Experiences in implementing Canada's prostate screening guidelines.

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Disclaimers

I have not received support from any commercial source
Canadian Task Force members are volunteers:
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with travel and accommodation reimbursement only.
The presentation reflects my views only.

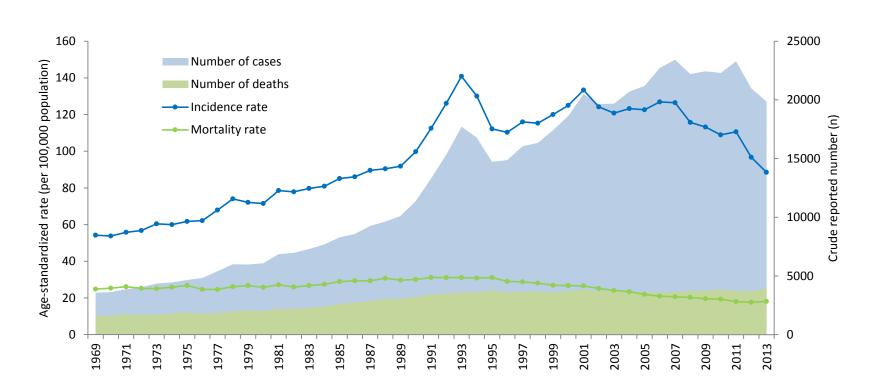
- Message
- Prostate Cancer in Canada
- Canadian Task Force methods
- Evidence review
- Recommendations
- Implementation in practice
- Challenges in Canada

Message

- PSA is a useful tumour marker, but poor screening test
- PSA screening may cure 1 per 1000 screened
- But harms large numbers 300, 30-50/1000
- It is beneficial to:
 - Companies that sell tests, devices or treatments
- Policies should limit PSA screening
 - Argue from position of men: not cost
 - Health care system

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Canada: Age-standardised incidence and mortality rates, number of cases and deaths 1969-2013



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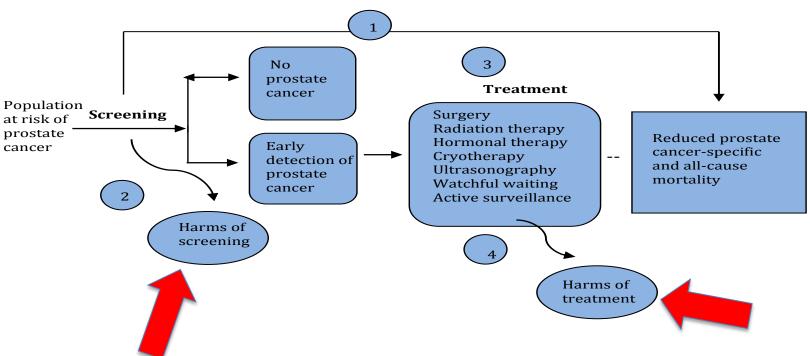
Background CTFPHC

- 1976-2005 originally Canadian Task Force on Periodic Health Examination
- Recommendations and updates
- Re-established 2010 by Public Health Agency of Canada
- Recommendations on primary and secondary preventive interventions
- Target audience primary care professionals

Task Force

- Independent panel
 - Primary Care and prevention experts
 - Methodologists
 - Not topic experts
 - Unpaid volunteers, No conflicts of interest
- Uses evidence-based methods
 - Systematic synthesis of published evidence
 - GRADE

Analytical Framework



Process of development

Formal standardized process

- Writing group
- Analytic framework
- Systematic search and review
 - Evidence Review and Synthesis Centre
- Harms, Overdiagnosis included
- Recommendations linked from evidence
- External reviews: including content experts
- Paper to CMAJ (reviewers)

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What do the trials show?

6 Trials: 3 with severe risk of bias: disregarded

PLCO (US) trial. Annual screening,
Substantial contamination of control group
No effect

ERSPC (European) trial 2014 report: 13 year F/U. 7 countries

Screening 2-4 years, threshold 3.5-2.

Variable results between centres: 2 show benefit

Overall benefit: Prostate Cancer relative risk 0.8 deaths

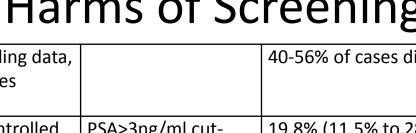
Absolute reduction 12.8/10,000 men screened

Gøteborg trial. Overlaps with ERSPC, included in ERSPC.

Harms of Screening			
Over-diagnosis	ERSPC modelling data, various sources		40-56% of cases diagnosed
False Positives	ERSPC [‡] Uncontrolled observational	PSA>3ng/ml cut- point biopsy referral	19.8% (11.5% to 28.1%) of men screened
	Intervention arm of PLCO§ Uncontrolled observational	PSA>4.0ng/ml cut- point biopsy referral	11.3% (9.9% to 12.7%) of men screened

< 30 days

Harms of Biopsy



Haematuria* Mean=30.9% (20.2% to 41.5%) of

Mean=0.94% (0.01% to 1.86%) of men who had a

Hospitalization=2.1% (1.6% to 2.5%) of men who

men who had a biopsy

Not requiring hospitalization

Death = 0.17% (0.09% to 0.25%)

Infection*

had a biopsy

biopsy

Harms of Carooning

Findings: harms of treatment

Most common treatments

Radical prostatectomy, radiation therapy and androgen deprivation therapy (ADT)

Potential harms include

- urinary incontinence
- erectile dysfunction
- bowel dysfunction

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Premature mortality

Prostatectomy and Post-surgical harms

ANY <30 days

Observational studies: VERY LOW QoE

- 2246/11010 20%; CI 95% (19.7-21.2)
- 247/1243 20%; CI 95% (17.8-22.2)
- 395/3458 11.4%; CI 95% (10.4-12.5)
- 60/280 21.4%; CI 95% (17.0-26.8)

Mortality <30days

Observational studies: VERY LOW QoE

- 53/11010 0.48 %; CI 95% (0.36-0.63)
- 1/280 0.36 %; CI 95% (0.02-2.3)

Harms of prostatectomy

Urinary incontinence

RCT: RR 3.22 (2.27 to 4.56)

178 more per 1000 (from 102 more to 286 more) HIGH QoE

Cohort: RR 3.68 (2.37 to 5.72)

167 more per 1000 (from 85 more to 293 more) MODERATE QoE

Erectile dysfunction

RCT: RR 1.39 (0.77 to 2.53)

221 more per 1000 (from 130 fewer to 867 more) LOW QoE

Cohort: RR 1.56 (1.33 to 1.83)

234 more per 1000 (from 138 more to 347 more) LOW QoE

Bowel dysfunction

RCT: RR 0.42 (0.04 to 4.14)

54 fewer per 1000 (from 90 fewer to 293 more) LOW QoE

Cohort: RR 0.69 (0.43 to 1.11)

15 fewer per 1000 (from 27 fewer to 5 more) VERY LOW QoE

Harms of Radiation Therapy

Urinary incontinence

RCT - RR 8.31 (1.1 to 62.63)

- 149 more per 1000 (from 2 more to 1000 more) MODERATE QOE Cohort RR 1.35 (0.9 to 2.02)
- 22 more per 1000 (from 6 fewer to 63 more) VERY LOW QOE

Erectile dysfunction

Cohort - RR 1.30 (1.17 to 1.43)

127 more per 1000 (from 72 more to 182 more) LOW QOE

Bowel dysfunction

Cohort - RR 1.65 (0.84 to 3.25)

31 more per 1000 (from 8 fewer to 106 more) VERY LOW QOE

Harms of hormone therapy (androgen deprivation)

Urinary incontinence

Observational studies: RR 1.32 (0.75 to 2.3)

• 19 more per 1000 (from 15 fewer to 76 more) VERY LOW QoE

Erectile dysfunction

Observational studies: RR 2.35 (1.53 to 3.59)

442 more per 1000 (from 174 more to 849 more) MODERATE QoE

Bowel dysfunction

Observational studies: RR 2.44 (0.24 to 24.4)

40 more per 1000 (from 21 fewer to 653 more) VERY LOW QoE

Higher risk populations

- Caribbean, African American
- Family history of prostate cancer

- No data on different benefits for "high risk" groups
- No data on harms

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Guidelines

Recommendations on screening for prostate cancer with the prostate-specific antigen test

Canadian Task Force on Preventive Health Care*

See related commentary on page 1201 and at www.cmaj.ca/lookup/doi/10.1503/cmaj.141252

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This guideline provides recommendations on nosed non-skin cancer in men and the screening for prostate cancer using the PSA test third leading cause of cancer-related death with or without digital rectal examination in men among men in Canada.1 The current estimated in the general population. The guideline updates lifetime risk of diagnosis is 14.3%, whereas the a prior guideline by the task force that was last

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CMAJ, November 4, 2014, 186(16) 1225

Prostate cancer 2014

CMAJ

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Task Force on Preventive Health Care is available at http://canadiantaskforce.ca /about-us/members/

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CMAI November 4 2014 186(16) 1225

Box 2: Summary of recommendations for clinicians and policy-makers

The recommendations apply to all men without a previous diagnosis of prostate cancer.

- For men aged less than 55 years, we recommend not screening for prostate cancer with the prostate-specific antigen (PSA) test. (Strong recommendation; low-quality evidence.)
- For men aged 55–69 years, we recommend not screening for prostate cancer with the PSA test. (Weak recommendation; moderate-quality evidence.)
- For men 70 years of age and older, we recommend not screening for prostate cancer with the PSA test. (Strong recommendation; low-quality evidence.)

CMAJ

GUIDELINES

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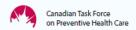
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Weak recommendation (against) indicates a valuesdriven, shared decision making approach between patient and physician, based on objective information on benefits and harms

Strong recommendation indicates clear advice against screening

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PSA Screening: Patient FAQ



1. What is the PSA test?

The PSA test is a blood test that is commonly used to detect possible prostate cancer. Elevated PSA levels may indicate the presence of prostate cancer, but can also be caused by other common non-cancer related conditions such as an enlarged prostate (also known as benign prostatic hyperplasia or BPH) or inflammation of the prostate gland (also known as prostatitis) due to an infection or other cause.

2. Why does the CTFPHC recommend against PSA screening for prostate

The CTFPHC recommends against PSA screening because they found that the potential harms of screening outweigh the benefits.

3. Are there any other tests that can detect prostate cancer?

Currently no other screening tests have been proven to accurately identify prostate cancer. Several tests are being developed to improve the accuracy of PSA screening. However, right now there is not enough evidence to tell us whether or not they are accurate.

4. Why are there harms with PSA screening? Isn't it a simple blood test?

The PSA test is a simple blood test, but if the result is positive, men are likely to then undergo further tests such as a biopsy. There are several harms associated with biopsies, as described in the table. In addition, there is a risk that you will be diagnosed and treated for a slow-growing cancer that would not have caused any trouble in your lifetime.

5. What if I still want the PSA test?

Because of recent efforts to encourage screening for prostate cancer, some men may still be interested in the test. Talk to your doctor about the benefits and harms of PSA screening.

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RENEEITS

LOWER RISK OF DYING FROM PROSTATE CANCER

 1 out of every 1,000 men will escape death from prostate cancer because they were screened with PSA.

HARMS

FALSE-POSITIVE RESULTS

- Most men who have a positive PSA result will undergo a prostate biopsy.
- A false-positive result occurs when a man with a positive PSA result undergoes a blops), with the biops) showing that he does not have prostate cancer.

178 out of every 1,000 men screened with the PSA test will have an unnecessary biopsy to confirm they do not have prostate cancer.

COMPLICATIONS OF PROSTATE BIOPSY

 Prostate biopsy carries a number of complications, including blood in the urine or semen, rectal bleeding, infection and in rare cases, death.

21 out of every 1,000 men who undergo prostate biopsy will have complications severe enough to require hospitalization.

2 out of every 1,000 men who undergo prostate biopsy will die within 120 days of the biopsy, because of complications.

OVERDIAGNOSIS

· Overdiagnosis is the detection of cancers that grow so slowly they would not have caused illness or death during the man's lifetime.

Almost half of all the cancers detected through PSA screening would NOT have caused illness or death in the man's lifetime. However, because of uncertainty about whether their cancer would progress, most men will choose treatment and may experience complications of treatment.

HARMS OF TREATMENT

For every 1,000 men who receive treatment for prostate cancer:

 114–214 will have short-term complications such as infections, additional surgeries, and blood transfusions

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- 127–442 will experience long-term erectile dysfunction
- up to 178 will experience long-term urinary incontinence
- 4 or 5 will die from complications of prostate cancer surgery

Statistics related to benefits and harms were calculated from the European Randomized Study of Screening for Prostate Cancer (ERSPC) and the prostate cancer

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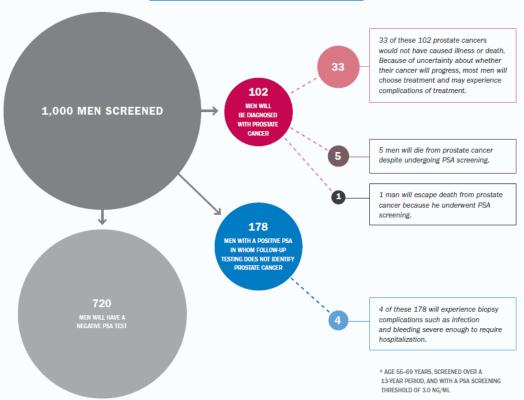
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RESULTS OF SCREENING 1,000 MEN WITH THE PSA TEST*



WHAT ARE MY RISKS IF I DON'T GET SCREENED?

- Among men ages 55 to 69 who do not get screened, the risk of dying from prostate cancer is 6 in 1,000.
- With regular PSA screening, the risk of dying from prostate cancer among men aged 55 to 69 may be reduced to 5 in 1.000.
- In many cases prostate cancer does not, and will not, pose a threat to a man's life.

ISN'T IT BETTER TO GET SCREENED THAN TO DO NOTHING?

- Screening with the PSA often leads to further testing, which carries with it its own serious risks and problems.
- For example, a biopsy involves a number of potential harms such as infection, blood in the urine, or even death.
- Additionally, if testing leads to treatment, such as a
 prostectomy (removal of the prostate gland), the
 chances of urinary incontinence and erectile dysfunction
 significantly increase. Other short term post-surgical
 complications include infections, additional surgeries
 and blood transfusions and death.

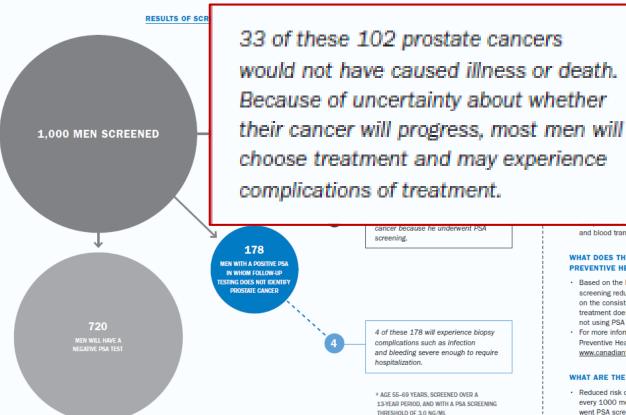
WHAT DOES THE CANADIAN TASK FORCE ON PREVENTIVE HEALTH CARE RECOMMEND?

- Based on the lack of convincing evidence that PSA screening reduces prostate cancer mortality, and based on the consistent evidence that screening and active treatment does lead to harm, the CTFPHC recommends not using PSA testing to screen for prostate cancer.
- For more information on the Canadian Task Force on Preventive Health Care's recommendations please visit: www.canadiantaskforce.ca.

WHAT ARE THE BENEFITS OF SCREENING?

 Reduced risk of dying from prostate cancer-1 out of every 1000 men will escape death because he underwent PSA screening.





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GET SCREENED THAN

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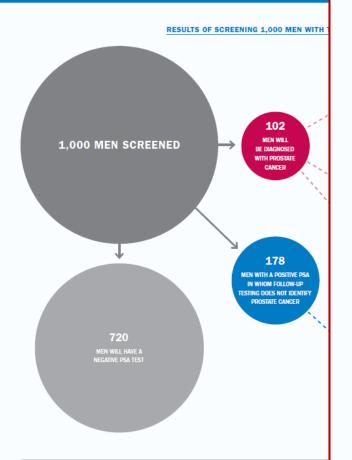
and blood transfusions and death

WHAT DOES THE CANADIAN TASK FORCE ON PREVENTIVE HEALTH CARE RECOMMEND?

- Based on the lack of convincing evidence that PSA screening reduces prostate cancer mortality, and based on the consistent evidence that screening and active treatment does lead to harm, the CTFPHC recommends not using PSA testing to screen for prostate cancer.
- For more information on the Canadian Task Force on Preventive Health Care's recommendations please visit: www.canadiantaskforce.ca.

WHAT ARE THE BENEFITS OF SCREENING?

 Reduced risk of dying from prostate cancer—1 out of every 1000 men will escape death because he underwent PSA screening.



WHAT ARE MY RISKS IF I DON'T GET SCREENED?

- Among men ages 55 to 69 who do not get screened, the risk of dying from prostate cancer is 6 in 1,000.
- With regular PSA screening, the risk of dying from prostate cancer among men aged 55 to 69 may be reduced to 5 in 1,000.
- In many cases prostate cancer does not, and will not, pose a threat to a man's life.

ISN'T IT BETTER TO GET SCREENED THAN TO DO NOTHING?

- Screening with the PSA often leads to further testing, which carries with it its own serious risks and problems.
- For example, a biopsy involves a number of potential harms such as infection, blood in the urine, or even death.
- Additionally, if testing leads to treatment, such as a prostectomy (removal of the prostate gland), the chances of urinary incontinence and erectile dysfunction significantly increase. Other short term post-surgical complications include infections, additional surgeries and blood transfusions and death.



Benefits and Harms of PSA Screening



The Canadian Task Force on Preventive Health Care recommends against screening for prostate cancer with the PSA test

- . The CTFPHC found that the potential small benefit from PSA screening is outwelphed by the potential significant harms of the screening and associated follow-up treatment.
- · Men should understand that PSA screening may result in additional testing if the PSA level is raised.
- · To save one life we would need to diagnose an additional 27 men with prostate cancer

RESULTS OF SCREENING 1.000 MEN WITH THE PSA TEST (age 55-69 years, screened over a 13-year period, and with a PSA screening threshold of 3.0 ng/ml)

What are my risks if I don't get screened? Among men who are screened with the PSA test, the risk of dying from prostate cancer is 5 in 1.000 ************************************* Among men who are not screened with the PSA test, the risk of dving from prostate cancer is 6 in 1.000 **************** 720 men will have a negative PSA test 178 men with a positive PSA in whom follow-up testing ************************ does not identify prostate cancer 4 of these 178 will experience biopsy complications such as infection and bleeding severe enough to require hospitalization ____ 102 men will be diagnosed with prostate cancer ****************** 33 of these 102 prostate cancers would not have ***** 9 5 men will die from prostate cancer despite undergoing

1 man will escape death from prostate cancer because he underwent PSA screening

PSA screening

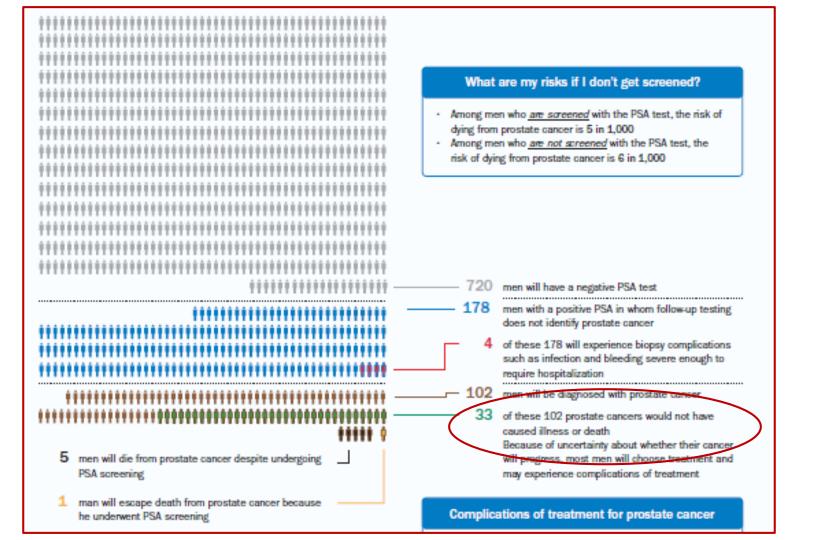
- caused illness or death Because of uncertainty about whether their cancer will progress, most men will choose treatment and
- may experience complications of treatment

Complications of treatment for prostate cancer For every 1,000 men who receive treatment for prostate cancer:

· 114-214 will have short-term complications such as infections, additional surgeries, and blood transfusions 127–442 will experience long-term erectile dysfunction

 up to 178 will experience urinary incontinence 4–5 will die from complications of prostate cancer treatment.

Statistics for benefits and harms were calculated from the European Randomized Study of Screening for Prostate Cancer (ERSPC).



- Message
- Prostate Cancer in Canada
- Canadian Task Force methods
- Evidence review
- Recommendations
- Implementation in practice
- Challenges in Canada

contributes to the choking transportation problems. public stage for keeping things going in the right direction.

PROSTATE CANCER

Scrapping the PSA test is an injustice to men



ROCCO ROSSI President and CEO of Prostate Cancer Canada

The Canadian Task Force on Preventive Health Care released guidelines Monday recommending against using the prostate-specific antigen (PSA) test to screen for prostate cancer. Quite simply, these guidelines do not only a great disservice but also a great injustice to men and their loved ones.

Why is that? Early detection of prostate cancer saves lives. That's especially important for a disease that often has no symptoms until it has advanced to a stage when there are fewer treatment options with less positive outcomes. The task force will say that the PSA test isn't a perfect test, and we don't disagree. But it is currently the best clinical indicator – a red flag – that

William.

something might be amiss and warrants further follow-up. That type of monitoring allows for the best possible outcomes.

The PSA test can and should be used to help determine an individual's risk of prostate cancer. That baseline test value, considered along with other risk factors such as family history and age, will better inform the patient-physician conversation about appropriate follow-up. That's not just screening - that's smart screening. We are not advocating for mass population screening, or annual PSA tests smart screening encompasses tailored clinical follow-up appropriate for the individual. But if PSA testing is climinated, men who are at high risk of prostate cancer won't benefit from early detection: this includes men of black African or black Caribbean descent or men with a family history of prostate cancer.

And men have a right to know their risk. Men have a right to decide how they will use that information. The reality suggested by the task force harkens back to the not-so-distant past of paternalistic medicine, rather

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than informed decision-making.

The task force will also say that PSA testing will lead to overtreatment. Let me be clear here: The PSA is one tool, really just the entry point to more specific diagnostics should there be any warning signs. One PSA test should never mean leaping into treatment. Perhaps, in the past, physicians were too quick to recommend treatment without determining whether the prostate cancer was low-risk or potentially aggressive. But the solution to that is more education about the appropriate interpretation of the test result, not a full-scale ban on using the test.

A recent study from the United States estimated what would happen if PSA testing was eliminated, as was recommended by the task force. It found that cases of metastatic disease would double, leading to a nearly 20-per-cent increase in deaths from prostate cancer. That outcome is simply unacceptable. Applied to the estimated Canadian mortality rate from prostate cancer of 4,000 deaths a year – that's 800 additional dads, brothers, husbands, sons

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and friends. The world has spent the past 20 years reducing the mortality rate for prostate cancer by more than 40 per cent, but following these guidelines will erase that progress.

Ultimately, we are campaigning to safeguard the benefit of the early detection of prostate cancer, which can lead to a survival rate of more than 90 per cent. Those are odds we want every man to have. Why would we discard a tool that makes that type of positive outcome possible?

We at Prostate Cancer Canada have met with thousands of men across the country who know that they are alive only because of early detection. Had this recommendation been in place previously, many would not be alive today. Men have a right to choose. A right to know. And everyone has a right to the best possible survival rates.

SUBMISSIONS: We welcome unsolicited articles. They should be about 650 words, argumentative and include your credentials. If the article is accepted, you'll be notified within three days.

E-mail: comment@giobeandmail.com

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Arguments *for* screening

- Prostate cancer is rising: one in 6 men will get
- The mortality rate is dropping since PSA was introduced
- Over 90% of men survive prostate cancer
 - 5 yr survival 96%
 - Compared with 35% previously
- If we don't screen, we will go back to the old days of presentation with advanced cancer
- Canadian urologists work differently from the US pattern of practice.

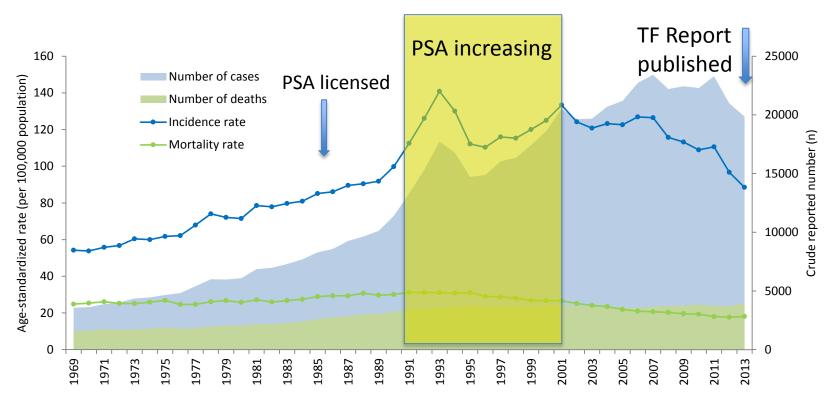


Prostate Cancer Canada

"In an age of informed healthcare, we believe the PSA test is one of the most powerful tools we have, early detection can be the difference between life and death".

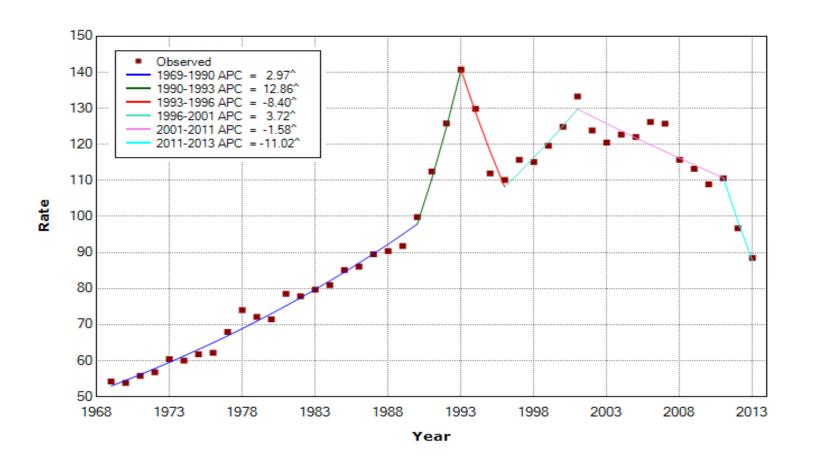
"Many individuals within the health care community agree with Prostate Cancer Canada and think it would be irresponsible to discontinue testing: ...".

Canada: Age-standardised incidence and mortality rates, number of cases and deaths 1969-2013

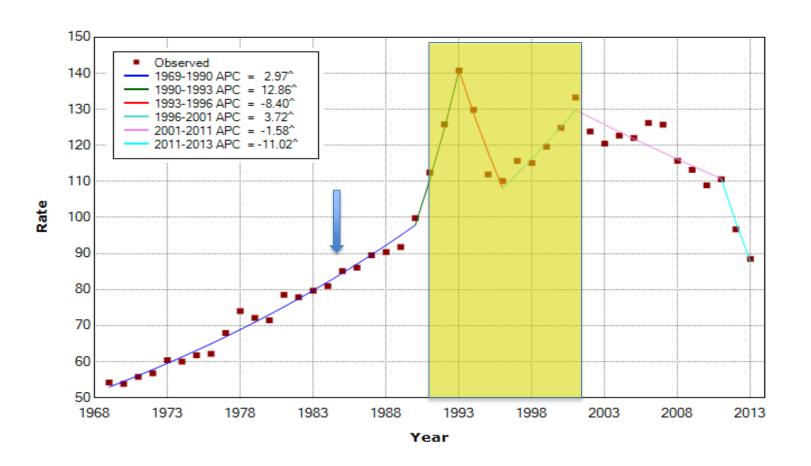


Dickinson et al CMAJ Open 2016 DOI: 10.9778/cmajo.20140079

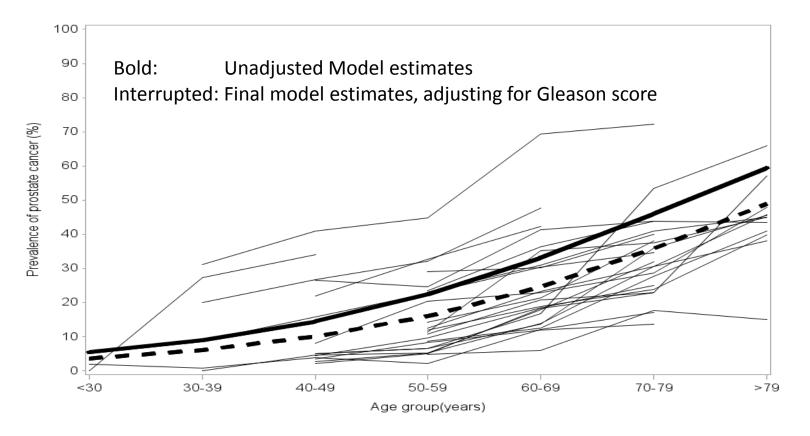
Age-standardized incidence and Annual % Change



Age-standardized incidence and Annual % Change

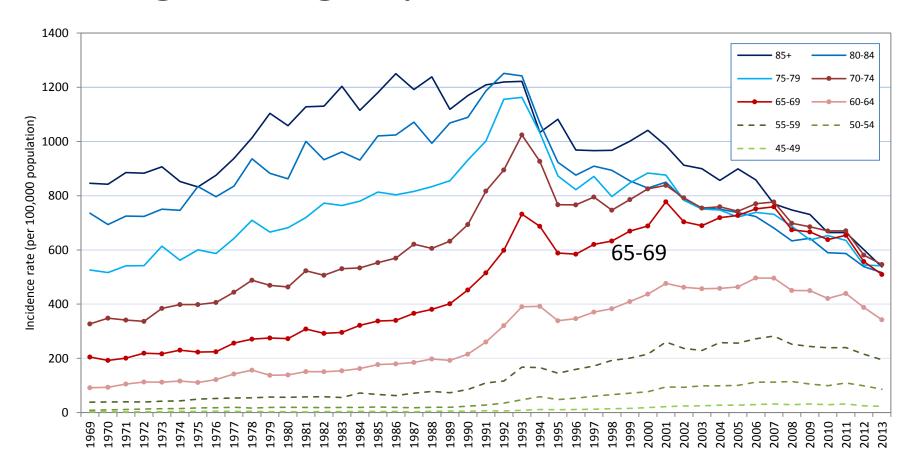


Prostate cancer prevalence by age from autopsy studies



Bell K, Del Mar C, Wright G, Dickinson J, Glasziou P. IJ Cancer 2015

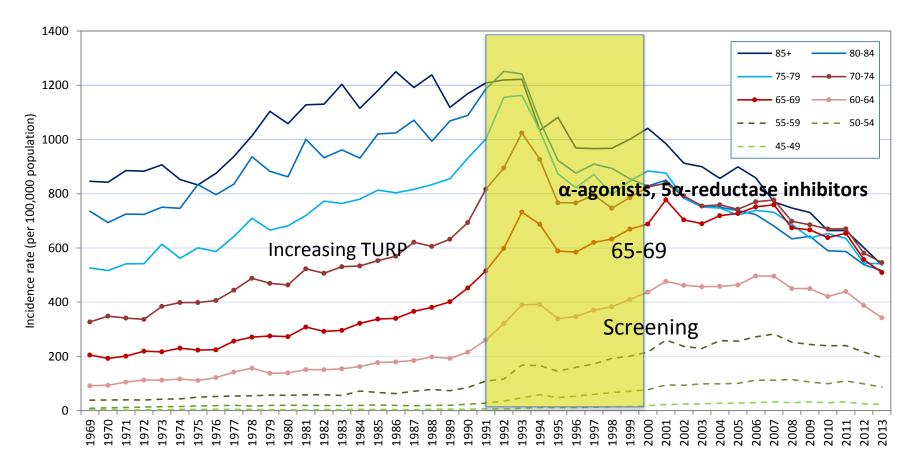
Changes in age-specific incidence rates



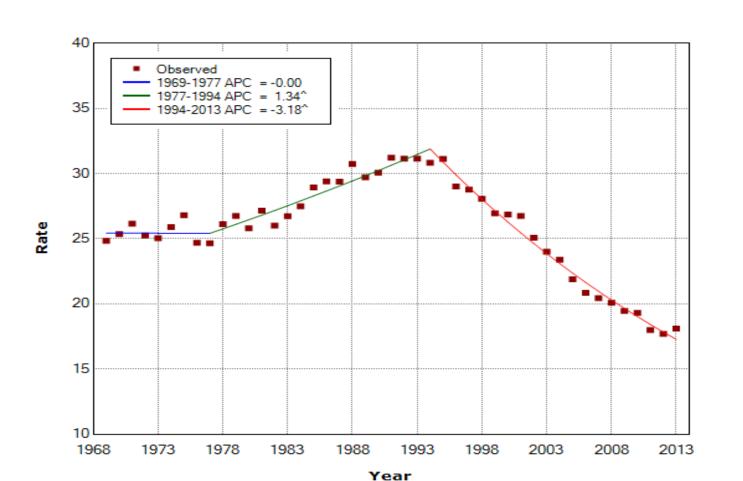
What else happened? Incidence

- From 1970s increasing TURP -> diagnosis
- 1991 Catalona NEJM, 1992 ACS advocated.
- 1994 Approved FDA for screening
- 1990s Increasing u/s guided prostate biopsies
- 1993 α -agonists, 5α -reductase inhibitors
- Modification to Gleason grading

Changes in age-specific incidence rates



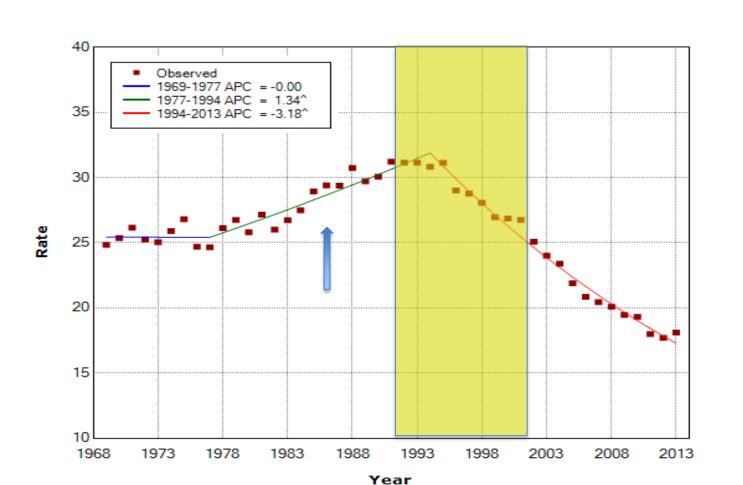
Age-standardized mortality and Annual % Change



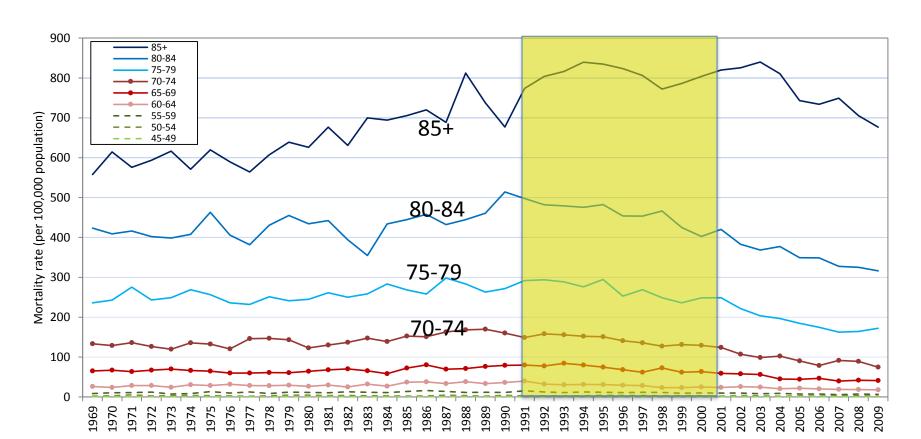
What else happened? Mortality

- Increase prior to PSA
 - Artefact of more diagnosis? CT
- Changed
 - surgical approaches
 - anti-androgens, chemotherapy, radiation
- Decline >> effects of surgery in trials

Age-standardized mortality and Annual% Change



Changes in age-specific mortality rates



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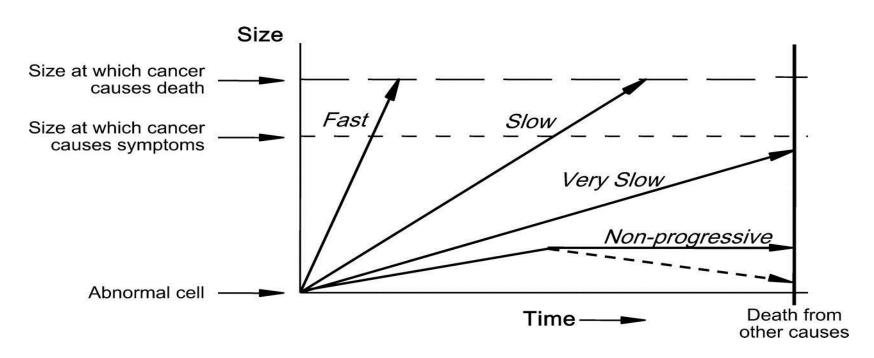
Janssen

Amgen

Astellas

Sanofi-Aventis

Heterogeneity of cancer progression



Welch H G, and Black W C JNCI J Natl Cancer Inst 2010;102:605-613



MAKING PEOPLE SICK IN THE PURSUIT OF HEALTH

DR. H. GILBERT WELCH, DR. LISA M. SCHWARTZ, AND DR. STEVEN WOLOSHIN

"This brilliantly researched, well-argued, and dearly written book will help us avoid the unnecessary tests, drugs, surge fies, and anxiety that are the inevitable outcome of our epidemic of overdiagnosis." SIDNEY WOLFE, MD, author of Worst Pills, Best Pills

and editor of WarstPills.org

"A tough-minded, solidly argued indictment of health care... Brawley's sense of outrage is polpoble." -THE BOSTON GLOBE

HOW WE DO HARM

A DOCTOR BREAKS RANKS ABOUT BEING SICK IN AMERICA



OTIS WEBB BRAWLEY, M.D. with Paul Goldham

Message

- PSA is a useful tumour marker, but poor screening test
- PSA screening may cure 1 per 1000 screened
- But harms large numbers 300, 30-50/1000
- It is beneficial to:
 - Companies that sell tests, devices or treatments
 - Urologists and Oncologists in private practice
- Policies should limit PSA screening
 - Argue from position of men: not cost
 - Health care system

It is difficult to get a man to understand something if his income depends on him not understanding it

Upton Sinclair 1935