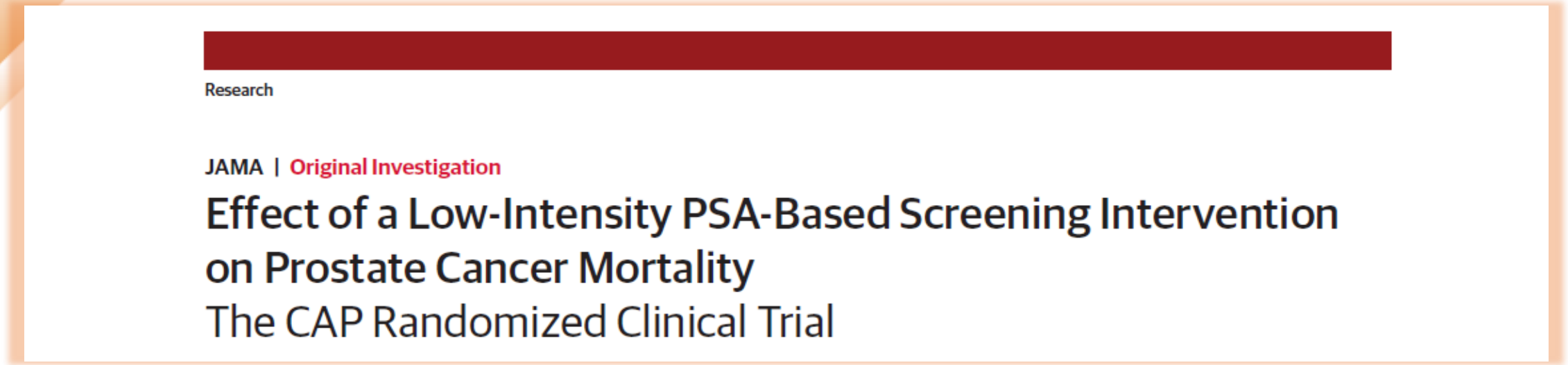
Annals of Internal Medicine ORIGINAL RESEARCH

Reconciling the Effects of Screening on Prostate Cancer Mortality in the ERSPC and PLCO Trials

Alex Tsodikov, PhD; Roman Gulati, MS; Eveline A.M. Heijnsdijk, PhD; Paul F. Pinsky, PhD; Sue M. Moss, PhD; Sheng Qiu, MS; Tiago M. de Carvalho, MS; Jonas Hugosson, MD; Christine D. Berg, MD; Anssi Auvinen, MD; Gerald L. Andriole, MD; Monique J. Roobol, PhD; E. David Crawford, MD; Vera Nelen, MD; Maciej Kwiatkowski, MD; Marco Zappa, PhD; Marcos Luján, MD; Arnauld Villers, MD; Eric J. Feuer, PhD; Harry J. de Koning, MD; Angela B. Mariotto, PhD; and Ruth Etzioni, PhD

- Controlled for differences in study design
- Adjusted for lead-time
- Both studies led to a ~ 25-32% reduction in prostate cancer mortality with screening compared with no screening

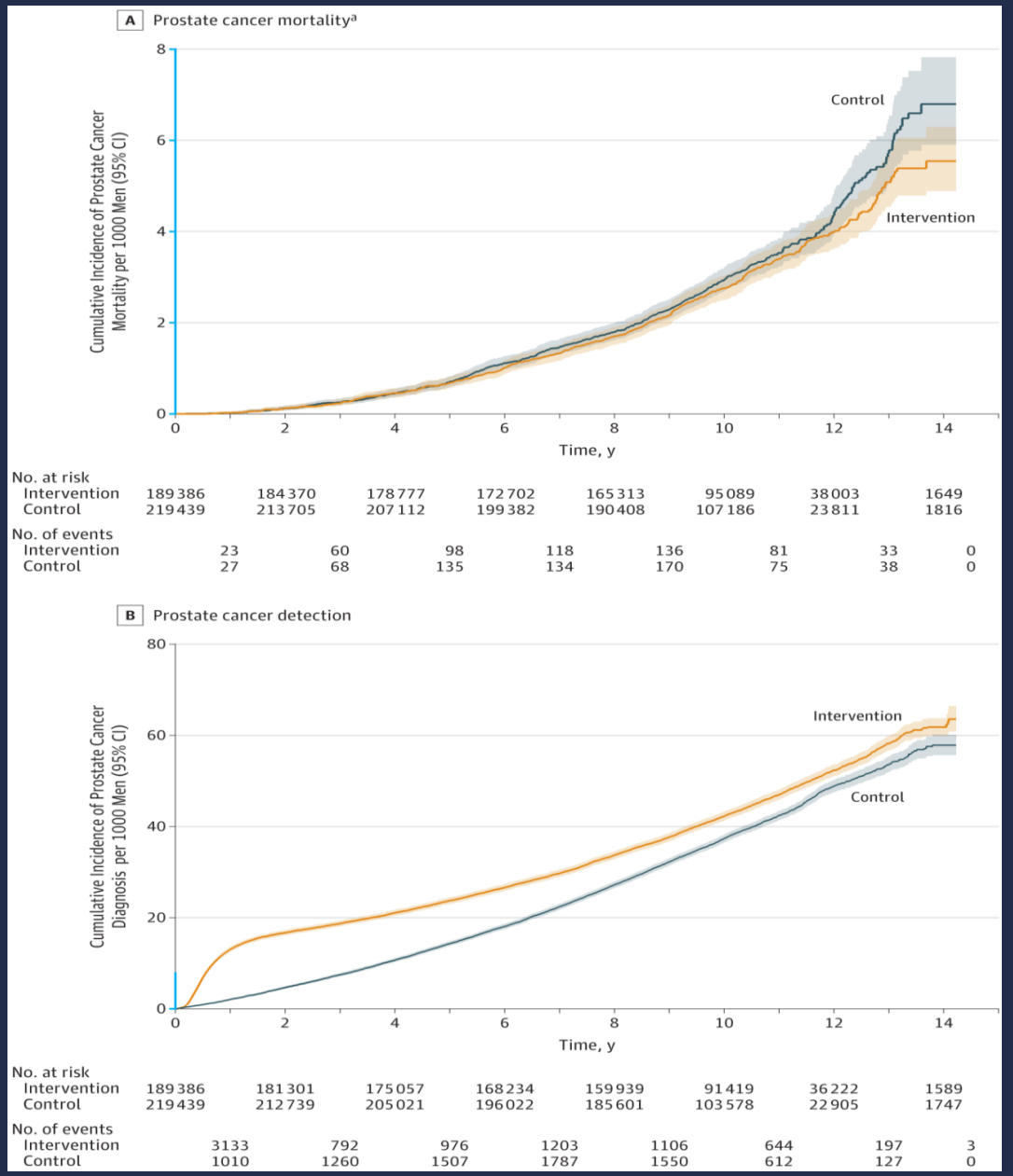
Ann Intern Med 2017;167:449-455



- 415,000 British men 50-69 randomized to a single ***offer*** to screen vs usual care (info sheet on request)
- One-time screen & then followed for 10 yrs
- Men dx'd with prostate cancer randomized to treatment vs active surveillance

JAMA 2018;319(9):883-895.

Single PSA Screen vs Control: CAP Trial Results



JAMA 2018;319(9):883-895

CAP Trial: Problems

- Wasn't a study of screening effectiveness; it examined the impact of *offering* screening
  - ***Only 1/3rd*** took them up on it vs 10-15% of controls
  - Likelihood of seeing a difference from the control group was very low!
- 10 year f/u is relatively short for prostate cancer
  - Though unlikely to see a difference even with longer f/u given low % screened
- Many diagnosed with cancer not treated as aggressively as in U.S.
- Designed to study the impact of a single screen
  - Not generalizable to serial screening strategies

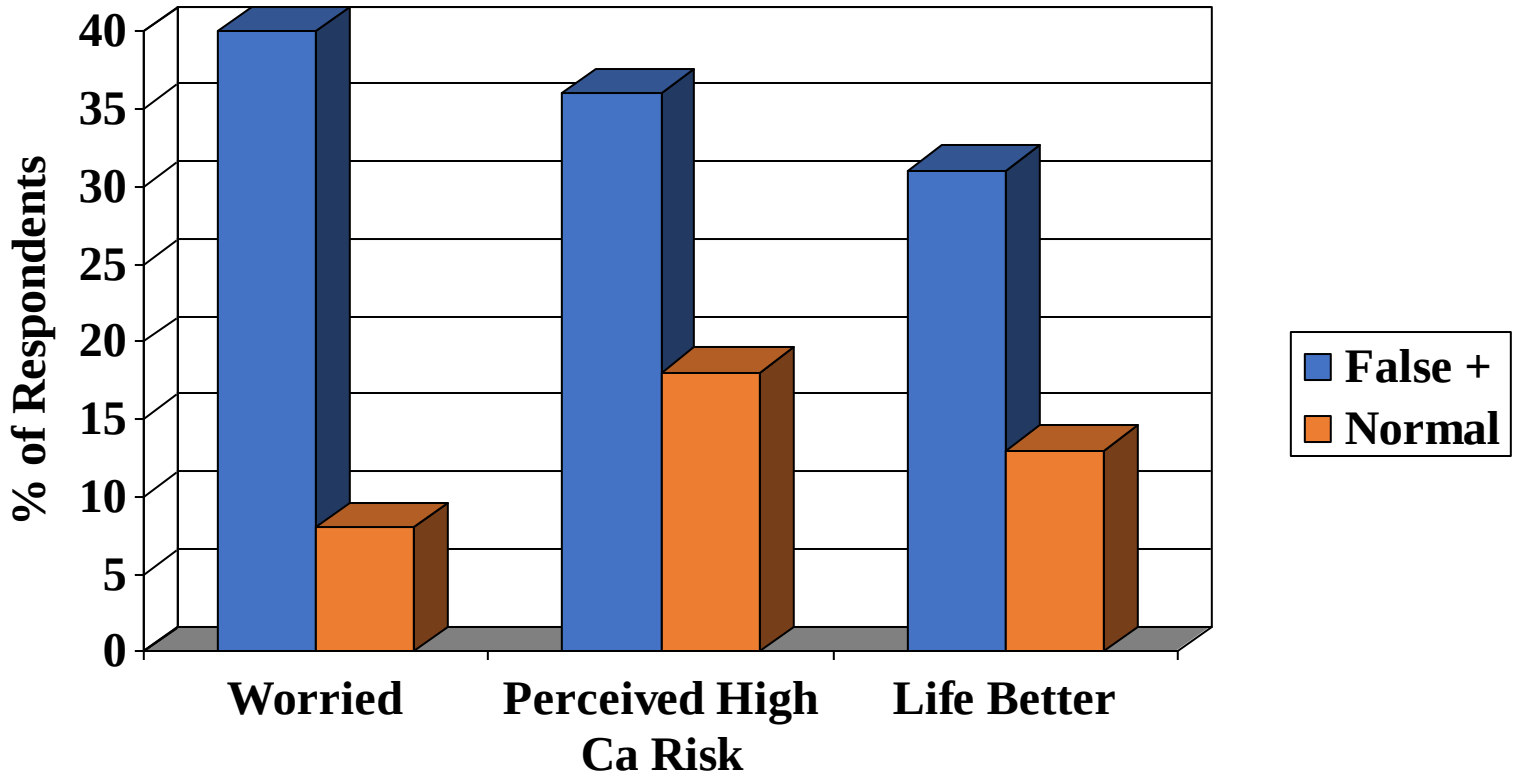
Do we have anything better than the PSA?

Test Characteristics of the PSA

- Using a PSA threshold of ≥ 4.0 ng/ml for referral for biopsy:
  - Sensitivity: 72%
  - Specificity: 93%
  - Positive Predictive Value: 25%
- 15-28% of men with PSA < 4 ng/ml will have prostate cancer on biopsy
  - 15% of these are high-grade
- False positives caused by:
  - BPH – the biggie
  - Prostatitis (often asymptomatic)
  - Ejaculation, long bike rides, probably not the DRE

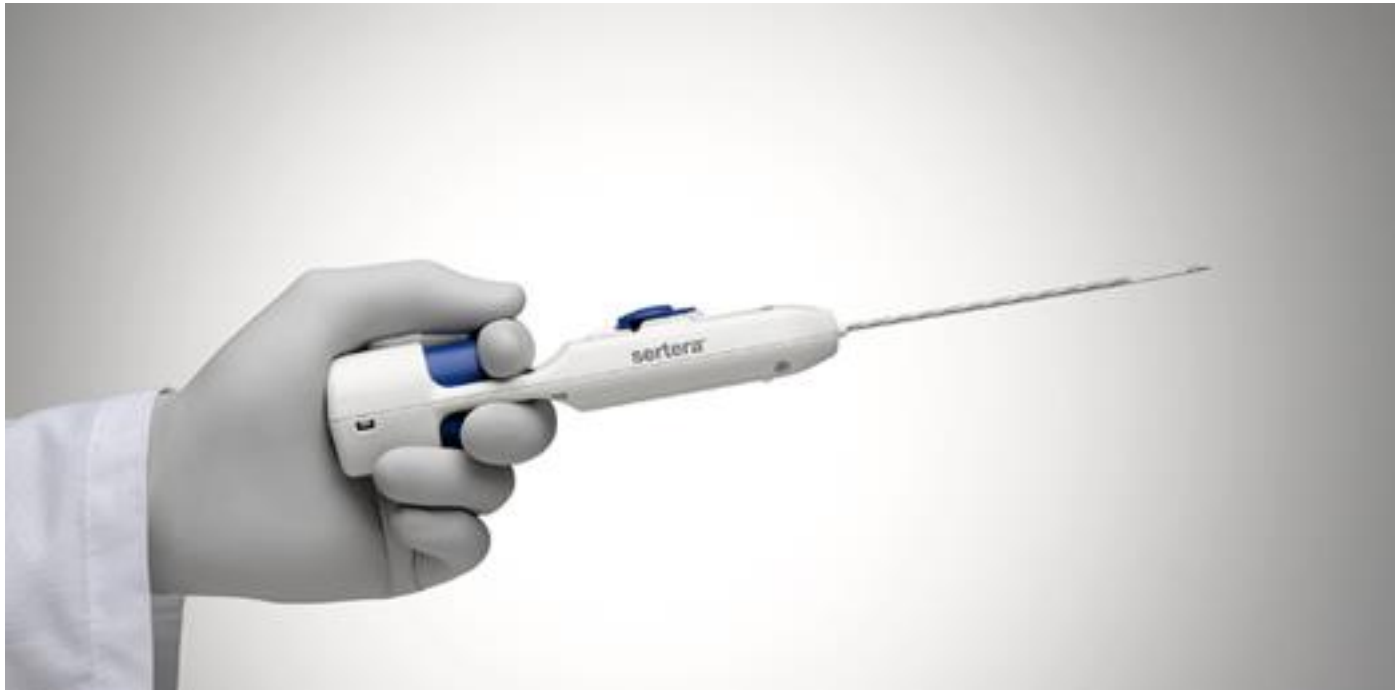
Am Fam Physician 2015;92:683-88; Ann Intern Med 2013;158:761-769;
J Am Board Fam Pract. 2003;16:95-101.

Impact of a False (+) PSA*



*High PSA led to normal biopsy vs normal PSA controls, surveyed 6 weeks later

McNaughton-Collins M. Am J Med 2004;117:719-25



Does this look like “dodging a bullet”?

Beyond PSA (alone)

- PSA Velocity
- PSA Density
- % Free PSA
- Prostate Health Index (PHI)
- 4K Test
- Multiparametric MRI (mpMRI)

PSA Velocity

- Velocity > 0.35 ng/dl per year associated with greater likelihood of death from prostate cancer in one study
- BUT: Didn't predict cancer on biopsy any better than absolute PSA level in most recent study
- Best role may be in predicting need for repeat biopsy after initial negative biopsy

JNCI 2006;98:152127; Br J Cancer 2018;118:266-76.

PSA Density

- PSA/Prostate Volume = PSA density
- Men with BPH have lower PSA density than men with cancer
  - Could help to differentiate the two
- Doesn’t add much predictive value to fPSA
- Requires a trans-rectal u/s
- Hasn’t gained much traction in initial evaluation of elevated PSA’s

Urology 2000:56:255-60.

% Free PSA (fPSA)

- The higher the % free PSA, the lower the risk of cancer
  - PSA produced by cancer cells is more likely to be complexed to a glycoprotein)
- FDA approved indication: PSA between 4 & 10 ng/dl with normal DRE
- Using a fPSA threshold of $\geq$ 25% detects 95% of cancers & reduces biopsy rate by 20%
  - But most men with elevated PSA's have fPSA levels below 25% (ie, they need a biopsy)

Prostate Cancer Prostatic Dis 1998;1:197-203.

Prostate Health Index (PHI)

- Combination of total PSA, free PSA, and proPSA tests
- Discriminates between high-grade cancer vs low-grade or no cancer
- A PHI score cut-off of 24 reduces biopsies by 36% at a cost of missing 2.5% of high-grade cancers (Gleason $\geq$7)
- FDA approved for PSA values between 4 & 10 ng/dl

J Urol 2015;194:65-72; BJU Int 2017;120:61-68.

4K Score

- Another combo test: total PSA, fPSA, human kallikrein 2, & ‘intact’ PSA
- Also factors in age, DRE result, and prior biopsy status
- Demonstrated to significantly improve accuracy & reduce need for biopsy, compared with PSA
- No optimal cut-off threshold for biopsy vs no-biopsy, just provides a probability of high-grade cancer.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 MAY 10, 2018 VOL. 378 NO. 19

MRI-Targeted or Standard Biopsy for Prostate-Cancer Diagnosis

V. Kasivisvanathan, A.S. Rannikko, M. Borghi, V. Panebianco, L.A. Mynderse, M.H. Vaarala, A. Briganti, L. Budäus, G. Hellawell, R.G. Hindley, M.J. Roobol, S. Eggener, M. Ghei, A. Villers, F. Bladou, G.M. Villeirs, J. Virdi, S. Boxler, G. Robert, P.B. Singh, W. Venderink, B.A. Hadaschik, A. Ruffion, J.C. Hu, D. Margolis, S. Crouzet, L. Klotz, S.S. Taneja, P. Pinto, I. Gill, C. Allen, F. Giganti, A. Freeman, S. Morris, S. Punwani, N.R. Williams, C. Brew-Graves, J. Deeks, Y. Takwoingi, M. Emberton, and C.M. Moore, for the PRECISION Study Group Collaborators*

Kasivisvanathan V et al. NEJM 2018;378:1767-77.

Multiparametric MRI vs Standard Biopsy

Table 2. Comparison of Cancer Detection between Groups.*

Outcome	MRI-Targeted Biopsy Group (N = 252)	Standard-Biopsy Group (N = 248)	Difference†	P Value
Biopsy outcome — no. (%)			—	—
No biopsy because of negative result on MRI	71 (28)	0		
Benign tissue	52 (21)	98 (40)		
Atypical small acinar proliferation	0	5 (2)		
High-grade prostatic intraepithelial neoplasia	4 (2)	10 (4)		
Gleason score				
3+3	23 (9)	55 (22)		
3+4	52 (21)	35 (14)		
3+5	2 (1)	1 (<1)		
4+3	18 (7)	19 (8)		
4+4	13 (5)	6 (2)		
4+5	7 (3)	2 (1)		
5+5	3 (1)	1 (<1)		
No biopsy‡	4 (2)	3 (1)		
Withdrawal from trial§	3 (1)	13 (5)		
Clinically significant cancer¶				
Intention-to-treat analysis — no. (%)	95 (38)	64 (26)	12 (4 to 20)	0.005
Modified intention-to-treat analysis — no./total no. (%)	95/245 (39)	64/235 (27)	12 (3 to 20)	0.007
Per-protocol analysis — no./total no. (%)	92/235 (39)	62/227 (27)	12 (3 to 20)	0.007
Clinically insignificant cancer — no. (%)	23 (9)	55 (22)	−13 (−19 to −7)	<0.001
Maximum cancer core length — mm	7.8±4.1	6.5±4.5	1.0 (0.0 to 2.1)	0.053
Core positive for cancer — no./total no. of cores (%)	422/967 (44)	515/2788 (18)	—	—
Men who did not undergo biopsy — no. (%)‖	78 (31)	16 (6)	—	—

Kasivisvanathan V et al. NEJM 2018;378:1767-77.

Multiparametric MRI vs Standard Biopsy
Complications

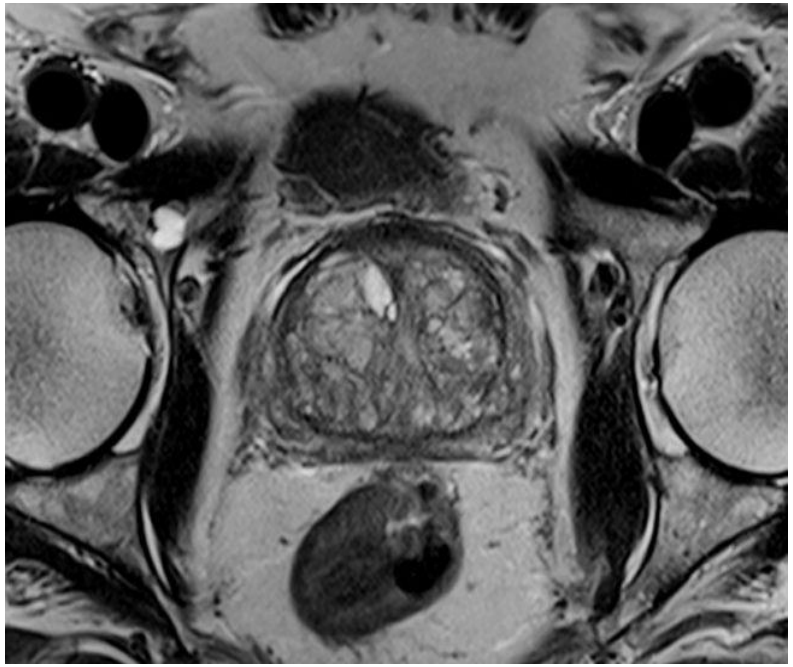
	MRI-Guided Biopsy	Standard Biopsy
Median # of core biopsies	4*	12
Blood in urine (%)	30%	63%
Blood in semen (%)	32%	60%
Post-procedural pain (%)	13%	23%
Rectal bleeding (%)	14%	22%

*Among men who underwent biopsy

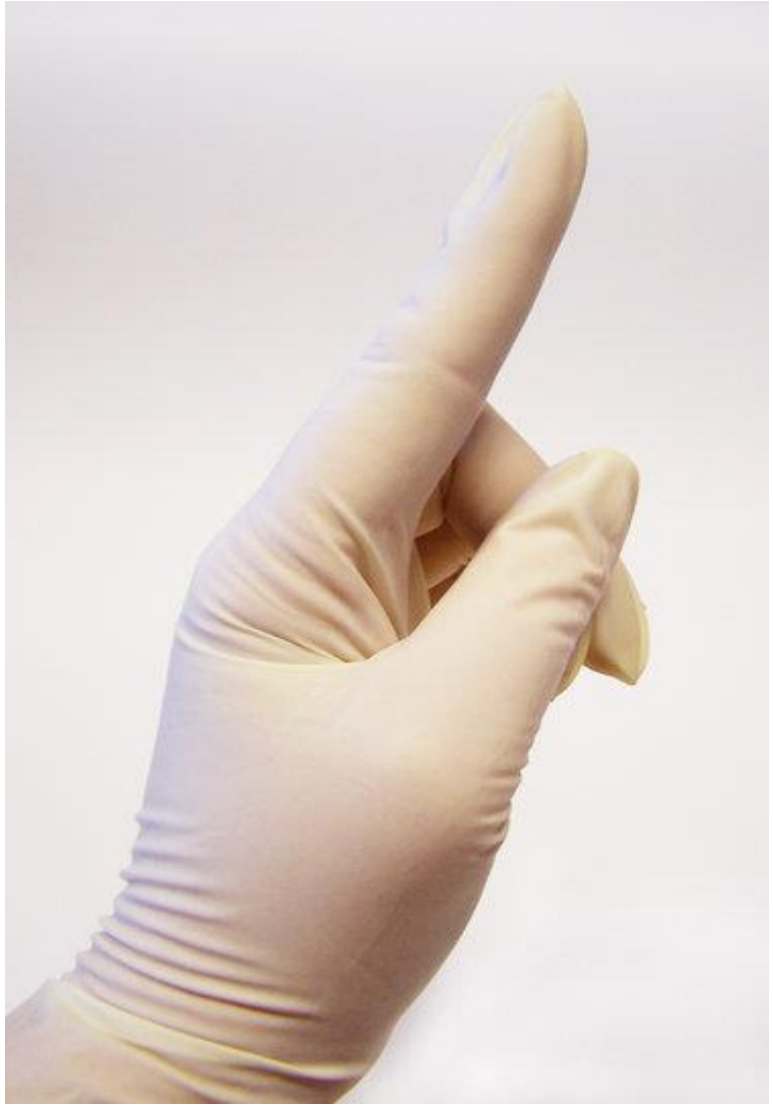
Kasivisvanathan V, et al. N Engl J Med 2018;378:1767-1777.

mpMRI: Caveat

- Not yet routinely covered by insurance prior to biopsy
- Requires peer-to-peer
- More likely to get covered if:
  - PSA>10
  - Abnormal PHI or 4K test
  - Subsequent biopsy confirms cancer diagnosis



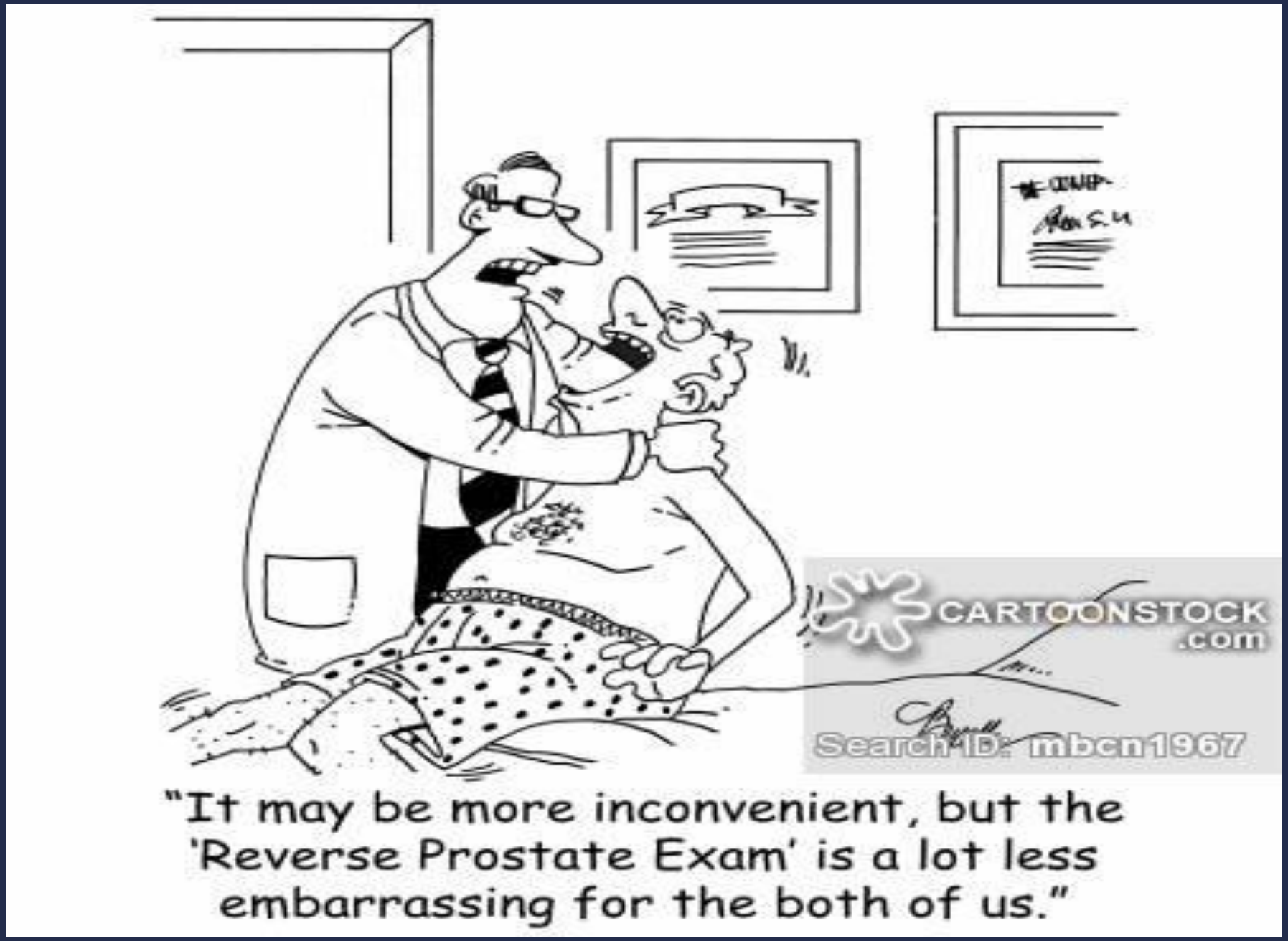
What about the good old digital rectal exam?



The Digital Rectal Exam

- 2018 meta-analysis: sensitivity 51%, specificity 59% (primary care docs)
  - Slightly better than flipping a coin
- One survey: ½ of medical school graduates never performed a DRE
- Only ½ of primary care docs are confident in their ability to detect prostate cancer with DRE
- Inter-examiner reliability between urologists to identify suspicious nodules is fair at best ($\kappa = 0.22$)
- Major guidelines now make DRE optional for primary screen
  - Makes sense to do it for abnormal PSA's, symptoms

Naji L, et al. Ann Fam Med 2018;16:149-54.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.com
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"It may be more inconvenient, but the 'Reverse Prostate Exam' is a lot less embarrassing for the both of us."

Are we doing any better identifying who needs to be treated?

Overdiagnosis and Overtreatment

- Overdiagnosis
  - The diagnosis of prostate cancers through screening that would not have been diagnosed during the man's lifetime if screening had not occurred
  - Estimates range from 23% to 42% of screen-detected cancers
- Overtreatment
  - The treatment of screen-detected prostate cancers that never would have become clinically apparent during the man's lifetime in the absence of screening
  - Active surveillance and watchful waiting have the potential to significantly decrease overtreatment

Overdiagnosis & Overtreatment: the PSA Quandary

"When cure is possible, is it necessary?

And when cure is necessary, is it possible?"

-- Willet Whitmore, MD, ~1990

Long-term Outcomes of Treating Localized Prostate Cancer

Table 2. Survey Responses on Selected Items Regarding Urinary, Bowel, and Sexual Function.*

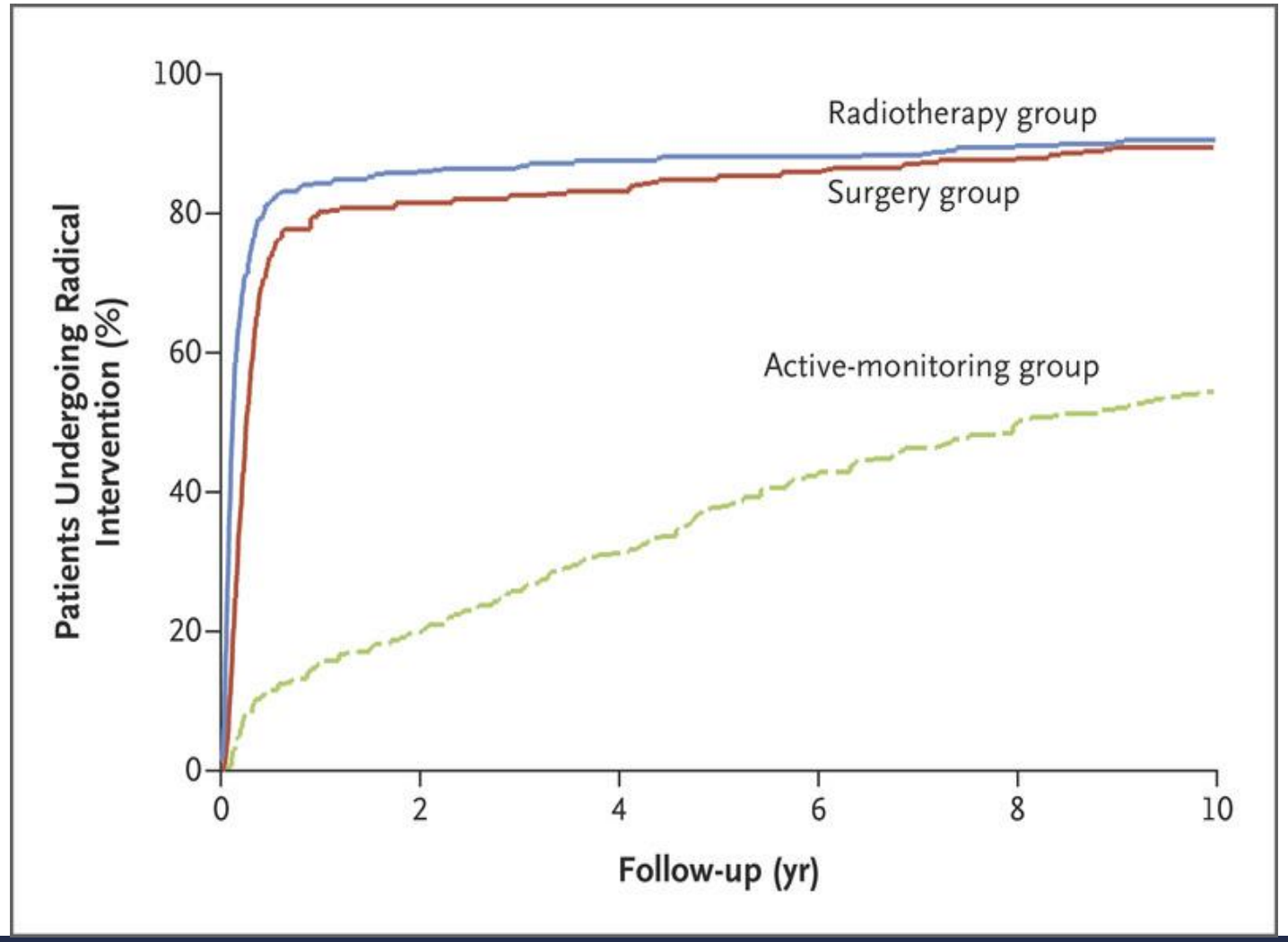
Outcome	Prostatectomy	Radiotherapy
	percent	
Urinary incontinence		
No control or frequent urinary leakage		
2 yr	9.6	3.2
5 yr	13.4	4.4
15 yr	18.3	9.4
Bothered by dripping or leaking urine‡		
2 yr	10.6	2.4
5 yr	12.9	2.9
15 yr	17.1	18.4
Sexual function		
Erection insufficient for intercourse		
2 yr	78.8	60.8
5 yr	75.7	71.9
15 yr	87.0	93.9
Bothered by sexual dysfunction‡		
2 yr	55.5	48.2
5 yr	46.7	39.7
15 yr	43.5	37.7
Bowel function		
Bowel urgency		
2 yr	13.6	34.0
5 yr	16.3	31.3
15 yr	21.9	35.8
Bothered by frequent bowel movements, pain, or urgency‡		
2 yr	2.9	7.9
5 yr	4.4	5.8
15 yr	5.2	16.0

Resnick MJ. NEJM 2013;368:436-445.

Emerging strategy to mitigate harm: "Active Surveillance"

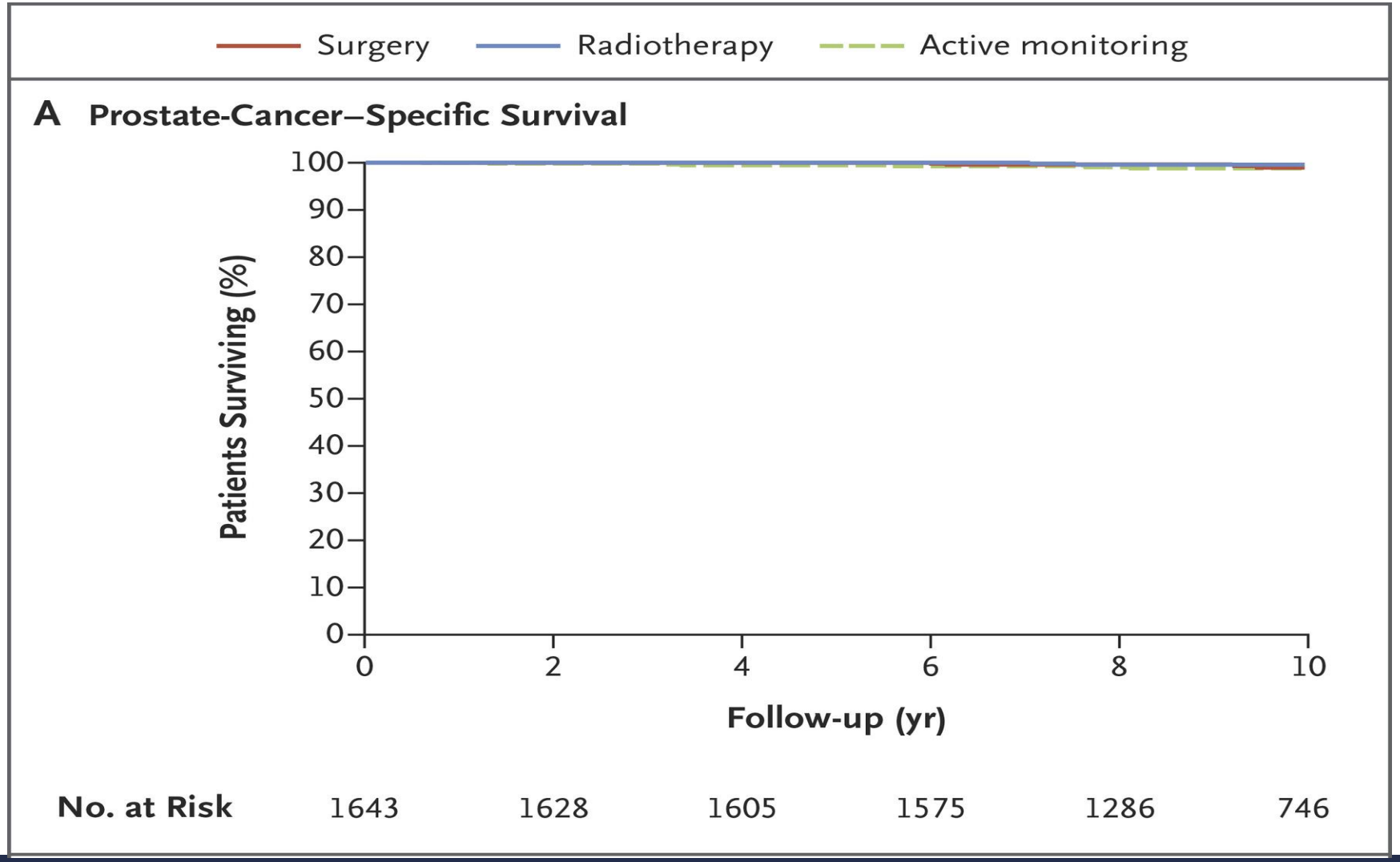
- Patients with low/intermediate grade cancers offered option to monitor cancer with PSA & periodic biopsies
  - Initiate treatment if cancer progresses
  - In the US, PSA done every 6 months & biopsy annually
  - In the US, Gleason 7 generally offered treatment, NOT active surveillance
- Reduces risk of overtreatment

ProtecT Trial: Treatment vs "Active Monitoring"



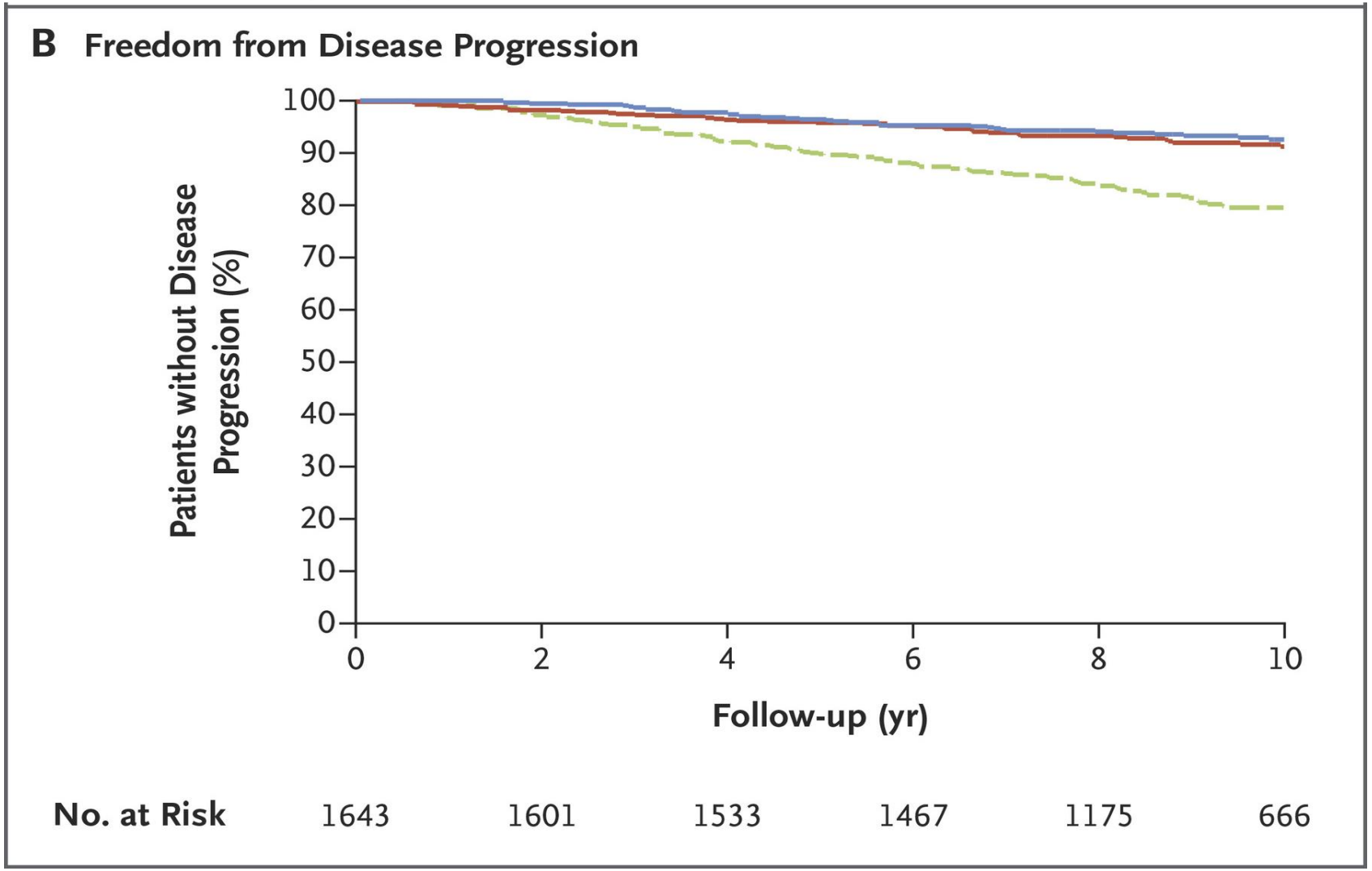
Hamdy FC, et al. *N Engl J Med*. 2016;375:1415-24.

ProtecT: Survival in treated vs active surveillance groups



Hamdy FC, et al. *N Engl J Med*. 2016;375:1415-24.

A price to pay for active surveillance?



Active Surveillance:
Are we creating a cohort of anxious men who are in “cancer limbo”?

Table 3. *Predicted risk of anxiety by overall health score and time on active surveillance in 413 patients*

	Median % Predicted Risk (IQR)		
Overall Health Score	2.5 Yrs	5 Yrs	7.5 Yrs
4	39 (28–49)	31 (21–41)	25 (13–36)
6	30 (24–36)	24 (18–29)	18 (11–25)
8	23 (19–27)	18 (14–21)	13 (8–18)
10	17 (11–22)	13 (8–17)	10 (5–14)

Marzouk K et al. J Urol 2018 Dec; 200:1250.

What do the experts recommend?

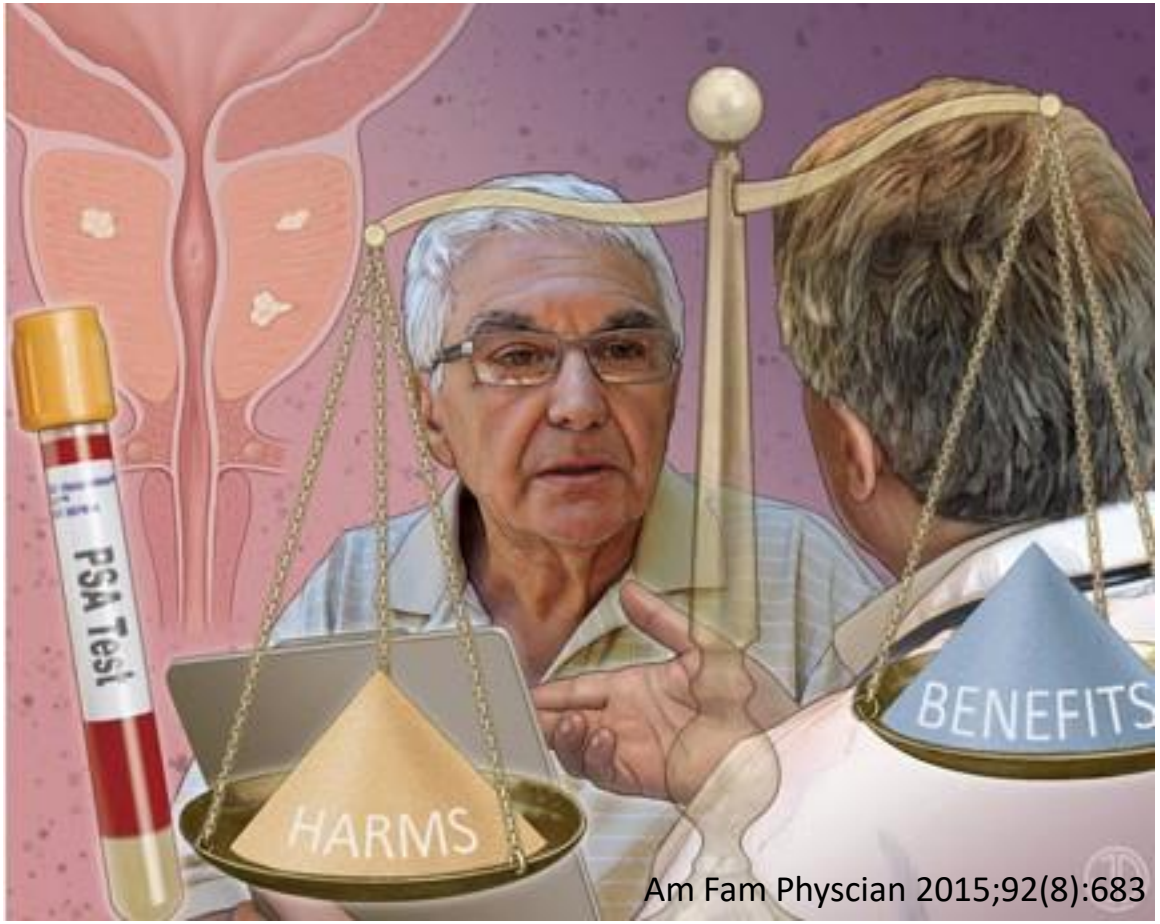
Prostate Cancer Screening Guidelines

	USPSTF (2018)	AUA (2013)	ACS (2010)
Guideline	"Men should have an opportunity to discuss the benefits and harms of screening with their clinician and to incorporate their values & preferences in the decision." (C rec)	"The panel recommends shared decision making … proceed based on a man's values & preferences"	"The ACS recommends that men…have an opportunity to make an informed decision with their health care provider about screening."
Age Range	55-69 Recommends against screening ≥ 70 (D rec) *No separate rec for (+) FH or AA*	55-69 Individualize 40-54 based on (+) FH, AA race Individualize over age 70 (only if life expectancy >10 y)	50-74 45 if AA or (+) FH No screening if life expectancy <10 yrs
Screening Tool	PSA without DRE	PSA (no mention of DRE)	PSA +/- DRE
Screening Interval	Not defined	2 yrs (consider 4 yrs if PSA <1	2 yrs (PSA <2.5), 1 yr (PSA 2.5-4)

USPSTF: JAMA 2018;319:1901-13; AUA guideline: Carter HB, et al. J Urol 2013;190:419-26.
ACS guideline: Wolf AMD, et al. CA Cancer J Clin 2010;60:70-98.

So, how do you do informed/shared decision-making in 5 minutes or less?

- Provide the core pieces of information needed for an informed decision
- Provide dichotomous “values matching” scenarios
- Assign homework



Am Fam Physcian 2015;92(8):683

Core elements for an informed decision

- PSA testing can find prostate cancer before you have symptoms
- Early detection may reduce your chances of suffering or dying from prostate cancer
- There is a good chance that if we find prostate cancer, it would never have caused problems during your lifetime.
- If we find one of these low-grade prostate cancers, you won't need treatment, but you'll need to undergo yearly biopsies
- Treating prostate cancer frequently leads to erectile dysfunction, urinary leakage, and/or bowel problems.

Wolf AMD, et al. CA Cancer J Clin 2010;60:70–98.

PROS

CONS

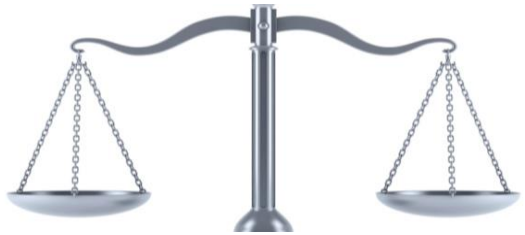
- PSA screening can detect cancer at an earlier stage than if no screening is performed.
- PSA screening can reduce the risk of dying from prostate cancer and from developing metastatic prostate cancer.

- Some cancers detected by screening would never have become apparent during the man's lifetime (**overdiagnosis**).
- The PSA has **false-positives** & false-negatives.
- A high PSA requires a **prostate biopsy** - biopsies are painful & may cause infection or bleeding.
- Treatment for prostate cancer often leads to ***urinary, sexual, or bowel problems***.
- **Not all prostate cancers need immediate treatment**, but they will require periodic blood tests and biopsies to determine the need for future treatment: this can be painful & anxiety-producing.

Wolf AMD, et al. CA Cancer J Clin 2010;60:70–98.

To Help Our Patients Decide: *Values Matching Scenarios*

- "You might want to be tested if you value finding cancer early, you're willing to be diagnosed with a cancer that we may not treat, and you're willing to risk significant injury to sexual, urinary, or bowel function if we do have to treat."
- "You might *not* want to be tested if you place a higher value on avoiding the potential harms of screening, such as anxiety about finding a cancer we don't treat, or injury to sexual, urinary or bowel function."



Volk RJ. *Am J Prev Med* 2007;33:428..

Assign homework

Prostate Cancer Screening

A Decision Guide

CDC

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Should I Get Screened for Prostate Cancer?

In 2018, the U.S. Preventive Services Task Force (USPSTF) made the following recommendations about prostate cancer screening —

- Men who are 55 to 69 years old should make individual decisions about being screened for prostate cancer with a prostate specific antigen (PSA) test.
- Before making a decision, men should talk to their doctor about the benefits and harms of screening for prostate cancer, including the benefits and harms of other tests and treatment.
- Men who are 70 years old and older should not be screened for prostate cancer routinely.

This recommendation applies to men who—

- Are at average risk for prostate cancer.
- Are at increased risk for prostate cancer.
- Do not have symptoms of prostate cancer.
- Have never been diagnosed with prostate cancer.

Should I Get Tested for Prostate Cancer?

Many men wonder if they should get screened for prostate cancer. Each man must decide for himself. That's why it's important for men to talk about screening (testing) with their doctor. This video helps men understand their prostate cancer screening options.


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Case Presentation

62 yo white man without significant past medical history presents for annual preventive visit. He has no family history of prostate cancer. He has mild urinary hesitancy and his prostate is mildly enlarged without induration or nodules. His PSA has been gradually rising:

- 2011: 2.35
- 2013: 2.17
- 2017: 3.75
- 2019: 4.51

Where do we go from here?

riskcalc.org/PCPTRC

Characteristics

Race

Caucasian

Age

62

PSA [ng/ml]

4.51

Family History of Prostate Cancer

No

Digital rectal examination

Normal

Prior biopsy

Never had a prior biopsy

☐ Percent free PSA available?

Result | More Information

Risk of prostate cancer if biopsy were to be performed

Based on the provided risk factors a prostate biopsy performed would have a:

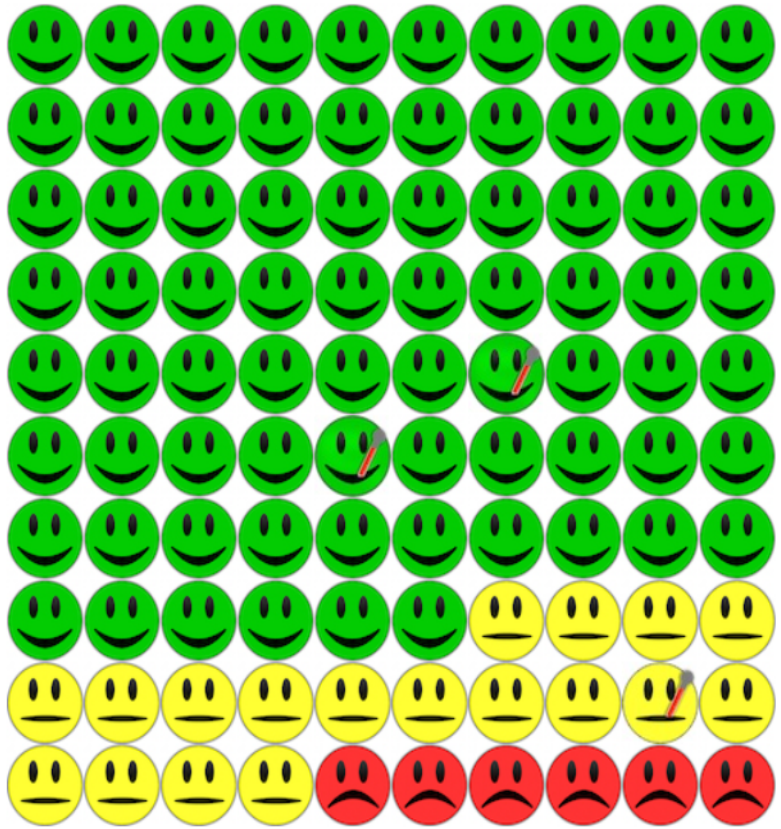
6% chance of high-grade prostate cancer,

18% chance of low-grade cancer,

76% chance that the biopsy is negative for cancer.

About 2 to 4% of men undergoing biopsy will have an infection that may require hospitalization.

Please consult your physician concerning these results.



Options

- Repeat – probably not (current value consistent with rate of rise)
- Other tests to refine risk assessment: % free PSA, PHI, 4K, mpMRI
- Biopsy

Take-Home Points

- Prostate cancer screening probably does save lives.
- Prostate cancer screening definitely subjects many men to unnecessary treatment that poses significant risk to urinary, sexual & bowel health.
- We have a growing array of tools to refine cancer probability and avoid unnecessary biopsy, including free PSA, prostate health index, & mpMRI.
- Active surveillance is a powerful tool to reduce unnecessary treatment – but leaves men with untreated cancer & its associated anxiety.
- Men need to know what they're getting into before screening…

Useful Resources

- USPSTF 2018 guideline: www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/prostate-cancer-screening1
- Prostate cancer risk calculator: www.riskcalc.org/PCPTRC
- CDC patient info: https://www.cdc.gov/cancer/prostate/index.htm
- Georgetown decision aid: http://prostatedecision.georgetown.edu


Thank you!