INESSS
LE SAVOIR PREND FORME

Tool for facilitating the discussion about INESSS's recommendations concerning prostate-specific antigen (PSA)-based prostate cancer screening

FOR HEALTH PROFESSIONALS

INESSS'S RECOMMENDATIONS	FURTHER DETAILS
 **INESSS recommends that health professionals not systematically propose the PSA test for prostate cancer screening.**	The current scientific data suggest that the PSA test should not be proposed systematically. However, if one of your patients wants to discuss it, you should be well equipped. Here is some useful information to help you:
 The PSA test should be available, in a screening context, to asymptomatic men who request it, if they meet all of the following conditions: 1) Are between the ages of **55 and 69 years**; 2) Have a life expectancy of more than **10 years**; and 3) Still want to have the test after being informed of the benefits and risks.	▸ There is no clear scientific evidence for assessing the advantages and drawbacks of screening in men considered to be at higher risk, such as those with a family history and those of African-American origin. ▸ A given patient's values and preferences should guide the decision whether or not to proceed with a PSA test. ▸ Men with urinary symptoms were not excluded from the randomized trials. In the presence of such symptoms, the clinician may determine that a PSA test is necessary for diagnostic purposes.
 A decision support tool for men should be available in order to facilitate the informed decision-making process.	To facilitate the risk/benefit discussion, consult the sections of this tool entitled: ▸ Information for discussing the decision whether or not to be screened for prostate cancer using the PSA test; ▸ The risks and benefits of PSA-based prostate cancer screening as illustrated using data from the ERSPC.
 In an asymptomatic patient with a non-suspicious digital rectal examination who wants to have the test, the management will be dictated by the test result. INESSS recommends the following management model: PSA < 1.5 ng/mL: repeat test every 2 to 4 years; PSA 1.5 – 4.0 ng/mL: repeat test every 1 or 2 years; PSA ≥ 4.0 ng/mL: repeat test within 8 weeks: a. Result < 4 ng/mL: repeat test every 1 or 2 years. b. Result ≥ 4 ng/mL: refer patient to a urologist.	▸ Although the digital rectal examination does not seem to show any screening benefit, it is recommended that it be used in conjunction with the PSA test because, based on study results, the two cannot be separated. ▸ The purpose of the proposed model is to guide the interpretation of the PSA result before referring the patient to a urologist. ▸ Monitoring the PSA level is part of the active surveillance done before referring the patient to a urologist. ▸ The practice suggesting that the approach be based on a different PSA level, depending on the patient's age, has not been validated.

? For further information, consult the report entitled: *Utilisation du dosage de l'APS pour le dépistage du cancer de la prostate au Québec* in the Publications section of INESSS's website.

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Information for discussing the decision whether or not to be screened for prostate cancer using the PSA test

Preamble

Prostate cancer is the most commonly diagnosed cancer in men in Quebec. It is also the third leading cause of cancer death in these men. The Canadian Cancer Society estimates that 4,800 new cases of prostate cancer will be diagnosed in 2017, or approximately 18 % of the new cancer cases in men, and that 880 deaths will be recorded (CCS, 2017). It is estimated that 1 man in 8 will be diagnosed with prostate cancer during his lifetime. However, despite the fact that this cancer is common, there is not necessarily an effective screening test for it.

With regard to prostate cancer screening, INESSS recommends that health professionals not systematically propose the PSA test. This practice is not robustly and unequivocally supported by the current scientific data. The studies have significant methodological limitations.

Observations have shown screening to have a certain impact on mortality reduction. This impact proved modest and, for a good number of men, came at the cost of sometimes significant untoward consequences, such as false positives and the harmful effects of the subsequent procedures, as well as overdiagnosis and the potential overtreatment. Therefore, the decision whether or not to go ahead with this test should be preceded by explanations so that it is an informed one.

References

Canadian Cancer Society's Advisory Committee on Cancer. Canadian Cancer Statistics 2017. Toronto, Ontario: Canadian Cancer Society; 2017.

Institut national d'excellence en santé et en services sociaux (INESSS). Utilisation du dosage de l'antigène prostatique spécifique (APS) pour le dépistage du cancer de la prostate au Québec. Report written by Dominique Arsenault and Michel Rossignol. Québec, QC: INESSS; 2017. 130 p.

Schröder FH, Hugosson J, Roobol MJ, Tammela TL, Zappa M, Nelen V, et al. Screening and prostate cancer mortality: Results of the European Randomised Study of Screening for Prostate Cancer (ERSPC) at 13 years of follow-up. Lancet 2014;384(9959):2027-35.

THE KEY COMPONENTS OF SHARED DECISION-MAKING

Shared decision-making implies a discussion between you and your patient with the objective of making an informed choice.

- Tell your patient that a decision needs to be made because he has different options.
- Gauge his desire to obtain information and to participate in the decision.
- Explain the different options to him using the best available data and point out the inherent uncertainties.
- Help him compare the benefits and risks associated with each option and check that he understands.
- Help him express what is important to him, his fears and his perceptions of the benefits and risks (values and preferences).
- Ask him if he needs any clarifications and remind him that he can take time to consider the matter before making a decision.
- Come to an agreement on an option.
- Check if he is comfortable with this decision and support him in the next steps.

Source: Pimlott N, ed. Holding a wolf by the ears: Preventive care and the family physician [Special series from the Canadian task force]. Can Fam Physician 2017; 63(7):502. Available at: http://www.cfp.ca/content/63/7/502/

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Information for discussing the decision whether or not to be screened for prostate cancer using the PSA test

Main points to convey to inform the patient:

- The PSA test for prostate cancer screening yields a considerable number of **false positives** (INESSS report, 2017). Several factors can cause an elevated PSA, such as prostatitis (inflammation of the prostate), an increase in the size of the prostate (benign hypertrophy), sexual relations with ejaculation a few days before the test, and bicycle riding. A false-positive test result can lead to other investigations (such as a biopsy), as well as to anxiety, which, in the end, will have been unwarranted. A **biopsy** in itself is not a benign procedure and can cause certain untoward effects or complications (bleeding or infection with or without hospitalization).
- As well, prostate cancer often progresses slowly (**indolent cancer**). Consequently, few men diagnosed with prostate cancer will die specifically from it. Most will die from some other cause. If not screened, many men would never be diagnosed with prostate cancer during their lifetime (**overdiagnosis**). In some cases, they will be offered treatments (surgery or radiation therapy) that can have considerable deleterious effects (impotence, incontinence and anxiety).
- The current practice for managing cases of prostate cancer favours **active surveillance**, an option that has been shown to be reasonable when compared to active treatments. The long-term psychological impact of this type of surveillance is unclear. Active surveillance does, however, enable one to avoid some of the physical consequences of surgery or other treatments.
- **When screening is not done**, false-positive results and, therefore, the anxiety and the potential investigations are avoided. Overdiagnosis, which might be followed by treatments that have sometimes significant untoward effects, are avoided as well.
- **The decision whether or not to be screened is unique to each individual and depends on his values and preferences.** Some men will attach far more importance to the possibility of reducing their risk of dying from prostate cancer thanks to screening than to that of experiencing the untoward effects associated with the investigations and treatments that follow a false-positive result or an overdiagnosis. For others, the risks associated with false-positive results or the possibility of being overdiagnosed outweigh the potential benefits of screening.

The following figure can be used to show the balance between the potential risks and benefits associated with the decision to be or not to be screened. It should be noted that only data from the European Randomised Study of Screening for Prostate Cancer (ERSPC) (Schröder et al., 2014) were used for estimation purposes in this figure.

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The risks and benefits associated with PSA-based prostate cancer screening as illustrated using data from the ERSPC

COMPARISON OF 2 GROUPS OF 1000 MEN

Data from the European Randomised Study of Screening for Prostate Cancer (ERSPC) are used here to show the balance between the potential risks and benefits associated with the decision to be or not to be screened. Because of the uncertainties inherent in this type of estimate, due mainly to methodological limitations and practice changes, the potential benefits and risks shown here may be greater or smaller, depending on the prevailing clinical practice.

PSA screening, on average, twice over a 13-year period

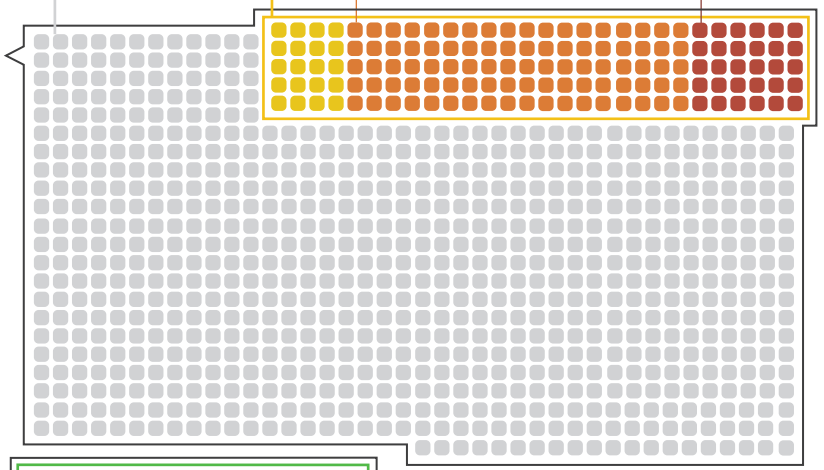
1000 men aged 55 to 69 years

~760 will have a NEGATIF PSA result and will feel reassured

~140* will have a POSITIVE PSA result but will not be diagnosed with cancer after further investigations

~120 of them will have a BIOPSY**

~30 of these men will experience a COMPLICATION** (sometimes serious) from the biopsy



~900 men **WILL NOT BE DIAGNOSED** with prostate cancer after screening

~100 men **WILL BE DIAGNOSED** with prostate cancer after screening

~95 will NOT DIE from prostate cancer

~40 will be **OVERDIAGNOSED**

If not screened, many men would never be diagnosed with prostate cancer during their lifetime (overdiagnosis). They will be treated for their cancer and may suffer the untoward effects (anxiety, impotence and incontinence) of these treatments.

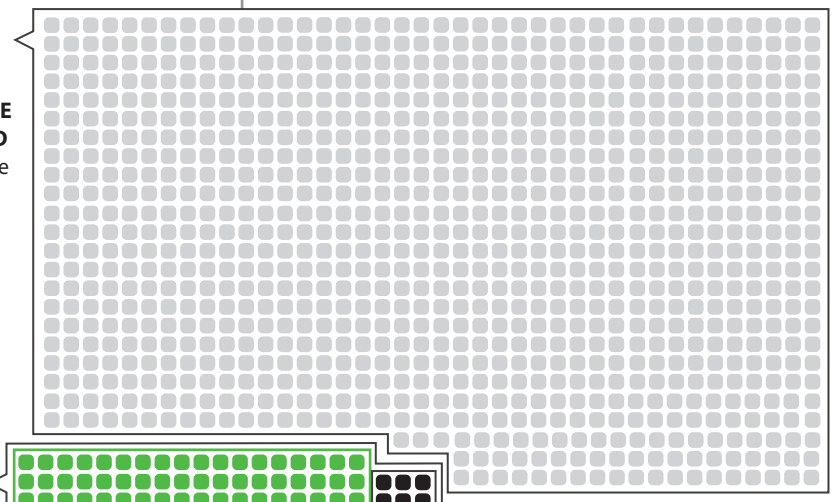
~1 cancer **DEATH AVOIDED** thanks to screening

~5 will **DIE** specifically from prostate cancer

No PSA screening

1000 men aged 55 to 69 years

No tests!
No **OVERDIAGNOSIS***
No **FALSE-POSITIVE**** PSA test results



~940 men **WILL NOT BE DIAGNOSED** with prostate cancer

~60 men **WILL BE DIAGNOSED** with prostate cancer following the symptom investigation

~54 **WILL NOT DIE** from prostate cancer

~6 will **DIE** specifically from prostate cancer

* In Québec, the investigation threshold has been set at a PSA level of ≥ 4.0 ng/mL, while the ERSPC estimates are based on a threshold of ≥ 3.0 ng/mL.

** Since the management of positive results has evolved since the randomized trials, it is very likely that fewer biopsies are performed and that there are, therefore, fewer biopsy-related complications. The impact of this practice change on complications and survival is not known. The potential complications associated with biopsies are infection and bleeding with or without hospitalization.

*~40 men will AVOID OVERDIAGNOSIS. No tests, no diagnosis, no treatment.
**~140 men will AVOID a FALSE-POSITIVE PSA screening result.

Sources: The data presented above were estimated from data from the European Randomised Study of Screening for Prostate Cancer (ERSPC) (Schröder et al., 2014). The figure is modeled after Adler R: Cancer Screening Decisions: A Patient-Centered Approach. Philadelphia: Wolters Kluwer, 2018.

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