PSA in the screening for prostate cancer

***Under review***

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This sheet is a recommendation to assist in the decision making process in health care. It is not mandatory and is not a substitute for the clinical judgment of health care personnel.

The determination of PSA as a population screening for prostate cancer should not be performed as it does not provide benefits in terms of mortality reduction.

**This recommendation is being reviewed in 2023.**

# Resum

* PSA determination is appropriate in men with a risk above the population risk (family history), in the presence of a suspicious examination and in the follow-up of prostate cancer.
* In Catalonia, 1 in 6 men could develop prostate cancer during their lifetime. However, the mortality rate for this type of tumor is slightly less than 3% of those affected.
* An elevated blood level of the PSA protein can be a warning indicator of the risk of having a prostate tumor. Estimation of the PSA concentration level is obtained by a diagnostic laboratory test.
* The number of complications and adverse effects on the quality of life of patients, in relation to the benefits that this test can cause, has led most scientific and professional societies not to endorse its use at the population level, except in specific cases of people who present a higher risk (family history, in the presence of symptoms or signs, or as a follow-up of patients who have already had this tumor).
* For these reasons, it is recommended not to use the PSA blood test as a population screening method for early detection of prostate cancer as it does not provide benefits in terms of mortality reduction.
* In any case, because of the possible benefits and harms associated with this test, it should always be performed after the patient has been informed in a thorough and detailed manner.

# More information

The principle on which cancer screening tests are based lies in the fact that early detection (very early stages of cancer) means a better prognosis in enabling more effective treatment. Screening can be done at the population level through a formal and organized program (eligible individuals are invited to participate, the criteria for inclusion and the periodicity of the screening test are clearly established, the management and intervention if malignancy is detected are well defined, the follow-up and quality assurance and evaluation processes are carried out) or it can be opportunistic screening that takes advantage of the visit of the person who goes to the doctor for another reason.

In Catalonia, in the period 2003-2007, prostate cancer accounted for 4,258 incident cases (new cases) annually, being the most frequent cancer in men (21.3%). The causes of this cancer are poorly understood; the most important risk factor is age and in a small number of cases (5-10%) there is family history. It is possible to say that 1 in 6 men will develop a cancer of the

lifetime prostate cancer. In contrast to the incidence, the annual mortality is 803 cases, which represents 8.2% of annual cancer mortality. This translates into the fact that most cases of prostate cancer have a good prognosis, the lifetime mortality risk being less than 3%, which means that most people affected will die "with" prostate cancer (but from other causes) and "not of" prostate cancer.

Screening for prostate cancer by determination of prostate specific antigen (PSA) in blood has been discussed since its inception in several studies that have examined its effectiveness in reducing prostate cancer mortality and mortality from any cause. The most recent review and meta-analysis of the Cochrane Collaboration (2013) includes five randomized comparative clinical trials, with more than 341,342 male participants (aged 40 to 80 years) and distributed in two groups: with intervention (screening by PSA determination with/without rectal ultrasound) or without. The results of the meta-analysis showed no statistically significant differences between the two groups, both in terms of mortality from prostate cancer and from any cause. However, the two most recent clinical trials (the American PLCO and the European ERSPC), included in the meta-analysis, have shown contradictory results. The European study shows a reduction in prostate cancer-specific mortality: a 21% reduction in men aged 55-69 years, which means that in order to prevent one death from prostate cancer over 11 years of follow-up, 1,055 men must be invited to participate and 37 cancers must have been detected. The American study showed no benefit in specific mortality. In none of these studies was a reduction in mortality from any cause observed. The differences between these two large studies could be explained by aspects of size, screening strategies, contamination of the control group or the homogeneity of the therapies applied.

Based on the results of these two large clinical trials, most (if not all) urological scientific societies consider the current practice of mass screening for prostate cancer to be inappropriate. A year before the Cochrane review, the US Preventive Services Task Force had also recommended against PSA-based prostate cancer screening. This recommendation applied to the entire male population regardless of age and specifically excluded the use of PSA as a follow-up or surveillance test after prostate cancer diagnosis or treatment.

The damage associated with prostate cancer screening can be minor or major. Among the former, apart from anxiety, there are the complications of the subsequent prostatic biopsy. It is worth saying that in 70% of men with positive PSA values (in general when it is ≥4 ng/ml), the biopsy is negative (false positives), but they are still exposed to the adverse effects of prostatic biopsy: hematuria (14-20%), hematospermia (38-50%), pain (8%) and fever (4%). Serious adverse effects (urinary retention, infection, sepsis) requiring hospitalization are present in 0.5-1% of cases. Greater harm results from overdiagnosis (up to 50% in the European study and between 17-30% in the American study) resulting from the detection of indolent cancers that would not give symptomatology and from overtreatment (surgery with different types of interventions and/or radiotherapy also of different meninges). Infection, bleeding that may require transfusion, erectile dysfunction (40-80%) and urinary incontinence (5-25% of patients) are complications of surgery, but radiotherapy also has its own complications such as toxicity on the organs of the veins or cystitis and rectitis (5-10%).

All of this could be expressed more comprehensively as follows: for every 1,410 men who regularly participate in a prostate cancer screening program, there would be 1 fewer deaths from prostate cancer compared to a group of men who did not participate in such a program. Of these 1,410 participants, 48 would be treated.

unnecessarily with the potential consequences referred to. It goes without saying, as mentioned above, that mortality from any cause is not affected.

In 2012, approximately 321,090 men aged 15 years or older underwent a PSA blood test in Catalonia, according to an estimate based on data from the ICS SISAP. More than half of the determinations (62.8%) were performed in individuals with no prostate pathology or history of prostate cancer recorded in the clinical history. The prevalence of PSA testing in this group (men older than 14 years without pathology) is 6.5%, but increases to 11.6% among men aged 40 years or older. The age group with the highest prevalence is 65-74 years, in which one in four men without prostate disease had a PSA test in the last year.

The total number of PSA determinations in blood has remained stable during the last four years, however, the determinations in patients without prostate pathology have decreased by 18.1%, while those in patients with prostate pathology have increased by 66.0%.

The prevalence of PSA determination in patients without prostate pathology aged 40 years or older shows moderate variability among primary care teams (PCS). The 25% of the PSA tests with lower prevalence are below 8.9%, while the 25% with higher values are above 14.1%.

It is considered appropriate to perform PSA testing in a percentage of the population without prostate pathology or history of prostate cancer when there are genetic factors (BCRA mutations) and/or family history (such as a history of a parent or sibling with prostate cancer before the age of 60 or two prostate cancers in the same family). family history (such as a history of a parent or sibling with prostate cancer before the age of 60 or two prostate cancers in the same family line) that may predispose (increased risk) to prostate cancer. These individuals should be aware of their (increased) risk, as well as the natural history of prostate cancer and the possible benefits and adverse consequences of screening.

However, the decrease in the unjustified territorial variability represents a decrease of up to

65,000 tests per year, which would significantly reduce the number of false positives and serious adverse effects related to prostate cancer screening.

Any consideration of a PSA test should be made only after full information has been obtained. People with a life expectancy of less than 10-15 years should be informed that prostate cancer screening is unlikely to be of benefit. The fact of routinely requesting PSA determination within a battery of other blood tests without knowledge of the patient is not an acceptable practice. Apart from the situations referred to, screening (population or opportunistic) for prostate cancer with PSA cannot be recommended if it does not show clear benefits in terms of mortality.

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# Links of interest

* Prostate-specific antigen test. National Cancer Institute, USA (information in Spanish). Available at: <https://www.cancer.gov/espanol/tipos/prostata/hoja-informativa-psa>

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