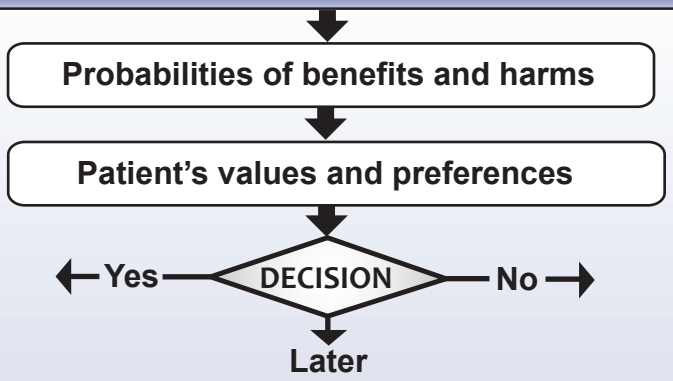
Decision Box
designed for
CLINICIANS

The prostate-specific antigen (PSA) test to screen men for prostate cancer



This document prepares the clinician to discuss scientific data with the patient so they can make an informed decision together.

Presenting the PSA test to patients

What is this test for?

- The PSA blood test estimates the **risk of having prostate cancer**. If the test shows the risk to be **high**, the physician offers to do a **biopsy of the prostate** to verify if the man has prostate cancer.

What is considered a high risk of prostate cancer?
The cutoff PSA level chosen to define a positive result (high risk) and distinguish it from a negative result is usually 4 ng/mL.

Who might consider being tested?

- Men **between 55 and 70 years of age** with at least a **10-year life expectancy**.
- Men of **less than 55 years of age** who are at higher risk (with **one or more affected first-degree relatives** -brother, father- or **African American men**).

Why do patient preferences matter when making this decision?

- **There are pros and cons to taking this test:**

PROS: For each 100 men screened, the test could prevent **0.1 death due to prostate cancer** over 11-13 years of follow-up,[1, 2] up to an estimate of **1** death over the entire life span, as shown in mathematical modeling studies based on one trial results obtained after 11 years of follow-up.[3, 4]

CONS: Screening can be **inaccurate** and **cause harms.** For each 100 men invited to screening and followed-up during 11 years, **3** have a cancer despite the negative results, **10** test positive but do not have a prostate cancer, and **3** among the 7 who have a prostate cancer have a **slow-growing cancer that may never cause a health problem**, leading to **unnecessary treatments.**[6]

- **There are uncertainties about screening outcomes:**
  The best longitudinal studies showed either **a small reduction** or **no reduction in mortality** in men invited to screening every 2-4 years over an 11-13 year period, compared to men not invited to screening.[1,2]

- **Both doing or not doing the test are acceptable options:**
  Major **guidelines** (USPSTF, AUA, ACP, CUA*) **disagree** on whether to be screened or not.
  However, **all recommend informed decision-making**. We propose that:

  ❶ the clinician **shares this information** with the patient
  ❷ the decision takes into account the **patient's values and preferences**

* USPSTF: United States Preventive Services Task Force; AUA: American Urologic Association; ACP: American College of Physicians; CUA: Canadian Urological Association.

See page 2 for the current state of knowledge

DECISION BOX

PSA test

www.decisionbox.ulaval.ca

State of knowledge – January 2013

Selection of best available studies

Unless referenced otherwise, results from the **ERSPC study**[1, 2] were used to calculate benefits and harms of the PSA test: randomized controlled trial including 162,000 men from 7 European countries, between 55 and 69 years old, followed during 11 years, screened on average 2 times every 4 years (**PSA cut-off level** of 3-4 ng/mL).

Benefits of screening

❶ Survival

- For each 100 men followed during 11 years, **0.1 death** from prostate cancer is prevented.[1, 2]
- For each 100 men followed **throughout life,** it is estimated that **1 deaths from prostate cancer** might be prevented.[3, 4]

Effects of screening : For every 100 men followed, compared to *100 men who are not screened, we oberve an increase (↑), or a decrease (↓) in number of men:*

Prostate cancer :	Length of follow-up	
	11 years[1,2]	lifetime[3,4]
Diagnostics	↑4	↑7
Metastasis	↓0.2	↓1.4
Death	↓0.1	↓1

❷ Reassurance

- For each 100 men followed during 11 years, about **83** are identified as being at low risk of having prostate cancer. These men are **reassured.**

Harms of screening

❶ False reassurance

Of the 83 men identified as being at low risk of having prostate cancer, about **3** will actually have prostate cancer. These men have been **falsely reassured**.

❷ False alarm

For each 100 men followed, **17** are identified as being at **high risk** of having prostate cancer. Of these, **10** are found **not to have prostate** cancer at the "confirmatory" biopsy. Among the men who received a biopsy: [5]

- 33 % have a **moderate to severe complication** (pain, fever, temporary urinary problems)
- 1 % to 4 % are **hospitalized**

❷ Overdiagnosis

For each 100 men followed during 11 years, **10** receive a prostate cancer diagnostic (4 more than the men who were not screened) and the majority are treated.[1] For **3** of the individuals diagnosed (**40 %**), cancer would not have progressed to cause illness or death, leading to **unecessary treatments**.[6]

Among the men who received a surgical treatment: [7, 8]

- **40 % to 50 %** experience **sexual dysfunction**
- **10 % to 20 %** experience **urinary incontinence**

Less false alarms:

Using the **digital rectal exam** with the PSA test helps identify other causes of PSA elevation (e.g. prostatitis). It can also help detect a cancer undetected by the PSA test.[11]

Grading of Recommendations Assessment, Development and Evaluation **(GRADE)**

How much confidence can we have in these results?

Survival : Low Results for prostate cancer mortality are inconsistent among trials. All available studies present high risks of bias. The numbers presented are the most conclusive results.[1,2]

Sexual dysfunction and urinary incontinence: Moderate The results are mainly based on studies of moderate quality and are imprecise (wide confidence intervals)

Questions to identify the patient's decision making needs:

- Do you have any questions about the benefits and harms of each option?
- Which benefits and harms matter most to you?
- Do you feel sure about the best choice for you?
- Who will support and advise you in making a choice?

References:

1. Schroeder et al. N Eng J Med 2012; 366: 981-90.
2. Schroeder et al. Eur Urol 2012; 62: 745-752.
3. Heijndijk et al. N Engl J Med 2012; 367: 595-605.
4. Wever et al. Br J Cancer 2012; 107: 778-784.
5. Rosario et al. BMJ 2012; 9 (344): d7894.
6. Welch et al. J Natl Cancer Inst 2010; 102: 605-13.
7. Wilt et al. N Eng J Med 2012; 367: 203-213.
8. Johansson et al. Eur Urol 2009; 55: 422-430.
9. Catalona et al. J Urol 1994; 151 (5): 1283-1290.
10. Chou et al. Ann Intern Med 2011; 155 (11): 762-71.