Prostate Cancer Screening Recommendations from the US Preventive Services Task Force:

Evidence and implementation to optimize health outcomes

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U.S. Preventive Services
TASK FORCE

What is your PSA screening practice?

- In your male patients do you:
  1) **Recommend and order a PSA test annually**
  2) **Recommend against the PSA test**
  3) **Discuss with all and leave decision to them**
  4) **Discuss only if they bring up the topic and leave decision to them**

Get Tested, Get Treated
It could save your life-
It did mine

MOVEMBER
CHANGING THE FACE
OF MEN'S HEALTH

Prostate
Cancer
Awareness
USA 33
Annual
Checkups
and
Tests
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PRELIMINARY DESIGN

Screening

Simple Messages…

Sometimes

Annals of Internal Medicine | Clinical Guideline

Screening for Prostate Cancer: U.S. Preventive Services Task Force Recommendation Statement

Virginia A. Moyer, MD, MPH, on behalf of the U.S. Preventive Services Task Force*

Description: Update of the 2008 U.S. Preventive Services Task Force (USPSTF) recommendation statement on screening for prostate cancer.

Methods: The USPSTF reviewed new evidence on the benefits and harms of prostate-specific antigen (PSA)–based screening for prostate cancer, as well as the benefits and harms of treatment of localized prostate cancer.

Recommendation: The USPSTF recommends against PSA-based screening for prostate cancer (grade D recommendation).

This recommendation applies to men in the general U.S. population, regardless of age. This recommendation does not include the use of the PSA test for surveillance after diagnosis or treatment of prostate cancer; the use of the PSA test for this indication is outside the scope of the USPSTF.

Ann Intern Med. 2012;157. www.annals.org
For author affiliation, see end of text.
* For a list of the members of the USPSTF, see **Appendix 1** (available at www.annals.org).
This article was published at www.annals.org on 22 May 2012.

http://www.uspreventiveservicestaskforce.org/prostatecancerscreening.htm

U.S. Preventive Services TASK FORCE

Talk goals

- Emphasize screening goals
- Describe USPSTF structure and processes
- Note areas of agreement and main controversies
- Offer implementation suggestions

Screening basics

- **Screening goal:**
  - Reduce overall and disease specific death and disability
  - Not just find and treat more
- Screening cannot eliminate death from target disease
- Screening programs & interventions have harms
- ***If*** and ***how*** to implement requires assessing:
  - Health outcomes
    - Benefits and harms
  - Values
    - Patient, provider, health system, society
  - Costs
    - Financial and opportunity

Achieving Screening Goals Difficult

- Patients undergoing screening are asymptomatic
- Screening detects slower progressing “disease” → many will never cause problems (Overdiagnosis)
- Vast majority will not benefit
  - If benefit → in distant future
- Screened/treated individuals at risk for harms
  - Harms occur earlier, more often and frequently persist
  - Overtreatment
- Burden of proof higher than for symptomatic individuals

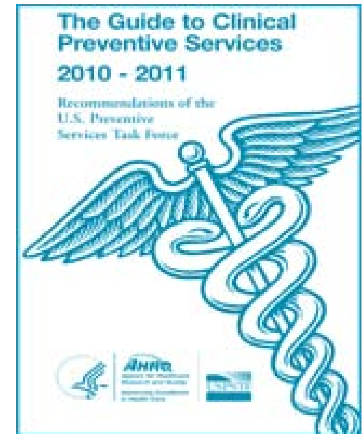
Prevention Question

- Would you take a pill with the *guarantee* that you would be twice as likely to be diagnosed with cancer if it *might* reduce your chance of dying of cancer from 3.0% to 2.4%?

  1) **Yes**

  2) **No**

USPSTF Mission



To improve the health of all Americans by making evidence-based recommendations about clinical preventive services and health promotion.

USPSTF

- A 16 member independent volunteer panel convened by AHRQ
- Non-federal experts in primary care & prevention
- Uses up-to-date, peer-reviewed evidence syntheses to create new & updated recommendations on screening, counseling & medications to prevent illness
  - Based on age, gender, & disease risk factors
  - Undergo extensive peer review and public comment
- Does not advise insurers, make coverage decisions or incorporate costs into recommendations
- Target audience: Primary care clinicians

USPSTF Recommendations Based On:

Magnitude & Certainty of Benefits and Harms (Net Benefit)

Benefits

Harms

USPSTF Recommendation Grid

Certainty of Net Benefit	**Magnitude of Net Benefit**			
	Substantial	Moderate	Small	Zero/Neg.
• High				
• Moderate				
• Low				

USPSTF Recommendation Grid

Certainty of **Net Benefit**	Magnitude of Net Benefit			
	Substantial	Moderate	Small	Zero/Neg.
• **High**	**A**			
• Moderate				
• Low				

USPSTF Recommendation Grid

Certainty of **Net Benefit**	**Magnitude of Net Benefit**			
	Substantial	**Moderate**	Small	Zero/Neg.
• **High**	A	B		
• **Moderate**	B	B		
• Low				

USPSTF Recommendation Grid

Certainty of Net Benefit	**Magnitude of Net Benefit**			
	Substantial	Moderate	**Small**	Zero/Neg
• **High**	A	B	**C**	D
• **Moderate**	B	B	**C**	D
• Low	Insufficient			

USSTF Recommendation Grid

Certainty of Net Benefit	Substantial	Moderate	Small	Zero/Neg
High				D
Moderate				D
Low				

USPSTF Recommendation Grid

Certainty of Net Benefit	**Magnitude of Net Benefit**			
	Substantial	Moderate	Small	Zero/Neg
• High				
• Moderate				
• Low	**Insufficient**			

Recommendation Statement

- Describes overall evidence & net benefit “certainty”
  - Convincing, Adequate, Inadequate
  - High, Moderate, Low
- Issues Recommendation
  - **"A" recommends**
  - **"B" recommends**
  - **"C" clinicians may consider providing**
  - **"D" recommends against**
  - **"I" insufficient evidence**

Recommendation Statement

- Describes overall evidence & net benefit “certainty”
  - Convincing, Adequate, Inadequate
  - High, Moderate, Low
- Issues Recommendation
  - "A" recommends (Convincing/High)
  - "B" recommends
  - "C" clinicians may consider providing
  - "D" recommends against
  - "I" insufficient evidence

Lower priority-
Selectively offer/provide depending on patient situation

Recommendation Statement

- Describes overall evidence & net benefit “certainty”
  - Convincing, Adequate, Inadequate
  - High, Moderate, Low
- Issues Recommendation
  - **"A" recommends**
  - **"B" recommends**
  - **"C" clinicians may consider providing**
  - **"D" recommends against**
  - **"I" insufficient evidence**

Why does controversy exist?

- Weighting of evidence, benefits and harms varies
- Physicians and patients have been told to fear cancer-the only hope is early detection and treatment
- Hard to accept that not all cancers need to be detected or treated, and that there are screening harms, not just benefits
- Few tools exist to assists providers & patients
- Change is hard

Area of agreement

- **Men should not receive PSA screening unless they have been fully informed of benefits and harms and request test**

Areas of disagreement

- **Clinicians' role and patients' rights**
  - **"Recommending against"**
  - **Choosing to obtain PSA**
  - ***Proactive* vs. *Reactive* counseling**
- **Including men most likely to benefit**
  - **Younger (40s-60s)**
  - **Increased risk**
    - **African-American men and +Family History**

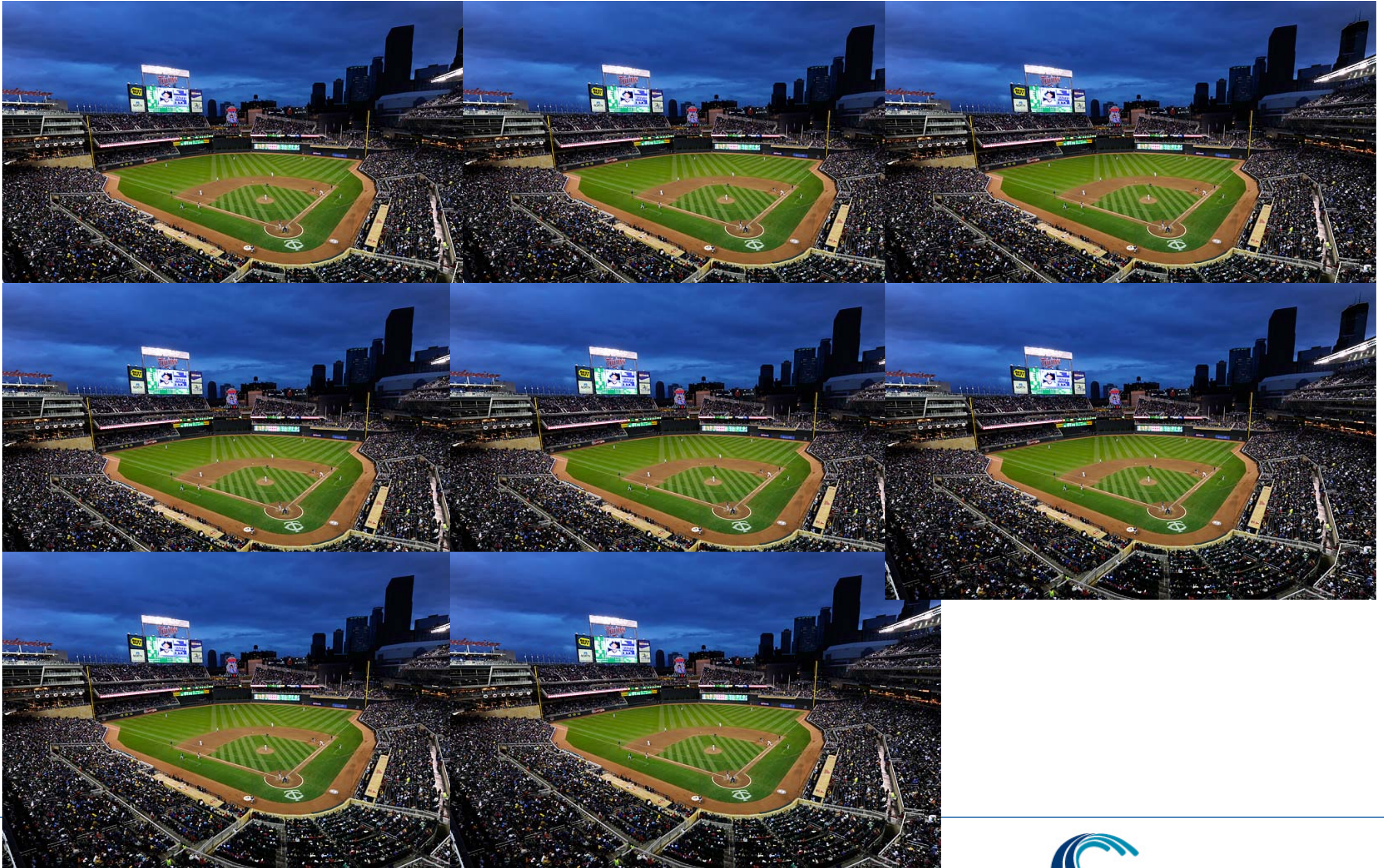
What do you think is “Futile Care”?

- Chance of intervention survival benefit:
  - 1) < 10% (1 in 10)
  - 2) < 1% (1 in 100)
  - 3) < 0.2% (1 in 500)
  - 4) < 0.1% (1 in 1000)

Evidence sources for USPSTF Recommendation

- **Screening Benefits:** 5 screening RCTs
  - Evaluated published meta-analyses (2)
- **Screening Harms:** 3 RCTs
- **Treatment Benefits:** 10* studies (2* RCTs)
- **Treatment Harms:** 32 studies (2* RCTs)
- **Public Comments:** 3000+ reviewed/addressed

Number Enrolled in 5 Screening Trials (315,000+) = 8+Target Fields



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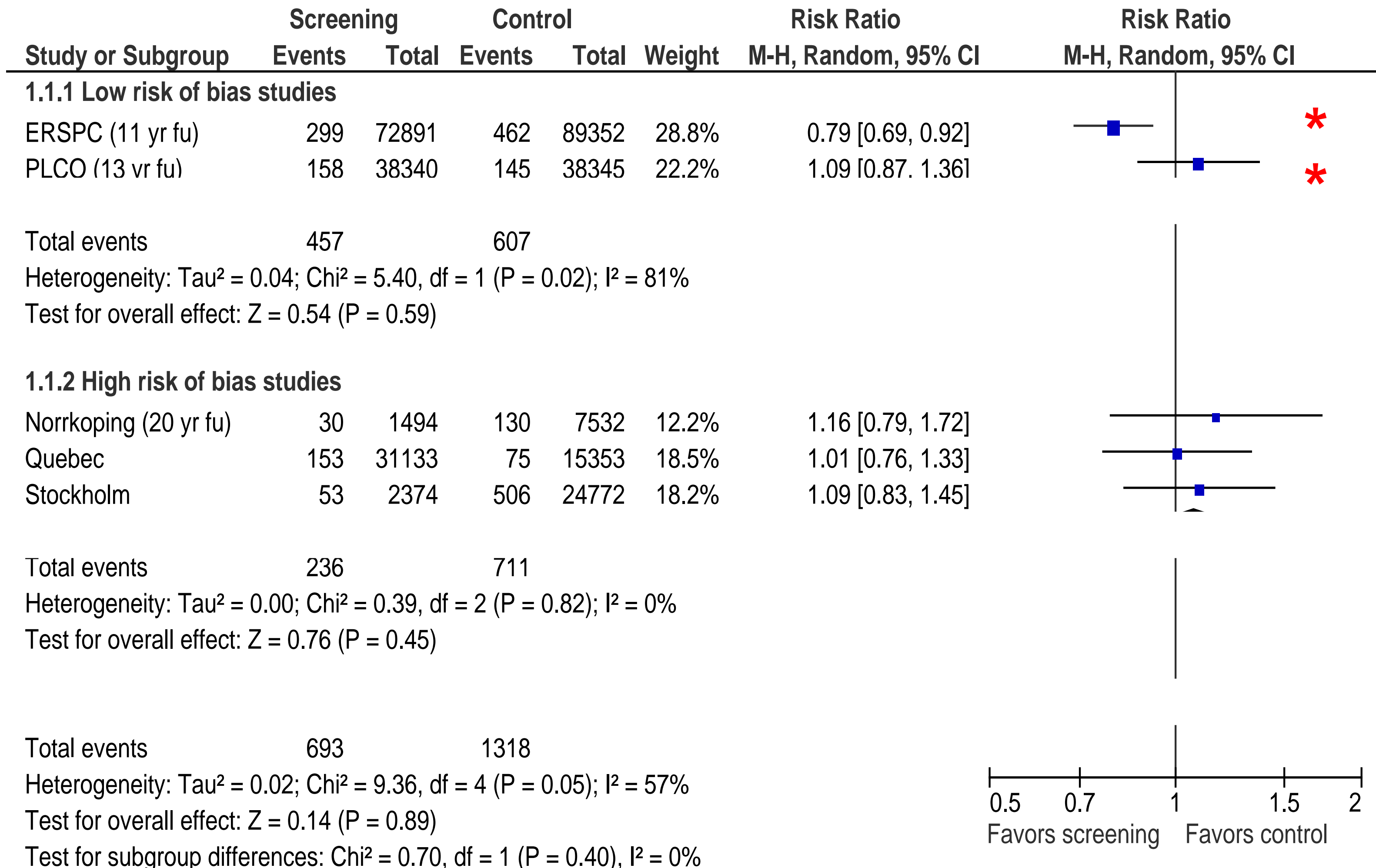
Prostate Cancer Mortality-5 Screening Trials



Prostate cancer Incidence-PLCO

PSA Screened

RR= 1.12; 95%CI=1.07 to 1.17

Controls

Cumulative number of cancers

4000
3500
3000
2500
2000
1500
1000
500
0

0 1 2 3 4 5 6 7 8 9 10 11 12 13

Study Year of Diagnosis

Study arm
○ Control
+ Intervention

Andriole JNCI 2012

U.S. Preventive Services TASK FORCE

Prostate cancer Mortality-PLCO

PSA screened

RR=1.09; 95%CI = 0.87 to 1.36

Results did not differ by:

- **Age**
- **Comorbidities**
- **Pretrial PSA**

Control

Cumulative number of deaths

150
125
100
75
50
25
0

0 1 2 3 4 5 6 7 8 9 10 11 12 13

Study Year of Death

Study arm
○ Control
+ Intervention

Andriole JNCI 2012

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Prostate Cancer Mortality

Cumulative Hazard of Death from Prostate Cancer

0.14
0.12
0.10
0.08
0.06
0.04
0.02
0.00

RR = 0.79 (0.68 to 0.91)

ARR = 0.1%

Control group

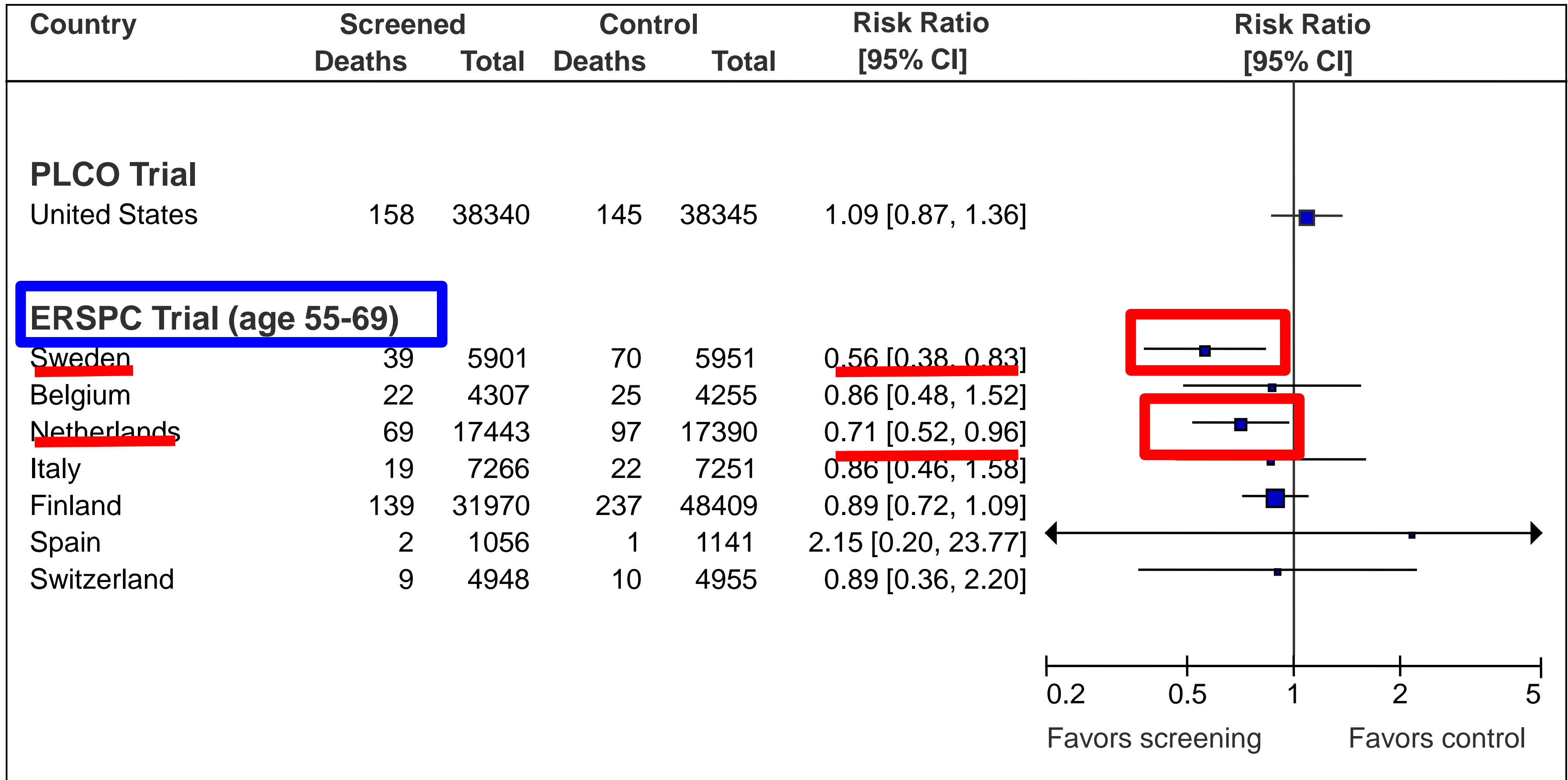
Screening group

0 2 4 6 8 10 12 14

Years since Randomization

Figure 2. Cumulative Hazard of Death from Prostate Cancer among Men 55 to 69 Years of Age.

Relative risk of prostate cancer death for men screened with PSA versus controls, by country



Country	Screened Deaths	Screened Total	Control Deaths	Control Total	Risk Ratio [95% CI]
PLCO Trial					
United States	158	38340	145	38345	1.09 [0.87, 1.36]
ERSPC Trial (age 55-69)					
Sweden	39	5901	70	5951	0.56 [0.38, 0.83]
Belgium	22	4307	25	4255	0.86 [0.48, 1.52]
Netherlands	69	17443	97	17390	0.71 [0.52, 0.96]
Italy	19	7266	22	7251	0.86 [0.46, 1.58]
Finland	139	31970	237	48409	0.89 [0.72, 1.09]
Spain	2	1056	1	1141	2.15 [0.20, 23.77]
Switzerland	9	4948	10	4955	0.89 [0.36, 2.20]

Potential Benefits

Screening 1,000 men ages 55-69 years with a PSA test every 1-4 years for 10 years

Reduced 10-year risk of dying from prostate cancer	
Number of men that die from prostate cancer with no screening	**5 in 1,000**
Number of men that die from prostate cancer with screening	**4-5 in 1,000**
Number that avoid death from prostate cancer because of screening	**0-1 in 1,000**

Potential Harms

Experiences at least one false +PSA	**100-120 in 1,000**
Most positive tests result in biopsy Of men undergoing biopsy, up to **33%** will experience moderate or major symptoms including pain, fever, bleeding, infection and temporary urinary difficulties; **1%** will be hospitalized	

Potential Harms

Diagnosed with prostate cancer	**110 in 1,000**
A diagnosis of prostate cancer may not be considered a harm, but currently **90%** of diagnosed men are treated and thus at risk for treatment harms A large majority of treated men would do well without treatment. A substantial percentage of these men would have remained asymptomatic for life.	

Potential Harms

Of men screened-Treatment harms:	Estimate
Serious cardiovascular event	2 in 1,000
Deep venous thrombosis or pulmonary embolus	1 in 1,000
Erectile dysfunction	29 in 1,000
Urinary incontinence	18 in 1,000
Die due to treatment	<1 in 1,000

USPSTF Evidence Summary

- **Benefit**
  - Evidence is convincing that for men aged 70 years and older screening has no CaP mortality benefit
  - For men aged 55-69 years, evidence is convincing that the reduction in prostate cancer mortality 10-14 years after screening is at most very small
- **Harms**
  - Evidence is convincing that the magnitude of screening and diagnostic harms is at least small
  - Evidence is convincing that the magnitude of treatment-associated harms is at least moderate

USPSTF Assessment-Net Benefit

- There is moderate certainty that the benefit of PSA-based screening for prostate cancer does not outweigh the harms

Recommendation Statement

- **The US Preventive Services Task Force recommends against prostate-specific antigen (PSA)-based screening for prostate cancer.**

Grade D recommendation

Including African-American Men and Men with + Family History

- No data from screening trials in men at “increased risk”
- At most, benefit would be small (assuming ERSPC trial)
- Problematic to selectively recommend PSA-based screening for black men or those with +Family History in absence of data supporting a more favorable balance of risks and benefits
- Including black men in the current recommendation provides them with the same protection from over-zealous screening without understanding or consent given to men of nonblack race

Prevention Question Reframed

- Would you take the PSA blood test with the *guarantee* that you would be twice as likely to be diagnosed with prostate cancer if it *might* reduce your chance of dying of prostate cancer from 3.0% to 2.4%?

  1) **Yes**
  2) **No**

CLINICAL GUIDELINE

High-Value, Cost-Conscious Health Care: Concepts for Clinicians to Evaluate the Benefits, Harms, and Costs of Medical Interventions

Douglas K. Owens, MD, MS; Amir Qaseem, MD, PhD, MHA; Roger Chou, MD; and Paul Shekelle, MD, PhD, for the Clinical Guidelines Committee of the American College of Physicians*

High-value care = good net benefit relative to expenditure

Owens et al. 2011

PSA screening is *NOT* High-Value Care

- **Lifetime cost**
  - $5,277,308 to prevent 1 prostate cancer death
- **Costs per life year saved**
  - $262,758
    - Based solely on ERSPC
    - Assumes all-cause mortality reduction = prostate cancer mortality reduction
    - Not *QALY*

Shteynshlyuger and Andriole J Urol 2011

Implementation

- USPSTF discourages the use of screening tests for which benefits do not outweigh harms
  - Recognizes the common use of PSA screening and understands that some men will continue to request and some physicians will continue to offer screening
- A decision to initiate or continue PSA screening should reflect an explicit understanding of the possible benefits and harms and respect for patient preferences
- Community and employer-based screening should be discontinued

Understanding Task Force Recommendations

Screening for Prostate Cancer

The U.S. Preventive Services Task Force (Task Force) has issued a **final** recommendation on *Screening for Prostate Cancer.*

This recommendation is for adult men of all ages. It does not apply to men who have been diagnosed with or are being treated for prostate cancer.

The Task Force reviewed research studies on the prostate-specific antigen (PSA) screening test for prostate cancer. It concluded that the expected harms of PSA screening are greater than the potential benefit. This fact sheet explains the Task Force recommendation and what it might mean for you.

Talking With Your Patients About Screening for Prostate Cancer

Screening messages for men

- *I recommend against the PSA blood test for prostate cancer screening because the benefit does not outweigh the harms. Specifically, new science shows:*
  - That it is extremely unlikely that the PSA test will prevent you from dying of prostate cancer over 10-15 years or help you live longer
  - Elevated PSA values are common and lead to additional tests that have harms
  - PSA testing finds many cancers that will not cause you health problems
  - Once we find cancer it is very hard not to treat it
  - Treatments have harms that occur early, can be serious and may persist-but very little, if any, benefit
  - By choosing not to have the PSA test you can live a similar length of life, have little to no difference in your risk of dying from prostate cancer and avoid the harms associated with tests, procedures and treatments

Thank you for your interest

www.USPreventiveServicesTaskForce.org