Translating Evidence Into Policy
The Case of Prostate Cancer Screening

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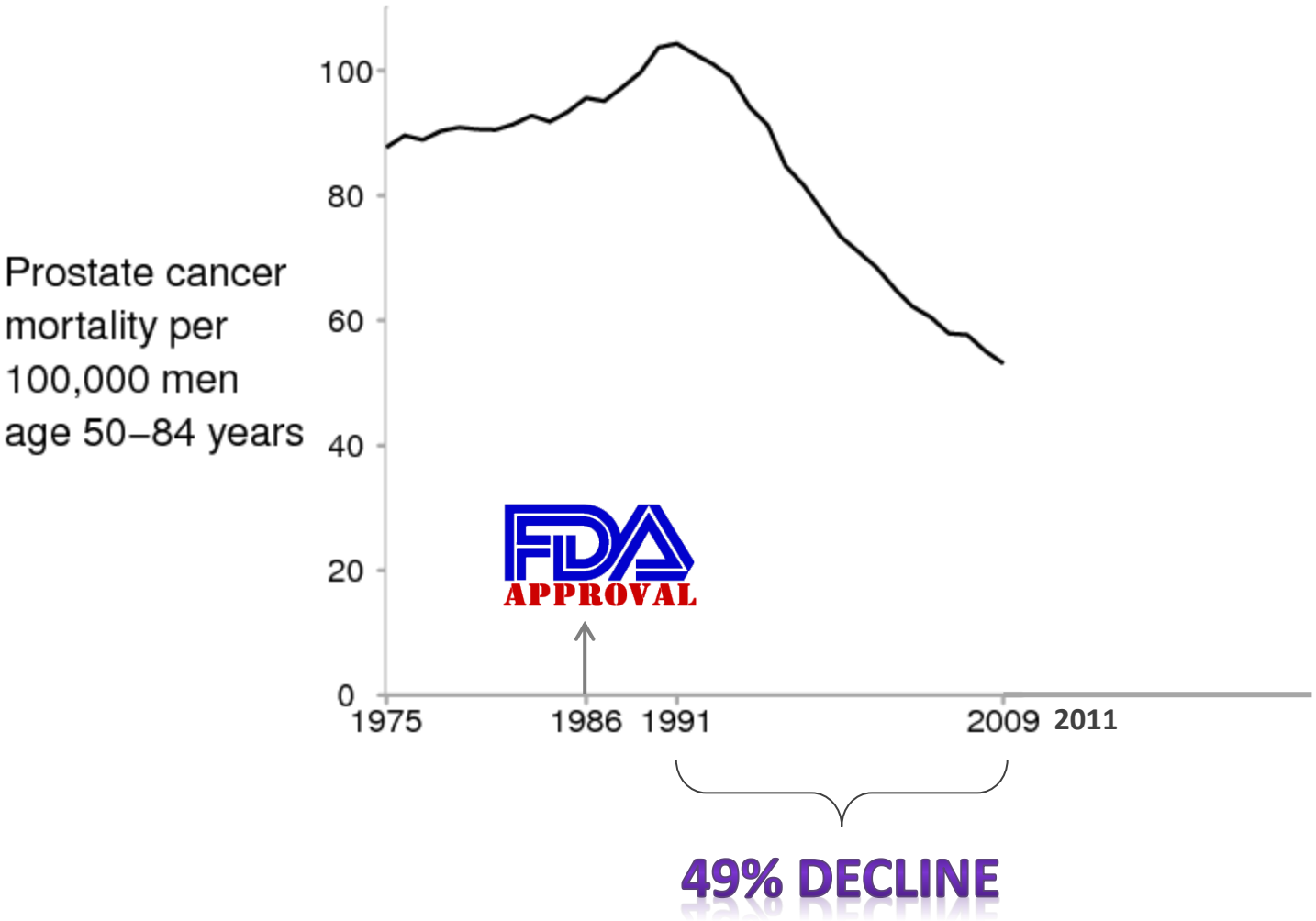
A LIFE OF SCIENCE

Prostate Cancer Mortality in the US



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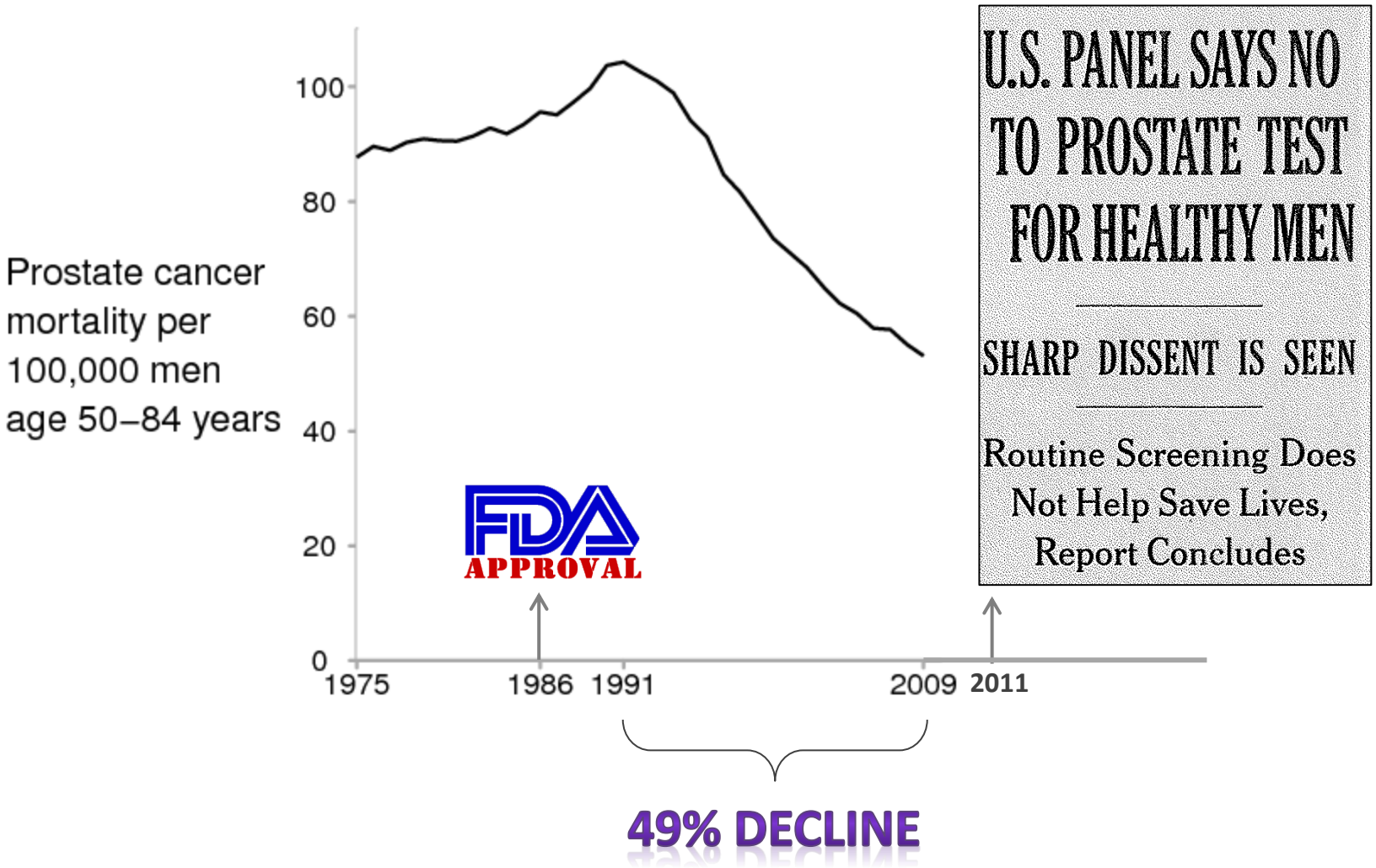


Today's Presentation

Trials

Policy

EVIDENCE?

What Evidence Do We Need?

SCREENING BENEFIT

The effect of screening on:

- Risk of prostate cancer (PC) death
- Risk of metastatic disease

SCREENING HARM

- Chance of a false-positive test
- Chance of overdiagnosis

HARM-BENEFIT TRADEOFF

- Chance of overdiagnosis / chance of avoiding PC death (NND)

HOW TO SCREEN

- Ages, intervals, cutoffs

TODAY:

Do the published results of the ERSPC and the PLCO trials provide the evidence we need to make policy recommendations? If not, what can we learn do to generate evidence we need?

The PLCO Trial

Not a comparison of Screening vs no Screening

CLINICAL TRIALS ARTICLE

Clinical Trials 2010; **7**: 303–311

Assessing contamination and compliance in the prostate component of the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial

Paul F Pinsky[a], Amanda Blacka[a], Barnett S Kramer[b], Anthony Miller[c], Philip C Prorok[a] and Christine Berg[a]

Mean number of routine PSA tests

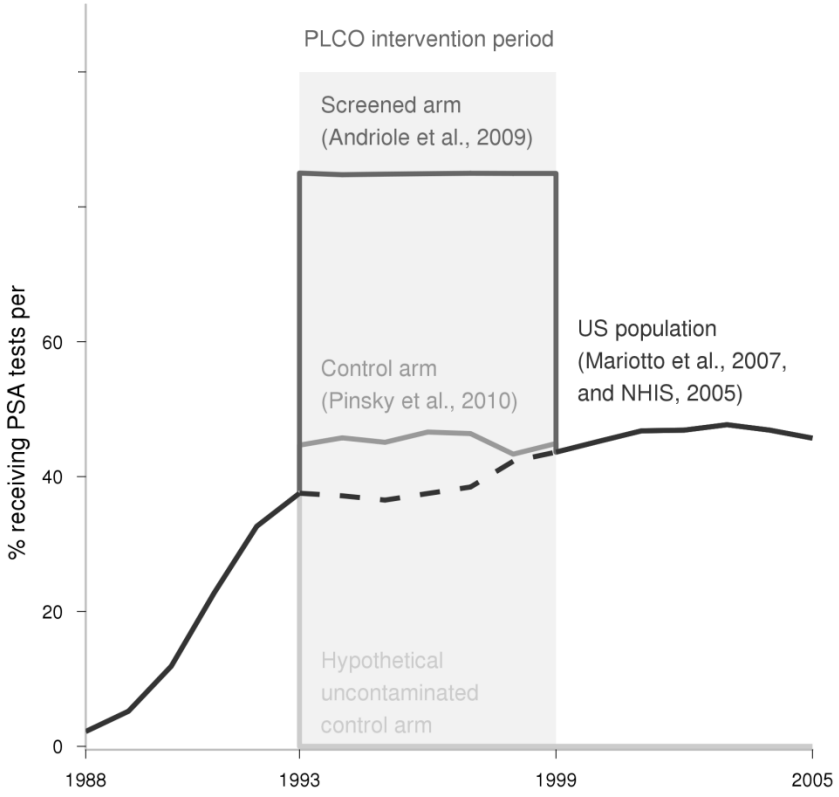
- 2.7 in control arm
- 5.0 in screening arm

Percent with at least one test:

- 74% in control arm
- 95% in screening arm

Numbers of cancers detected

- 1984 in control arm
- 1611 in concurrent population



Gulati et al, Cancer Causes and Control 2012

Prostate Cancer Screening in the Randomized Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial: Mortality Results after 13 Years of Follow-up

Gerald L. Andriole, E. David Crawford, Robert L. Grubb III, Saundra S. Buys, David Chia, Timothy R. Church, Mona N. Fouad, Claudine Isaacs, Paul A. Kvale, Douglas J. Reding, Joel L. Weissfeld, Lance A. Yokochi, Barbara O'Brien, Lawrence R. Ragard, Jonathan D. Clapp, Joshua M. Rathmell, Thomas L. Riley, Ann W. Hsing, Grant Izmirlian, Paul F. Pinsky, Barnett S. Kramer, Anthony B. Miller, John K. Gohagan, Philip C. Prorok; for the PLCO Project Team

Manuscript received March 17, 2011; revised November 8, 2011; accepted November 9, 2011.

Correspondence to: Philip C. Prorok, PhD, Biometry Research Group, Division of Cancer Prevention, National Cancer Institute, 6130 Executive Blvd, Ste 3132, Bethesda, MD 20892-7354 (e-mail: prorokp@mail.nih.gov).

Background The prostate component of the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial was undertaken to determine whether there is a reduction in prostate cancer mortality from screening using serum prostate-specific antigen (PSA) testing and digital rectal examination (DRE). Mortality after 7–10 years of follow-up has been reported previously. We report extended follow-up to 13 years after the trial.

Methods A total of 76 685 men, aged 55–74 years, were enrolled at 10 screening centers between November 1993 and July 2001 and randomly assigned to the intervention (organized screening of annual PSA testing for 6 years and annual DRE for 4 years; 38 340 men) and control (usual care, which sometimes included opportunistic

"Conclusion: After 13 years of follow-up, there was no evidence of a mortality benefit for organized annual screening in the PLCO trial compared with opportunistic screening, which forms part of usual care "

cer mortality between trial arm and age, comorbidity status, and pretrial PSA testing. All statistical tests were two-sided.

Results Approximately 92% of the study participants were followed to 10 years and 57% to 13 years. At 13 years, 4250 participants had been diagnosed with prostate cancer in the intervention arm compared with 3815 in the control arm. Cumulative incidence rates for prostate cancer in the intervention and control arms were 108.4 and 97.1 per 10 000 person-years, respectively, resulting in a relative increase of 12% in the intervention arm (RR = 1.12

What Can We Learn From PLCO Results?

SCREENING BENEFIT

The effect of screening on:

- Risk of PC death — X
- Risk of metastatic disease

SCREENING HARM

- Chance of a false-positive test — ✓
- Chance of overdiagnosis — X

HARM-BENEFIT TRADEOFF — X

- NND

HOW TO SCREEN — ✓

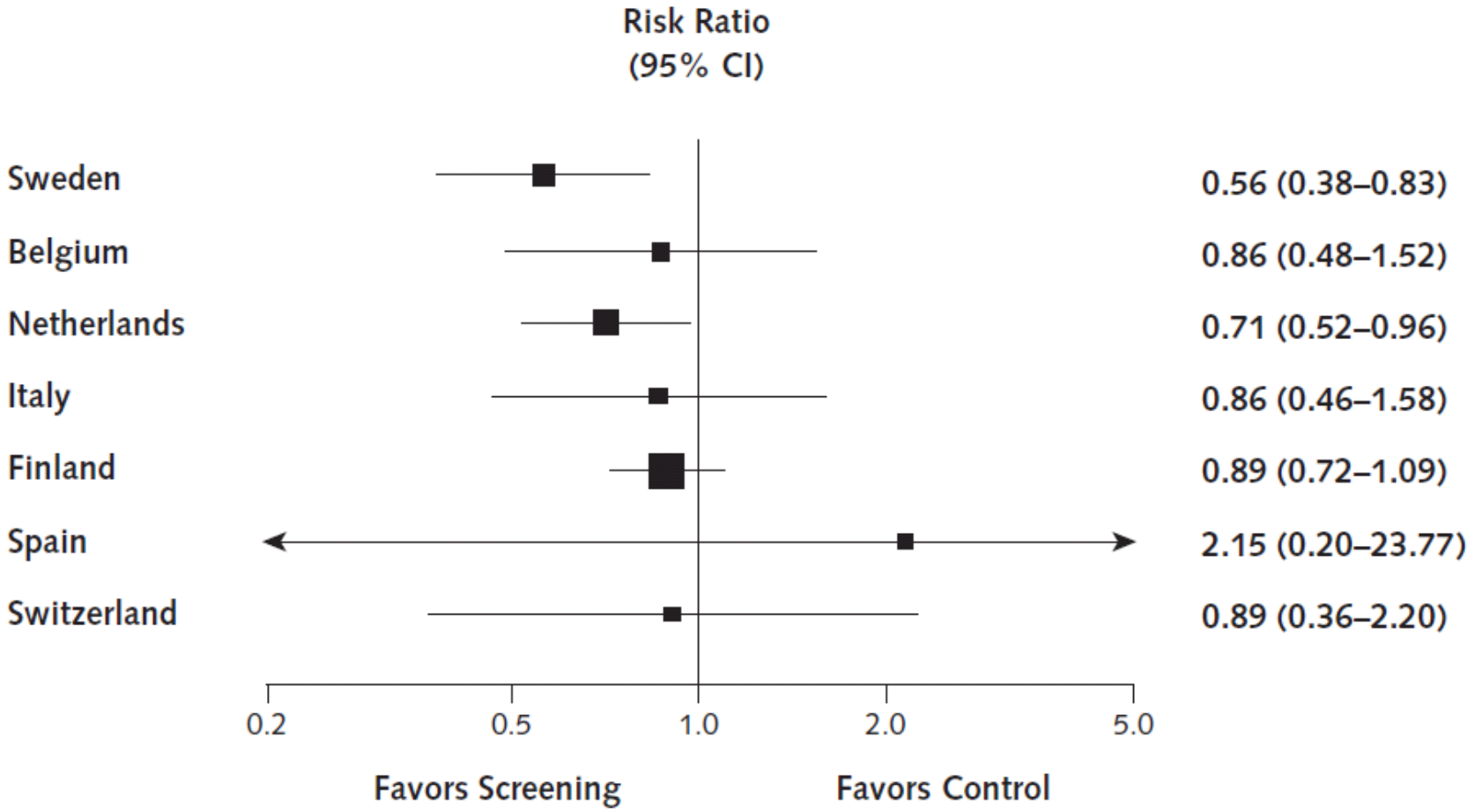
- Ages, intervals, cutoffs

(1) Trial does not compare screening with no screening

(2) Among men biopsied following a positive PSA test, 35%-45% had cancer on biopsy

(3) Very little benefit to screening about every year over about every other year

The ERSPC Trial



The ERSPC Centers

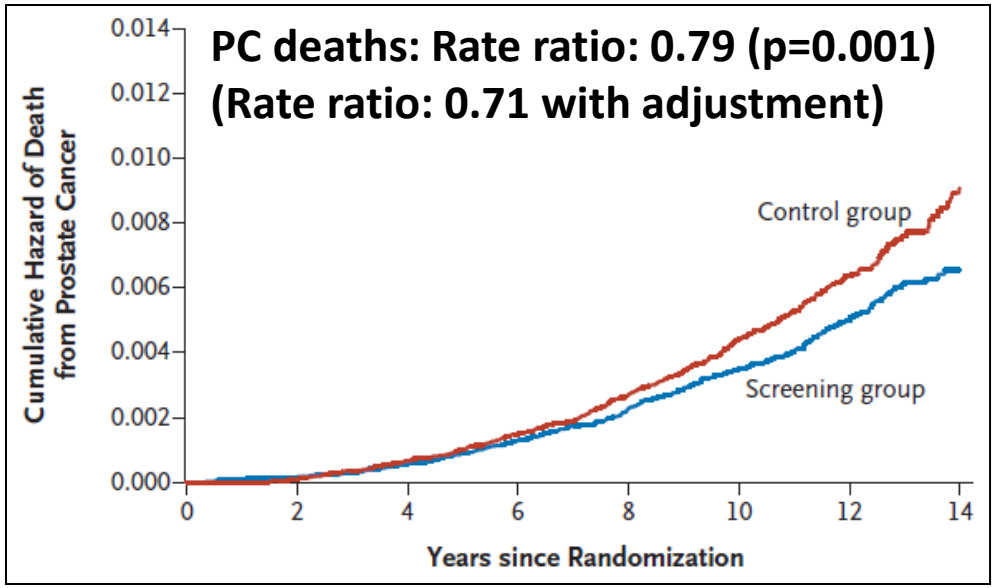
	Nether-lands	Belgium	Sweden	FInland	Italy	Spain	Switzer-land
Start year	1993	1991	1994	1996	1996	1996	1998
N	34,833	8,562	11,852	80,379	14,517	2,197	9,903
Screen interval	4	4-7	2	4	4	4	4
Proportion Attending (Round 1) (Round 2)	 95 78	 88 61	 62 85	 68 87	 68 84	 100 69	 96 83
Proportion Biopsied (Round 1) (Round 2)	 91 89	 68 78	 91 82	 94 90	 44 32	 86 67	 86 76
Incidence -screening -control	 11.6% 5.2%	 9.8% 7.3%	 12.9% 8.5%	 8.9% 6.6%	 5.1% 3.5%	 6.5% 2.1%	 9.6% 4. 5%

*: France excluded: only began randomization in 2000

Schroder et al NEJM 2012

The ERSPC Trial: Results

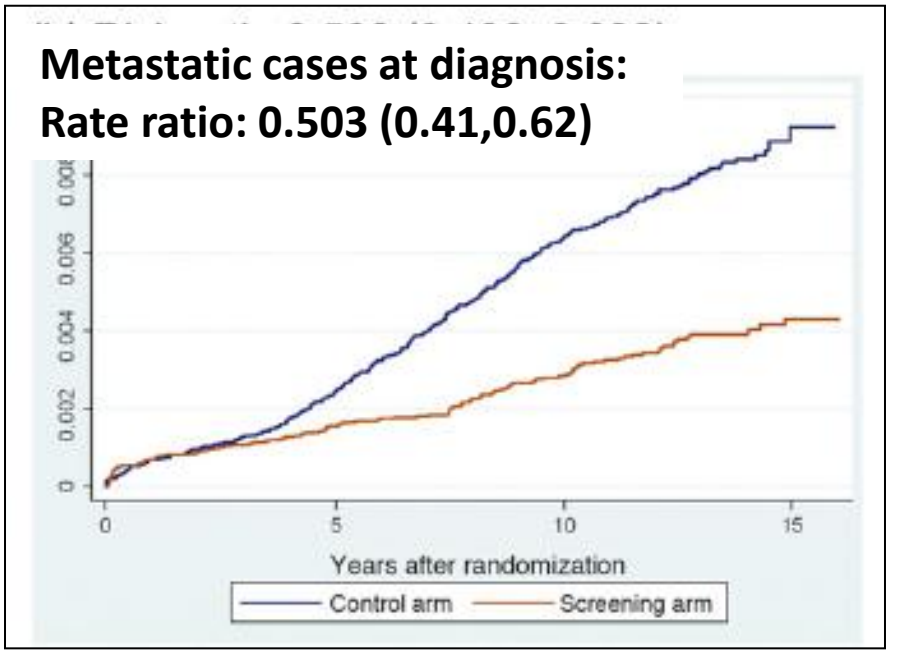
Prostate-Cancer Mortality at 11 Years of Follow-up



Control group: 5 deaths per 1,000 screened at 11 years

Schroder et al NEJM 2012
Schroder et al European Urology 2012

Screening for Prostate Cancer Decreases the Risk of Developing Metastatic Disease: Findings from the European Randomized Study of Screening for Prostate Cancer (ERSPC)



The Great Prostate Mistake

By Richard J. Ablin

TUSCON

EACH year some 30 million American men undergo testing for prostate-specific antigen, an enzyme made by the prostate. Approved by the Food and Drug Administration in 1994, the P.S.A. test is the most commonly used tool for detecting prostate cancer.

The test's popularity has led to a hugely expensive public health disaster. It's an issue I am painfully familiar with — I discovered P.S.A. in 1970. As Congress searches for ways to cut costs in our health care system, a significant savings could come from changing the way the antigen is used to screen for prostate cancer.

Americans spend an enormous amount testing for prostate cancer. The annual bill for P.S.A. screening is at least $3 billion, with much of it paid for by Medicare and the Veterans Administration.

Prostate cancer may get a lot of press, but consider the numbers: American men have a 16 percent lifetime chance of receiving a diagnosis of prostate cancer, but only a 3 percent chance of dying from it. That's because the majority of prostate cancers grow slowly. In other

reach old age are muc

tate cancer than to die

Even then, the test i

coin toss. As I've be

many years now, P.S.A

cancer and, more imp

tween the two types

Richard J. Ablin is a r

biology and pathology

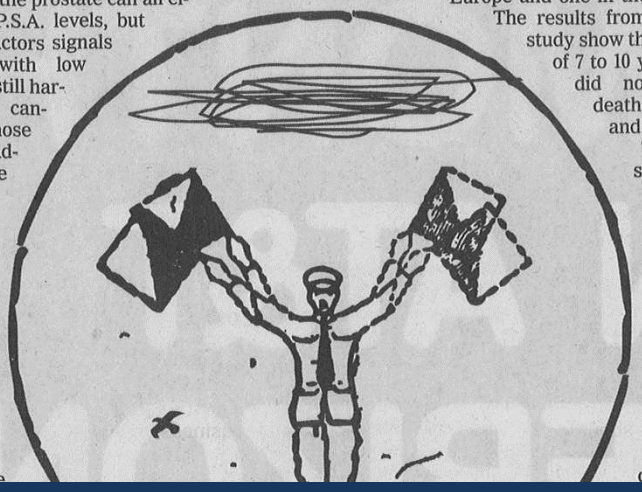
College of Medicine ar

Benjamin Ablin Foundation for Cancer Research.

that will kill you and the one that won't.

Instead, the test simply reveals how much of the prostate antigen a man has in his blood. Infections, over-the-counter drugs like ibuprofen, and benign swelling of the prostate can all elevate a man's P.S.A. levels, but none of these factors signals cancer. Men with low readings might still harbor dangerous cancers, while those with high readings might be completely healthy.

In approving the procedure, the Food and Drug Administration relied heavily on a study that showed testing could detect 3.8 percent of prostate



The medical community is slowly turning against P.S.A. screening. Last year, The New England Journal of Medicine published results from the two largest studies of the screening procedure, one in Europe and one in the United States. The results from the American study show that over a period of 7 to 10 years, screening did not reduce the death rate in men 55 and over.

The European study showed a small decline in death rates, but also found that 48 men would need to be treated to save one life. That's 47 men who, in all likelihood, can no longer function sexually or stay out of the bathroom

radiation or other damaging treatments.

So why is it still used? Because drug companies

continue peddling the tests and advocacy groups push "prostate cancer awareness" by encouraging men to get screened. Shamefully, the American Urological Association still recommends screening, while the National Cancer Institute is vague on the issue, stating that the evidence is unclear.

The federal panel empowered to evaluate cancer screening tests, the Preventive Services Task Force, recently recommended against P.S.A. screening for men aged 75 or older. But the group has still not made a recommendation either way for younger men.

Prostate-specific antigen testing does have a place. After treatment for prostate cancer, for instance, a rapidly rising score indicates a return of

A single test has cost billions in unneeded treatment.

the disease. And men with a family history of prostate cancer should probably get tested regularly. If

eting, it could mean can-

ted. Testing should abso-

screen the entire pop-

age of 50, the outcome

to profit.

y discovery four decades

rofit-driven public health

munity must confront re-

riate use of P.S.A. screen-

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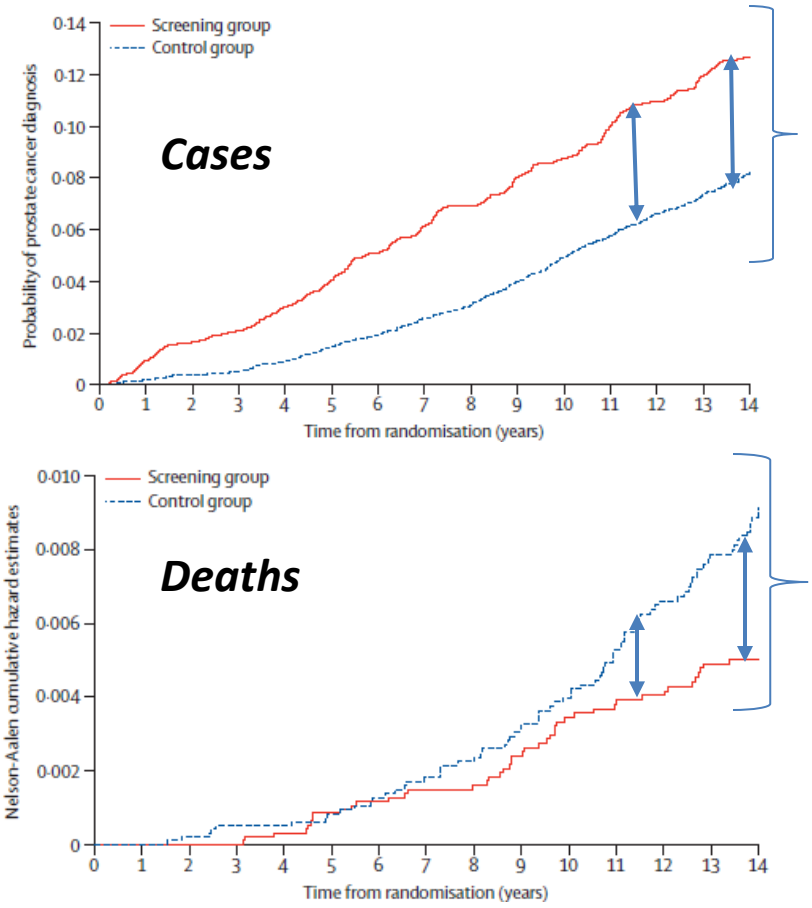
"The European Study showed a small decline in death rates but also found that 48 men would need to be treated to save one life. That's 47 men, who in all likelihood can no longer function sexually or stay out of the bathroom for long …"

NY Times, April 2010

ERSPC Estimate of NND



8.2% of screened group diagnosed

– **4.8%** of control group diagnosed

3.4%

÷ **0.07%**

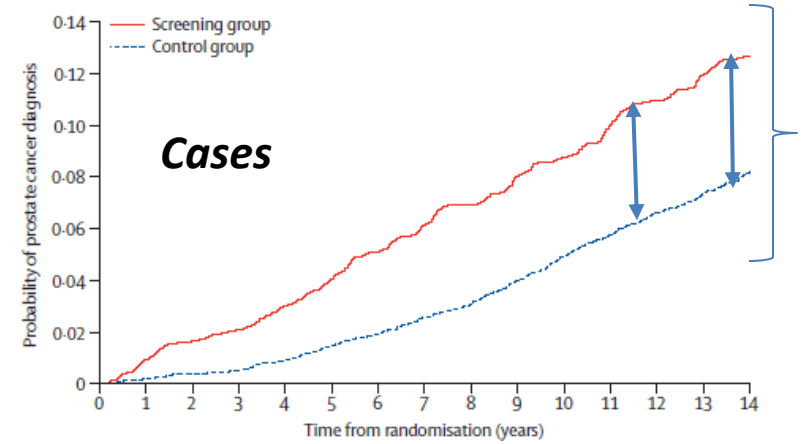
48

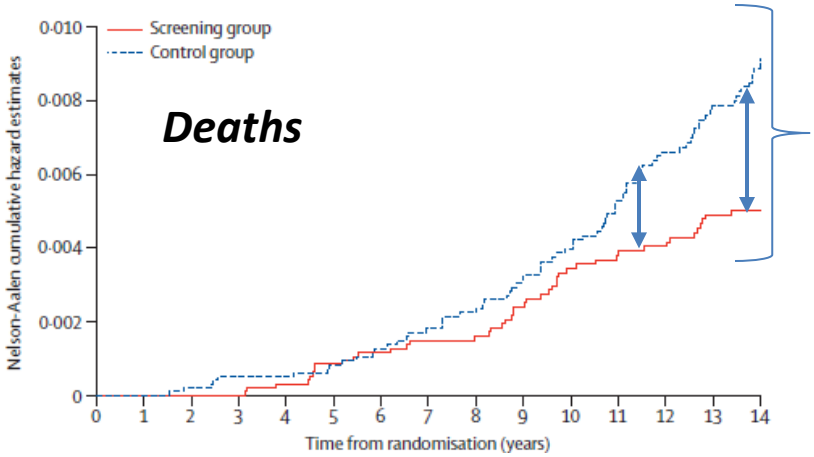
excess incidence / lives saved after median 11 years

NND

Schroder et al NEJM 2009, 2012

ERSPC Estimate of NND





8.2%	of screened group diagnosed
– **4.8%**	of control group diagnosed
3.4%	
÷ **0.07%**	excess incidence / lives saved after median 11 years
48	

NND (37 in updated report)

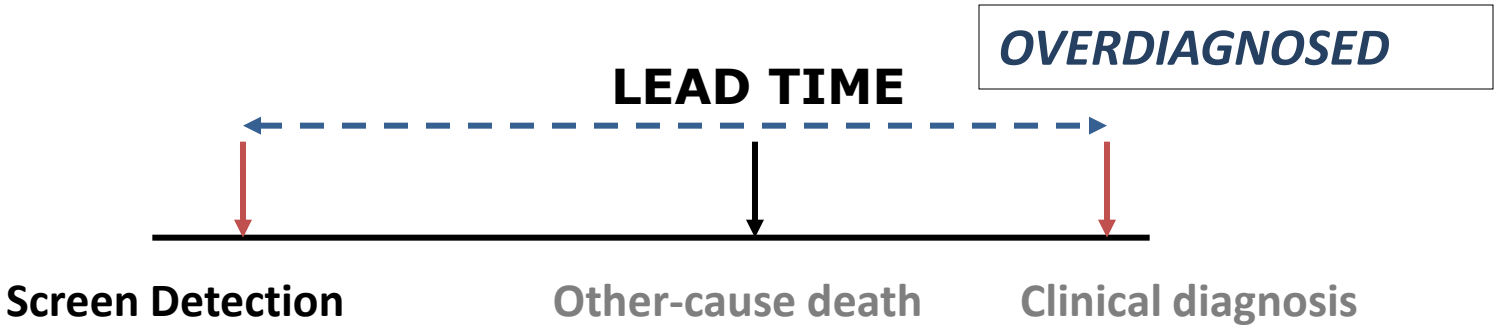
! Excess incidence overestimates overdiagnosis

! Lives saved is time-sensitive; increases with follow-up

Schroder et al NEJM 2009

Excess Incidence and Overdiagnosis

- Overdiagnosis: detection by screening of cases who would never have been diagnosed in the absence of screening



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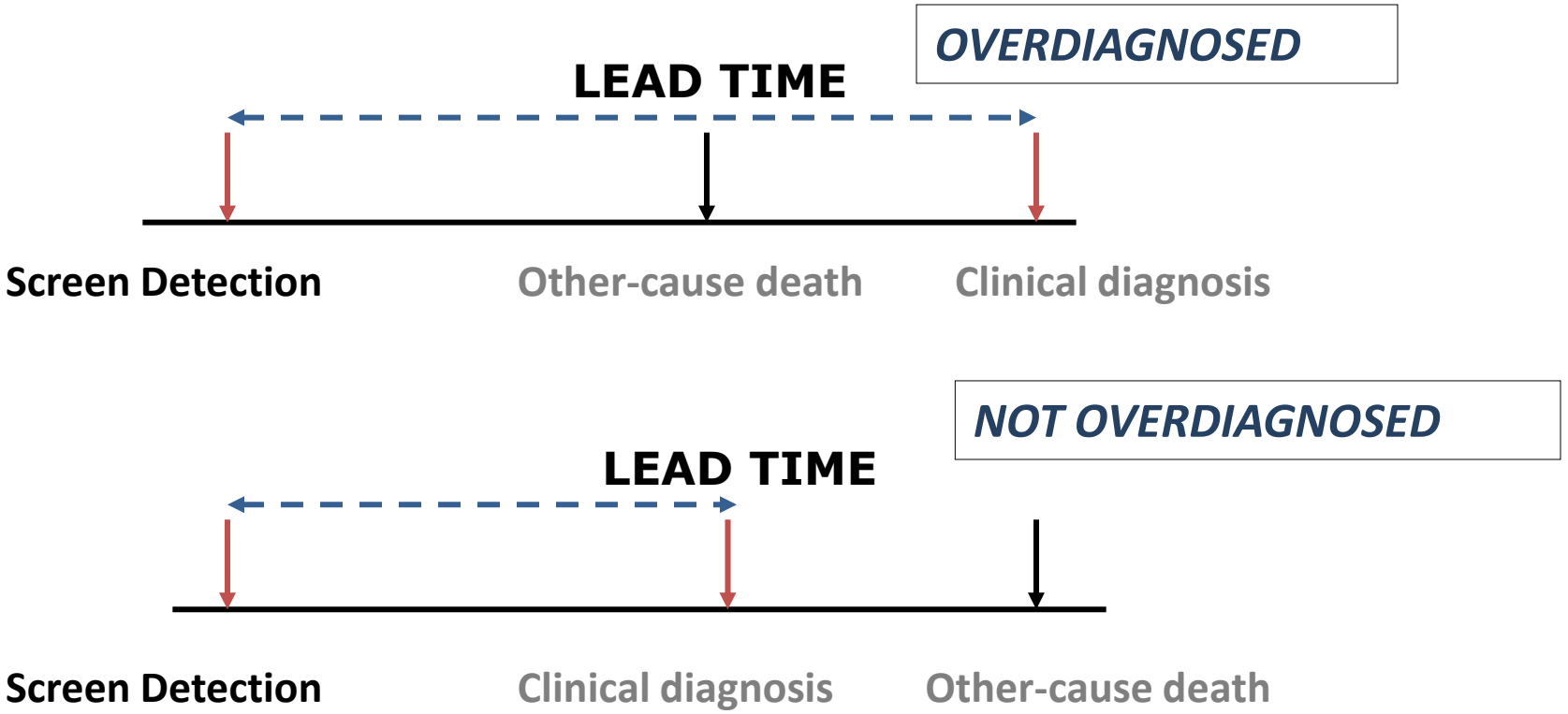

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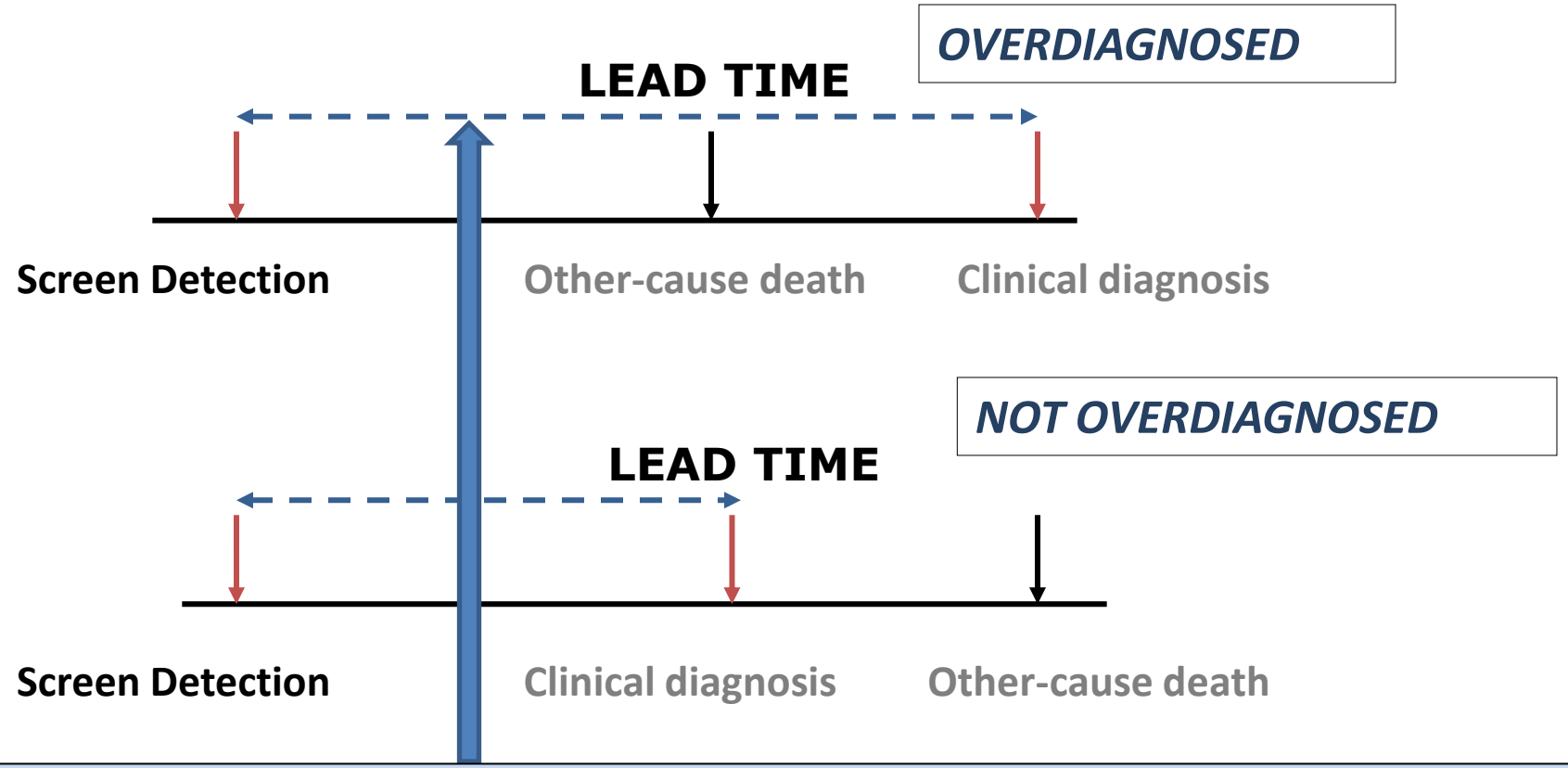

Under short-term followup we don't know if screen-detected cases are overdiagnosed or not!

What Can We Learn From ERSPC Results?

SCREENING BENEFIT

The effect of screening on:

- Risk of PC death ✓
- Risk of metastatic disease ✓

SCREENING HARM

- Chance of a false-positive test ✓
- Chance of overdiagnosis X

HARM-BENEFIT TRADEOFF

- NND X

HOW TO SCREEN

- Ages, intervals, cutoffs X

(1) Among men 55-69 <u>in Europe</u> screening every few years:
   - Reduces risk of PC death by 20-30%
   - Reduces risk of metastatic disease at diagnosis by 50%

(2) Among men biopsied following a positive PSA test, 25% had cancer on biopsy (Rotterdam)

(3) ERSPC estimate of NND will not be representative of long-term tradeoffs

(4) Comparisons of intervals across centers can only be suggestive

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

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

- **The U.S. trial did not demonstrate any reduction of prostate cancer mortality.**
- The European trial found a reduction in prostate cancer deaths of approximately 1 death per 1000 men screened in a subgroup aged 55 to 69 years.
- *There is adequate evidence that the benefit of PSA screening and early treatment ranges from 0 to 1 prostate cancer deaths avoided per 1000 men screened*

Moyer et al, 2012

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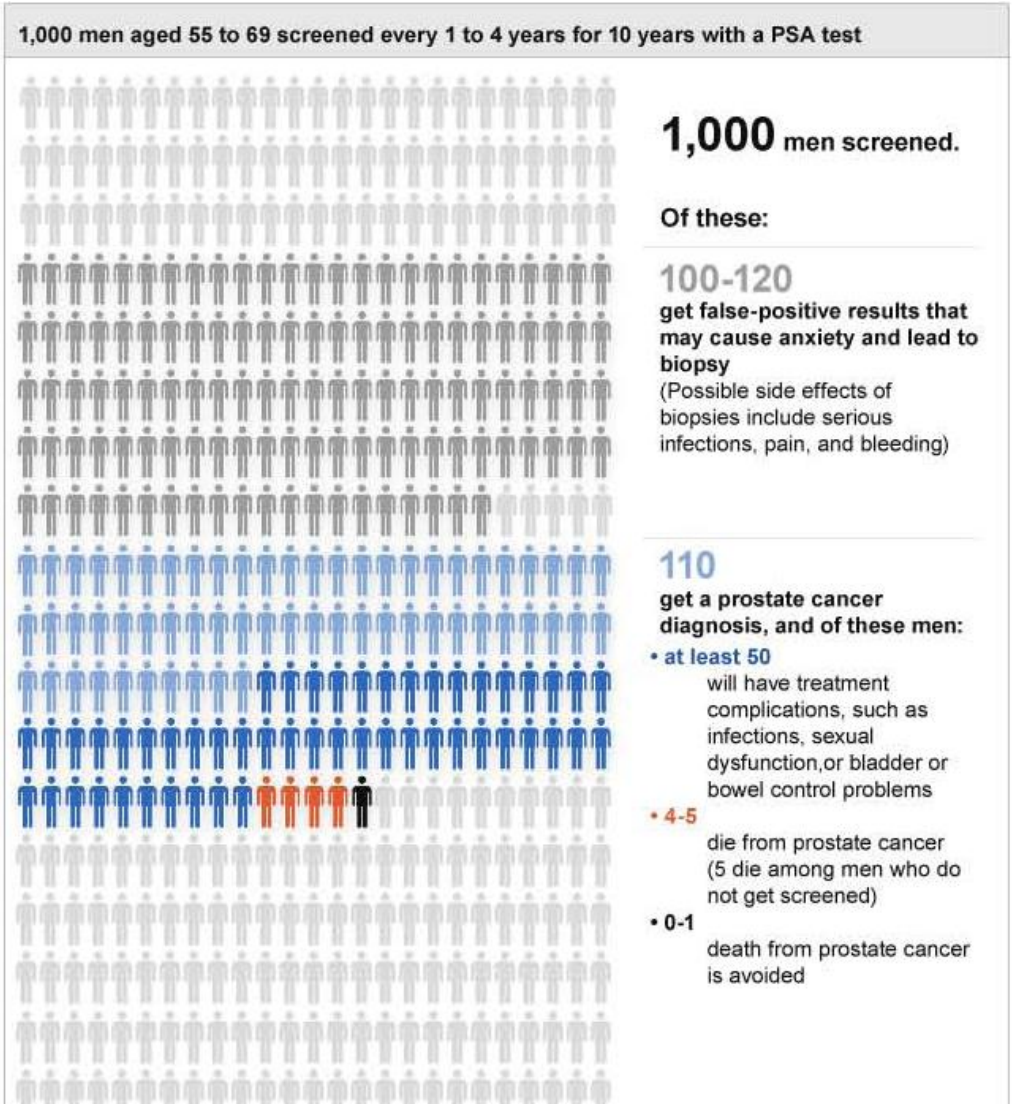
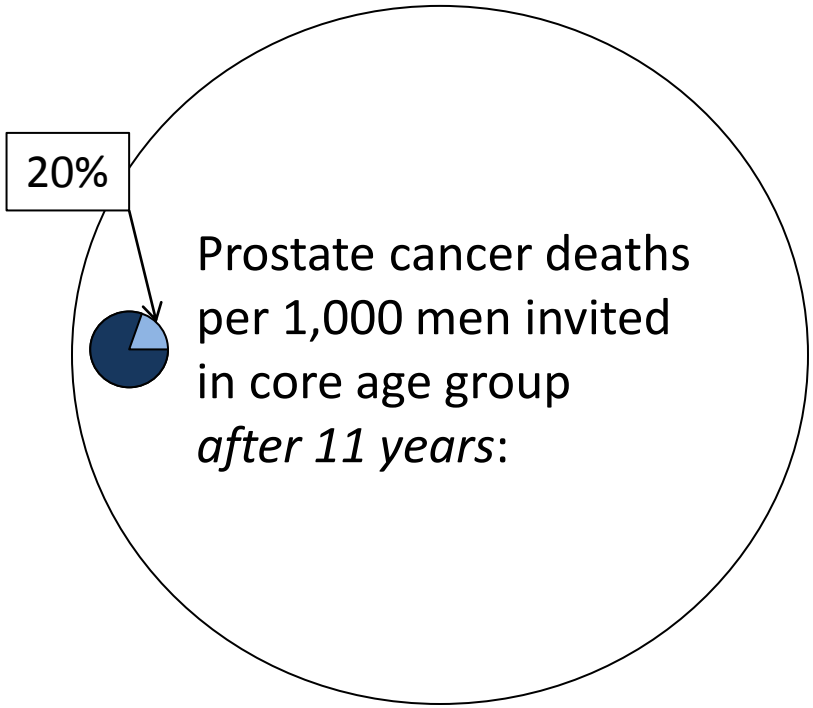
Moyer et al, 2012

USPSTF Infographic



Lives Saved By Screening: Trial versus Population?

Short-term, trial (ERSPC)



Trial arm	**Deaths**
Control	**5.17**
Screening	**4.10**
Absolute Difference	**1.07**

Lives Saved By Screening: Trial versus Population?

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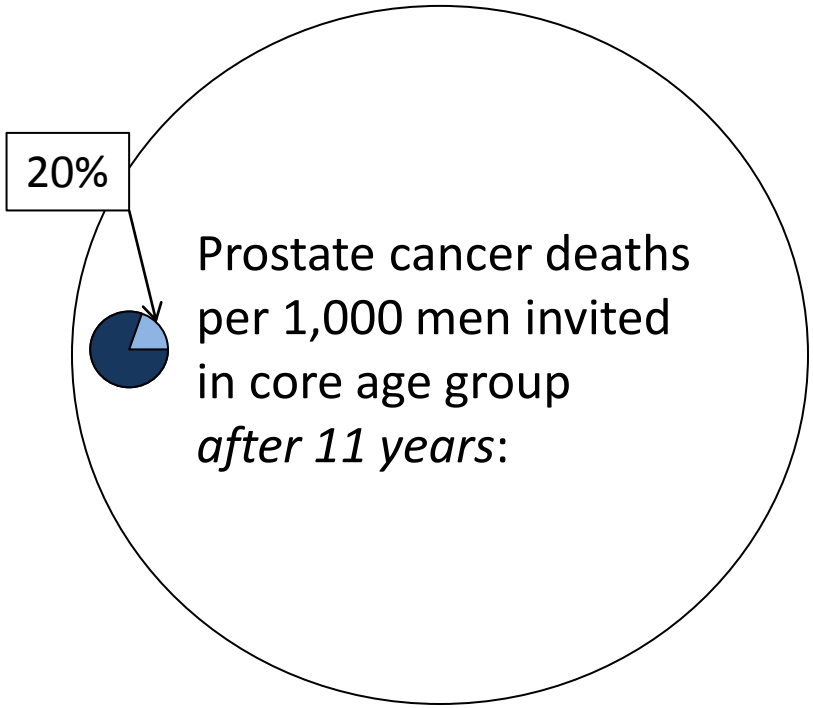
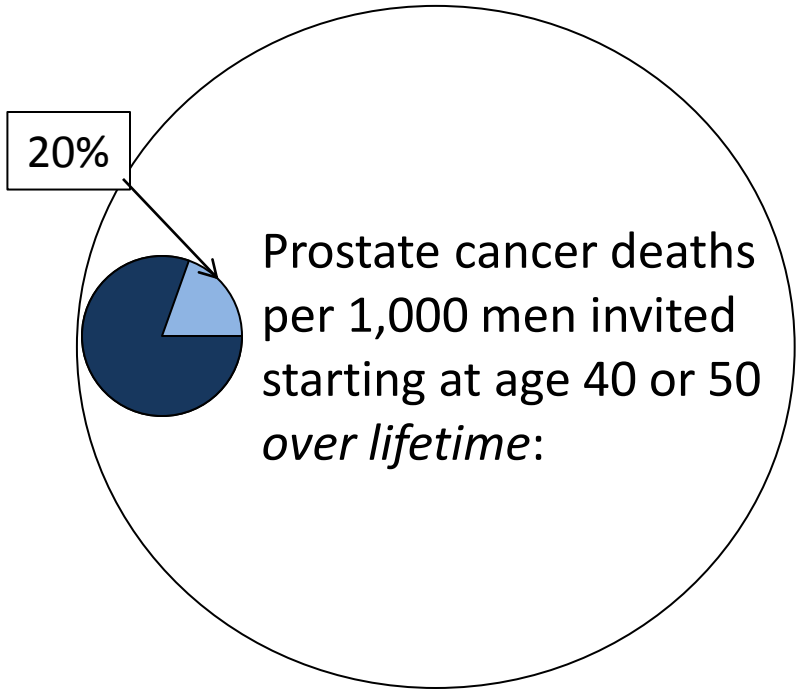


Trial arm	Deaths
Control	**5.17**
Screening	**4.10**
Absolute Difference	**1.07**

Long-term, population (SEER)



Trial arm	Deaths
Control	**30**
Screening	**24**
Absolute Difference	**6**

Trials Have Fundamental Limitations

1. Limited follow-up does not permit assessment of absolute screening benefit in the long-term population setting

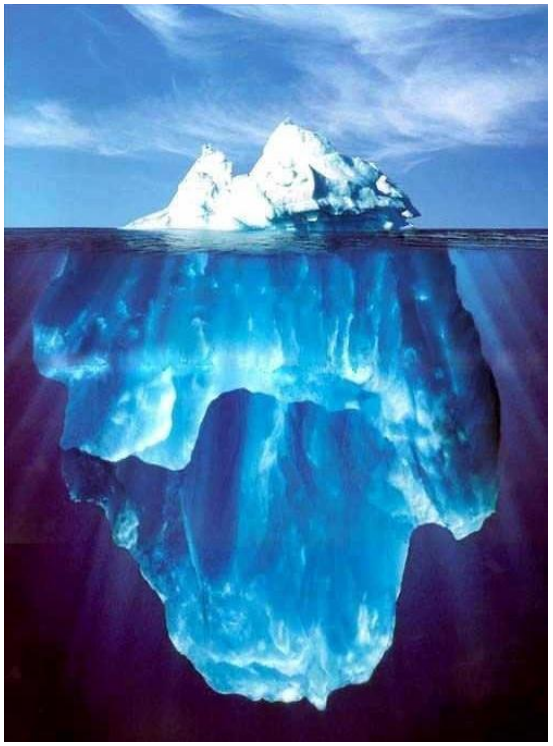
2. Empirical incidence results mislead about the extent of overdiagnosis and harm-benefit tradeoffs

3. We cannot make inferences about the comparative effectiveness of multiple candidate screening strategies

Use trial data to learn about the underlying disease process via modeling

Use models to extrapolate beyond trials

Disease Modeling



1. Observed data

2. Underlying disease progression

+

3. Survival Benefit Mechanism

Virtual population for projecting short- and long-term screening outcomes including non-observable outcomes

National Cancer Institute

The Cancer Intervention and Surveillance Modeling Network (CISNET)

http://cisnet.cancer.gov

Overview

CISNET is a consortium of NCI-sponsored investigators who use statistical/simulation modeling to examine the impact of prevention, screening, and treatment on cancer incidence and mortality. These models then can project future trends and help determine optimal cancer control strategies. Established in 2000, CISNET comprises five cancer site groups: breast, prostate, colorectal, lung, and esophageal.

Approaches to Modeling

of intermediate and final outputs are developed. Results then are compared across models.

– Standardized model documentation—Model profiles are standardized descriptions that facilitate the comparison of models and their results. Users can read documentation about a single model or side-by-side descriptions that contrast how models address different components of the process. Journal articles seldom contain extensive model descriptions; links from publications to model profiles provide a more complete model description. *http://cisnet.cancer.gov/profiles*

CLINICAL GUIDELINES | Annals of Internal Medicine

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

U.S. Preventive Services Task Force*

Annals of Internal Medicine | CLINICAL GUIDELINES

Screening for Breast Cancer: An Update for the U.S. Preventive Services Task Force

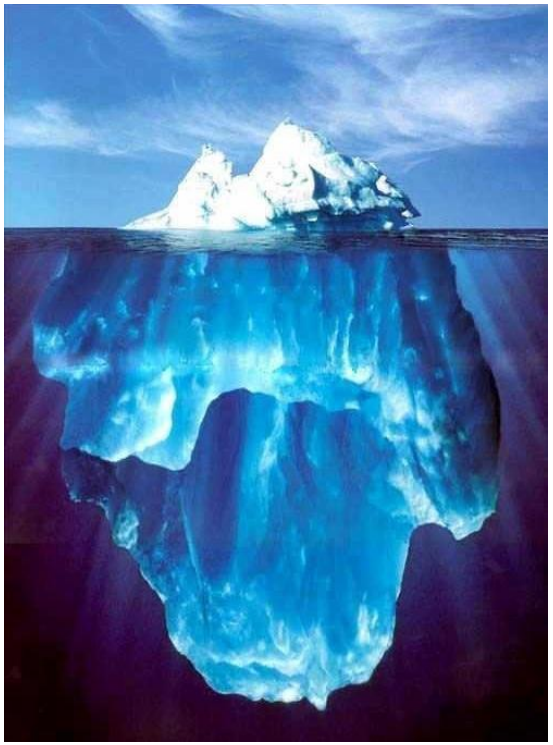
Heidi D. Nelson, MD, MPH; Karl Tyne, MD; Arpana Naik, MD; Christina Bougatsos, BS; Benjamin K. Chan, MS; and Linda Humphrey, MD, MPH

CLINICAL GUIDELINES | Annals of Internal Medicine

Effects of Mammography Screening Under Different Screening Schedules: Model Estimates of Potential Benefits and Harms

Jeanne S. Mandelblatt, MD, MPH; Kathleen A. Cronin, PhD; Stephanie Bailey, PhD; Donald A. Berry, PhD; Harry J. de Koning, MD, PhD; Gerrit Draisma, PhD; Hui Huang, MS; Sandra J. Lee, DSc; Mark Munsell, MS; Sylvia K. Plevritis, PhD; Peter Ravdin, MD, PhD; Clyde B. Schechter, MD, MA; Bronislava Sigal, PhD; Michael A. Stoto, PhD; Natasha K. Stout, PhD; Nicolien T. van Ravesteyn, MSc; John Venier, MS; Marvin Zelen, PhD; and Eric J. Feuer, PhD; for the Breast Cancer Working Group of the Cancer Intervention and Surveillance Modeling Network (CISNET)*

FHCRC Prostate Model



1. SEER Incidence

2. Onset and stage progression linked with PSA growth

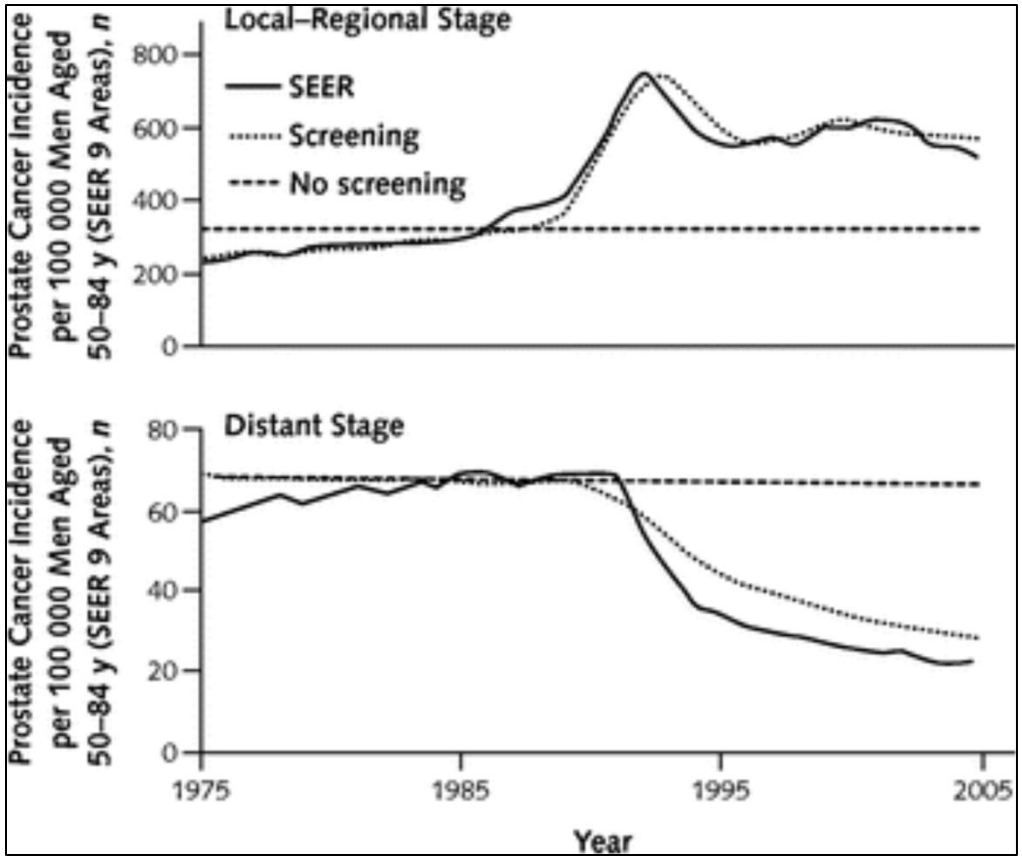
+

3. Survival benefit via stage shift

Project outcomes for 35 competing screening strategies

CISNET

FHCRC Prostate Model: Calibration



Also note:

Model projects 28% PC mortality reduction over 11 years in replication of ERSPC with full compliance with screening and no contamin-ation

Gulati, Gore Etzioni, Annals 2013 (appendix)

Modeling a Virtual Trial

Comparative Effectiveness of Alternative Prostate-Specific Antigen–Based Prostate Cancer Screening Strategies

Model Estimates of Potential Benefits and Harms

Roman Gulati, MS; John L. Gore, MD; and Ruth Etzioni, PhD

Background: The U.S. Preventive Services Task Force recently concluded that the harms of existing prostate-specific antigen (PSA) screening strategies outweigh the benefits.

Objective: To evaluate comparative effectiveness of alternative PSA screening strategies.

Design: Microsimulation model of prostate cancer incidence and mortality quantifying harms and lives saved for alternative PSA screening strategies.

Data Sources: National and trial data on PSA growth, screening and biopsy patterns, incidence, treatment distributions, treatment efficacy, and mortality.

Target Population: A contemporary cohort of U.S. men.

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ages, sc

men aged 50 to 74 years annually with a PSA threshold for biopsy referral of 4 μg/L reduces the risk for prostate cancer death to 2.15% with risk for overdiagnosis of 3.3%. A strategy that uses higher PSA thresholds for biopsy referral in older men achieves a similar risk for prostate cancer death (2.23%) but reduces the risk for overdiagnosis to 2.3%. A strategy that screens biennially with longer screening intervals for men with low PSA levels achieves similar risks for prostate cancer death (2.27%) and overdiagnosis (2.4%) but reduces total tests by 59% and false-positive results by 50%.

Results of Sensitivity Analysis: Varying incidence inputs or reducing the survival improvement due to screening did not change conclusions.

Limitation: The model is a simplification of prostate cancer natural

"This modeling study compared 35 screening strategies that differed by ages to start and stop screening, screening intervals, and thresholds for biopsy."

Modeling Outcomes of Competing Screening Policies

Screening policy components	Policy 1	Policy 2	Policy 3	Policy 4	Policy 5
Screening ages	45-75	50-75	40-75	50-75	40-75
Interscreening interval	age-specific	biennial	biennial	annual	annual
PSA test-positive threshold	4.0	4.0	age-specific	4.0	4.0
Outcomes	**3% die of prostate cancer in absence of screening**				
Average number of PSA tests	8.3	10.6	15.5	20.3	30.0
Probability of at least 1 false positive	18.8%	19.7%	14.2%	21.4%	21.8%
Probability of cancer diagnosis	14.4%	14.7%	13.8%	15.3%	15.5%
Probability of overdiagnosis	2.4%	2.7%	1.8%	3.3%	3.5%
Probability of life saved	0.6%	0.6%	0.5%	0.7%	0.7%

Gulati, Gore, Etzioni, Annals of Internal Medicine 2013

Model-generated "Evidence"

SCREENING BENEFIT

The effect of screening on:

- Risk of PC death ✓
- Risk of metastatic disease ✓

SCREENING HARM

- Chance of a false-positive test ✓
- Chance of overdiagnosis ✓

HARM-BENEFIT TRADEOFF

- NND ✓

HOW TO SCREEN

- Ages, intervals, cutoffs ✓

(1) Under stage shift expect about 20-30% reduction in PC deaths

(2) Among strategies with at least 0.6% chance of life saved the specific strategy used strongly influences
  - FP tests (15-45% probability of at least one FP)
  - Overdiagnoses (2.3-6%)

(3) NND ranges from 4-7

(4) To preserve benefit and reduce harms:
  - Don't screen every year
  - Use higher PSA cutoffs for men over 70
  - Screen men with lower PSA levels less frequently

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JOURNAL OF CLINICAL ONCOLOGY

COMMENTS AND CONTROVERSIES

Prostate Cancer Screening: Facts, Statistics, and Interpretation in Response to the US Preventive Services Task Force Review

Avoid PSA tests in men with little to gain

- No justification for PSA screening with limited life expectancy
- Extend PSA screening interval if level is low
- End screening at age 60 if PSA is below 1 ng/ml

Do not treat low-risk disease

- Most screening detected cancers do not need treatment

"PSA testing is not likely to go away, and on the basis of the ERSPC results—which do indicate reductions in mortality—this is perhaps a good thing. Our goal should therefore be to maximize the benefits of PSA testing and minimize its harms."

Screening strategy	No PSA 0	MSKCC+ERSPC 1	ERSPC 2	SS15+MSKCC 3	SS15+SS22 4	MSKCC 5	Welch 6	SS15 7	SS22 8	SS8+SS22 9	SS20 10	SS8 11
Screening ages (years)	—	45-69	45-69	45-69	45-69	45-69	50-74	45-69	45-74	50-74	50-74	50-74
Interscreening interval (years)	—	4	4	PSA	PSA	PSA	1	1	AS	AS	1	1
PSA level threshold (ng/mL)	—	3.0	3.0	AS	AS	3.0	10.0	AS	4.0	4.0	AS	4.0
Early stopping age (PSA < 1 ng/mL)	—	60	—	60	—	60	—	—	—	—	—	—
Harms and benefits		**3% die of prostate cancer in absence of screening**										
Average number of PSA tests	—	5.3	6.2	6.5	7.6	6.5	20.6	22.1	8.3	7.2	20.4	20.3
Average number of false positives	—	0.4	0.4	0.4	0.4	0.8	0.5	0.8	0.8	0.8	1.2	1.6
Probability of cancer diagnosis	12.0%	13.3%	13.5%	13.1%	13.2%	13.8%	13.5%	13.5%	14.4%	14.7%	14.3%	15.3%
Probability of overdiagnosis	—	1.3%	1.5%	1.1%	1.2%	1.8%	1.5%	1.5%	2.4%	2.6%	2.3%	3.3%
Probability of cancer death	3.0%	2.6%	2.6%	2.5%	2.5%	2.5%	2.5%	2.4%	2.4%	2.3%	2.3%	2.2%
Probability of life saved	—	0.4%	0.4%	0.4%	0.5%	0.5%	0.5%	0.6%	0.6%	0.7%	0.7%	0.7%

Notes

Strategies 3, 4, and 5 have interscreening interval 2 years if PSA ≥ 1 ng/mL and 4 years otherwise.
Strategies 8 and 9 have interscreening interval 2 years if PSA ≥ median for age decade and 4 years otherwise.
Strategies 3, 4, 7, and 10 use PSA thresholds 2.5, 3.5, 4.5, and 6.5 ng/mL for ages 45-49, 50-59, 60-69, and 70-74 years.

Summary

Trials

MODELS

Policy

POINT-COUNTERPOINT

Limitations of Basing Screening Policies on Screening Trials

The US Preventive Services Task Force and Prostate Cancer Screening

Ruth Etzioni, PhD, Roman Gulati, MS,* Matt R. Cooperberg, MD,† David M. Penson, MD,‡ Noel S. Weiss, PhD,§ and Ian M. Thompson, MD‖*

POINT-COUNTERPOINT

Counterpoint: Randomized Trials Provide the Strongest Evidence for Clinical Guidelines

The US Preventive Services Task Force and Prostate Cancer Screening

Joy Melnikow, MD, MPH, Michael LeFevre, MD, MSPH,†‡ Timothy J. Wilt, MD, MPH,§‖ and Virginia A. Moyer, MD, MPH¶*

POINT-COUNTERPOINT

Response: Reading Between the Lines of Cancer Screening Trials

Using Modeling to Understand the Evidence

Ruth Etzioni, PhD and Roman Gulati, MS

Screening Facts of Life

- A small minority of the population will die of any specific cancer
- An efficacious screening test will reduce a person's chance of dying of disease by a small absolute amount (e.g. 1%)
- Evan an efficacious screening test will not affect all-cause mortality over a defined follow-up period
- In the case of prostate cancer screening, up to 1% may be helped, but 15-20% will be diagnosed
- *Therefore the vast majority of screen-detected cases will not have been helped by their screen detection*
- No screening test can diagnose all cancers unless it
  - Calls everyone positive
  - Biopsies everyone

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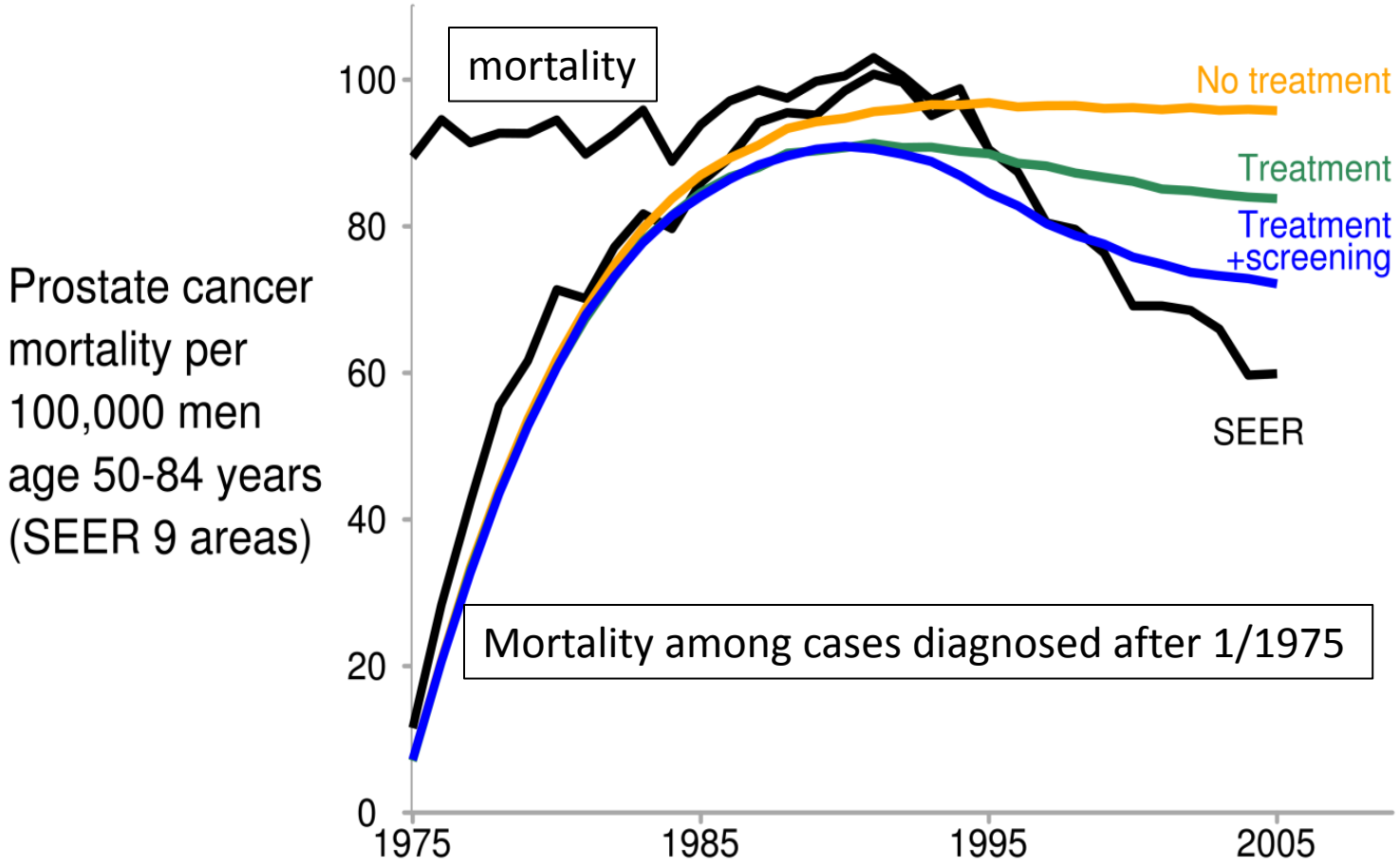
Cancer Intervention and
Surveillance Modeling Network

Prostate Cancer Mortality in the US



WELL | Tara Parker-Pope

Mammogram's Role as Savior Is Tested

Has the power of the mammogram been oversold?

At a time when medical experts are rethinking screening guidelines for prostate and cervical cancer, many doctors say it's also time to set the record straight about mammography screening for breast cancer. While most agree that mammograms have a place in women's health care, many doctors say widespread "Pink Ribbon" campaigns and patient testimonials have imbued the mammogram with a kind of magic it doesn't have. Some patients are so committed to annual screenings they even begin to believe that regular mammograms actually prevent breast cancer, said Dr. Susan Love, a prominent women's health advocate. And women who skip a mammogram often beat themselves up for it.

The number of women helped by screening is lower than many think.

"You can't expect from mammography what it cannot do," said Dr. Laura Esserman, director of the breast care center at the University of California, San Francisco. "Screening is not prevention. We're not going to screen our way to a cure."

A new analysis published Monday in Archives of Internal Medicine offers a stark reality check about the value of mammography screening. Despite numerous testimonials from women who believe "a mammogram saved my life," the truth is that most women who find breast cancer as a result of regular screening have not had their lives saved by the test, conclude two Dartmouth researchers, Dr. H. Gilbert Welch and Brittney A. Frankel.

Dr. Welch notes that clearly some women are helped by mammography screening, but the numbers are lower than most people think. The Dartmouth researchers conducted a series of calculations estimating a woman's 10-year risk of developing breast cancer and her 20-year risk of death, factoring in the added value of early detection based on data from various mammography screening trials as well as the benefits of improvements in treatment. Among the 60 percent of women with breast cancer who detected the disease by screening, only about 3 percent to 13

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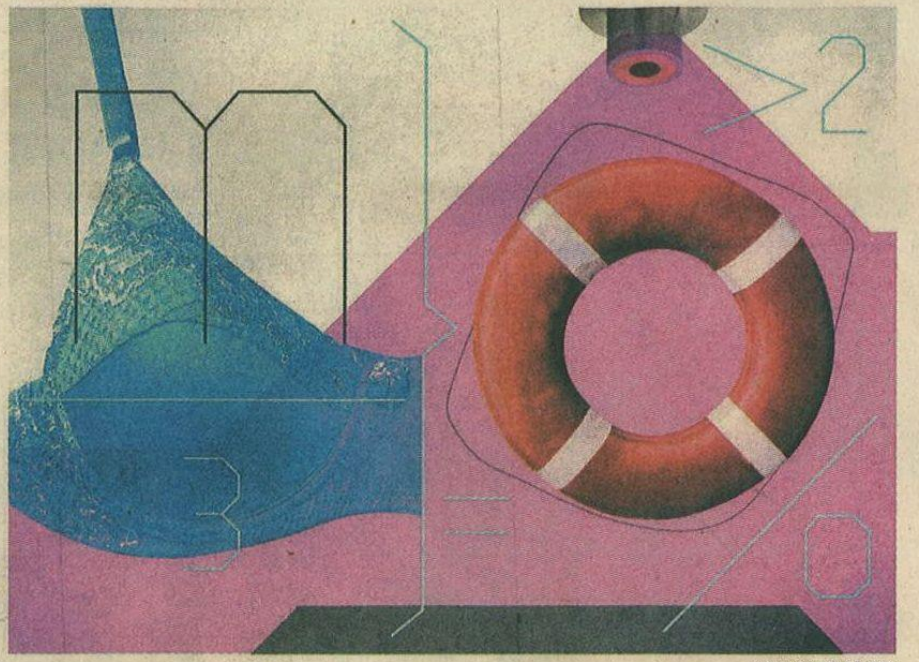

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