Viet-Thi Tran, Elena Kisseleva-Romanova, Laurent Rigal and Hector Falcoff

Impact of a printed decision aid on patients' intention to undergo prostate cancer screening:

a multicentre, pragmatic randomised controlled trial in primary care

Abstract

Background
Despite recommendations against systematic screening for prostate cancer, 70% of patients still request prostate-specific antigen testing.

Aim
To assess the impact of a decision aid on patients' intention to undergo prostate cancer screening.

Design and setting
Randomised controlled trial with two-arm parallel groups in 86 general practices in urban and rural areas in France.

Method
Males aged 50–75 years were randomised to receive either the decision aid (intervention group) or usual care (control group). The primary outcome was the proportion of patients' intending to undergo prostate cancer screening, assessed immediately after reading the decision aid. The reasons underlying their choice were elicited and the proportion of patients citing each reason to undergo, or not undergo, prostate cancer screening were compared between the two arms.

Results
A total of 1170 patients were randomised (588 in the intervention arm) from November 2012 to February 2013. The proportion of patients who intended to be tested for prostate cancer in the intervention arm (123 patients [20.9%]) was significantly reduced compared with the control arm (57 patients [9.8%]) (difference 11.1%, 95% confidence interval [CI] = 7.0 to 15.2, $P<0.0001$). In the intervention group, a lower proportion of individuals expressed that cancer screening would protect them from the disease, compared with the control group ($P<0.0001$), while a greater proportion of individuals stated that prostate cancer screening would not benefit their health ($P<0.0001$) and may involve procedures with harmful side effects ($P = 0.0005$).

Conclusion
The decision aid improved participants' informed decision making and reduced their intent to undergo prostate cancer screening.

Keywords
decision making; early detection of cancer; primary care; prostatic neoplasm; randomised controlled trial.

INTRODUCTION

Prostate cancer is the second-most prevalent cancer in males and a leading cause of mortality and morbidity, contributing to approximately 9000 deaths per year in France[1] and 30 000 in the US.[2] Screening for prostate cancer intends to increase chances of successful treatment by detecting the disease early but a review of five randomised controlled trials showed that screening using digital rectal examination and levels of prostate-specific antigen (PSA) did not significantly decrease prostate cancer-specific mortality.[3] Rather, screening for prostate cancer often led to overdiagnosis by detecting tumours that would not otherwise have become symptomatic or by producing false–positive results. Screening could, therefore, result in unnecessary supplementary testing (including prostate biopsies), inadequate and/or harmful treatment, and negative psychological outcomes.

Despite the lack of evidence, PSA testing is frequently requested by patients and prescribed by physicians. In the US, approximately 50% of patients aged 50–79 years undergo prostate cancer screening every year.[4] The vast majority of citizens in nine European countries systematically overestimate the benefits of PSA screening and are unaware of its limitations and risks.[5] In a US general medicine clinic, 76% of patients requested screening prior to any information about it.[6] Since 2012, the US Preventive Services Task Force has recommended against prostate cancer screening in all age groups for patients who are asymptomatic.[7] Similarly, in France, screening for prostate cancer is not recommended systematically for such patients.[8]

To help patients understand the complexities about PSA testing for prostate cancer screening, professional organisations encourage physicians and patients to use decision aids to make informed decisions. Decision aids should be clear and simple to understand, and contain up-to-date information about the harms and benefits of screening for prostate cancer. They should also be short enough to be usable in daily practice. Such decision aids improve patients' knowledge regarding options and reduce their decisional conflict related to feeling uninformed.[9]

The aim of this study was to evaluate how a decision aid that could be used by GPs in daily practice and presented the harms and benefits of prostate cancer screening impacted on patients' intention to undergo screening.

METHOD

The impact of a decision aid on prostate cancer screening was evaluated in a multicentre, pragmatic randomised controlled trial with two parallel groups. It

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How this fits in

Recently published decision aids for prostate cancer screening are able to improve men's informed decision making, but their usability in daily practice is unknown. This study showed that a two-page, simple-to-use, evidence-based decision aid significantly reduced the proportion of males intending to undergo prostate cancer screening. The decision aid is read by patients in the waiting room and so does not take up consultation time, although physicians must check whether further explanations are needed for patients who have a low level of education.

was conducted in 86 GP clinics in France.

Participants and setting

Participants were male, aged 50–75 years and consulting their GP. They were included regardless of their history of prostate cancer screening, but excluded if they had:

- a personal history of prostate cancer;
- any urinary tract symptoms;
- a history of prostate cancer in a first-degree relative;
- a known exposition to chlordecone (found to be a risk factor);[10] and
- a cognitive or psychiatric condition that could affect the patient's comprehension of the decision aid and/or the study questionnaire.

All eligible male patients attending any of the participating sites were invited to take part consecutively. The study took place in 86 GP clinics in France, in both urban and rural environments. Participating physicians were members of the Société de Formation Thérapeutique du Généraliste (SFTG — Society of Generalist Therapeutic Training) and were responsible for recruiting the patients; their characteristics are outlined in Appendix 1. All patients gave informed consent to participate in the study.

Randomisation and allocation concealment

The randomisation was stratified by GPs. The randomisation ratio was 1:1 and the list was computer generated by a person who was neither involved in conducting the study nor the analysis of the results. Each participating GP received numbered, opaque, sealed envelopes; patients were recruited sequentially, with each participant receiving the next numbered envelope. This process ensured allocation concealment.

Intervention

The intervention was the use of a decision aid explaining the context, benefits, and harms of prostate cancer screening, according to the most recent literature at the time of the study. This decision aid was intended to be used in waiting rooms, without the direct presence of a physician.

The decision aid was developed by a group of physicians including GPs, epidemiologists, and urologists. The group defined the aid's key messages and developed a preliminary version, comprising two printed A4 pages. The first page contained:

- information on the epidemiology of prostate cancer;
- a description of the PSA test, and advantages and limitations of using it to screen for prostate cancer (including the risk of overtreatment and that of becoming impotent and/or incontinent); and
- the position on screening for prostate cancer of major scientific societies in France at the time of the study.

The second page contained a visual representation of the benefits of PSA screening for prostate cancer versus usual care, based on the results of the European Randomized Study of Screening for Prostate Cancer trial.[11] This visual representation used an explicit values clarification strategy, which has been shown to result in a higher proportion of patients making decisions.[12] The decision aid (Appendix 2) was piloted with 20 patients to ensure clarity and wording, then revised according to their comments.

The control group received usual care, with physicians answering their patients' questions as they would normally.

Outcomes

The primary outcome was patients' intention to undergo screening for prostate cancer. This was assessed with a self-administered questionnaire including the question: 'Do you want to be screened (or, in case you have already been screened before, do you intend to continue to be screened) for prostate cancer?'. Patients could answer 'yes', 'no', or 'I don't know', which was measured after they had had time to read the contents of the numbered envelope they had received from the GP. In addition to giving their answer, patients were systematically asked to cite the reasons for those answers by responding to open-ended questions.

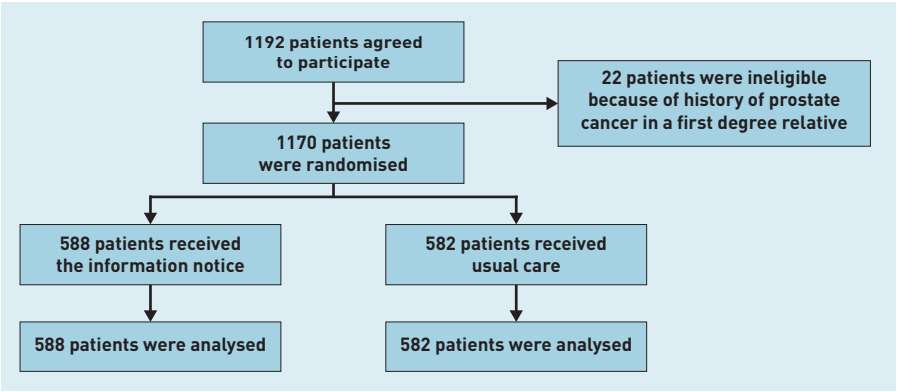

Figure 1. Study flow chart.

Answers were read by one researcher and classified into categories.

Conduct of study

Patients were included in the study during a visit to their GP. At the end of the normal consultation with the patient, the physician asked them if they would like to participate in the study by asking the following:

'Do you wish to participate in a study about screening of prostate cancer? If yes, could you open this envelope and answer the questionnaire. This questionnaire is anonymous. We can discuss this topic on your next visit if you want.'

The envelopes contained:

- demographic and clinical questionnaires for all participants; and
- the decision aid for patients in the intervention group, or blank pages for those in the control group.

Table 1. Demographic and clinical characteristics of patients

Characteristic	Total (*n* = 1170)	Intervention (*n* = 588)	Control (*n* = 582)
Age in years, mean (SD)	61 (6.4)	61 (6.5)	61 (6.3)
Educational level, *n* (%)			
Primary	456 (39.0)	226 (38.4)	230 (39.5)
Secondary	235 (20.1)	113 (19.2)	122 (21.0)
College	434 (37.1)	215 (36.6)	219 (37.6)
Missing data	45 (3.8)	34 (5.8)	11 (1.9)
Patient already had PSA testing, *n* (%)	709 (60.6)	353 (60.0)	356 (61.2)
Family history of prostate cancer, *n* (%)	113 (9.7)	52 (8.8)	61 (10.5)
Patients' intent to undertake prostate cancer screening prior to intervention, *n* (%)			
Yes	878 (75.0)	446 (75.8)	432 (74.2)
No	113 (9.7)	56 (9.5)	57 (9.8)
I don't know	174 (14.9)	85 (14.5)	89 (14.6 15.3)
Missing data	5 (0.4)	1(0.2)	4 (0.6 0.7)

PSA = prostate-specific antigen. SD = standard deviation.

In the intervention group, patients were instructed to answer the question on intention to undergo screening twice: once before, and once after, reading the decision aid. The participant read and completed all questionnaires in the waiting room outside of the doctor's office so the physician could not influence their answers.

As completed questionnaires were deposited in a specific box in the waiting room, this study did not take into account any patient–clinician discussion that could have occurred afterwards.

Statistical analyses

In the literature, it was found that 60–76% of patients were interested in prostate cancer screening.[6] The sample size was calculated to achieve a power of 90% with an α level of 0.05. Based on the results of the pilot testing, it was assumed that in the control group, 60% of patients would be in favour of PSA screening and that the intervention could decrease this proportion by 10% in absolute terms. As such, it was calculated that 1036 participants (518 participants per group) would be needed.

A descriptive analyses with means and proportions was performed. Comparisons between groups were performed in intention to treat: all patients were analysed in the group into which they were randomised, independent of whether or not they read the decision aid while χ^2-squared and student *t*-tests were used for bivariate analyses. Within-group comparisons were performed using McNemar tests. Multivariable analyses were performed using logistic regression to adjust for age, educational level, previous PSA testing, and a family history of PSA cancer. All reported *P*-values are two-sided.

In order to respect intention to treat, patients who answered 'I don't know' or for whom data concerning the main outcome measure were missing were classified as 'willing to perform PSA screening', thereby putting the intervention in the least favourable situation for demonstrating efficacy. Sensitivity analyses was performed to inform the impact of this choice on results.

Patients in the intervention group answered the question before and after reading the decision aid. If they answered 'No, I don't want to be screened for prostate cancer using PSA' after reading the aid, having responded 'Yes' or 'I don't know' before doing so, a change in opinion against screening for prostate cancer was noted.

Statistical analyses were carried out using SAS (version 9.3).

Table 2. Primary outcome: patients intention to undergo prostate cancer screening (*n* = 1170)

Intention to undergo screening	Intervention (*n* = 588)	Control (*n* = 582)	*P*-value
Yes, *n* (%)	331 (56.3)	432 (74.2)	
I don't know, *n* (%)	132 (22.4)	89 (15.3)	
Missing data, *n* (%)	2 (0.3)	4 (0.7)	<0.0001
Total, n (%)	465 (79.1)	525 (90.2)	
No, *n* (%)	123 (20.9)	57 (9.8)	

Table 3. Sensitivity analyses for the primary outcome: patients intent to undertake prostate cancer screening (*n* = 943)[a]

	Intervention (*n* = 454)	Control (*n* = 489)	*P*-value[b]
Patient wants to be screened for prostate cancer ('Yes'), *n* (%)	331 (73.0)	432 (88.3)	<0.0001
Patient doesn't want to be for screened prostate cancer ('No'), *n* (%)	123 (27.0)	57 (11.7)	

[a]Missing data or patients answering 'I don't know' were excluded from analyses. [b]Difference between intervention and control group for intent to undergo prostate cancer screening was: 15.4%; 95% CI = 10.4 to 20.4.

Table 4. Patients' underlying reasons for decision on prostate cancer screening

Intention to undergo screening	Underlying reason [a]	Total (*n* = 588) *n* (%)	Intervention (*n* = 588) *n* (%)	Control (*n* = 582) *n* (%)	*P*-value
Yes	**I will follow my physician's advice**	**58 (5.0)**	**44 (7.6)**	**14 (2.4)**	**<0.0001**
	I have a family history of prostate cancer	23 (2.0)	11 (1.9)	12 (2.0)	0.85
	I'm afraid of cancer	95 (8.1)	49 (8.4)	46 (7.8)	0.69
	I believe prostate cancer screening can protect me from the disease	**372 (31.8)**	**215 (36.9)**	**157 (26.7)**	**0.0001**
	I have other prostate conditions	35 (3.0)	21 (3.6)	14 (2.4)	0.21
	I have a family history of cancer (aside from prostate cancer)	16 (1.4)	9 (1.5)	7 (1.2)	0.59
	I wish to know about my health	42 (3.6)	20 (3.4)	22 (3.7)	0.79
	Other reasons	77 (6.6)	38 (6.5)	39 (6.6)	0.95
No	**I don't think prostate cancer screening would benefit my health**	**101 (8.6)**	**21 (3.6)**	**80 (13.6)**	**<0.0001**
	I will follow my physician's advice	12 (1.0)	7 (1.2)	5 (0.9)	0.55
	I'm afraid of side effects	**16 (1.4)**	**5 (0.9)**	**15 (2.6)**	**0.0005**
	I don't want to know	27 (2.3)	17 (2.9)	10 (1.7)	0.16
	No explanation	14 (1.2)	1 (0.2)	7 (1.2)	0.98
I don't know	There is no consensus about prostate cancer screening	11 (0.9)	5 (0.9)	6 (1.0)	0.77
	I wish to have more information before I make my decision	125 (10.7)	55 (9.5)	70 (11.9)	0.17
	I'm afraid of side effects	**8 (0.7)**	**1 (0.2)**	**7 (1.2)**	**0.03**
	No explanation	45 (3.8)	23 (4.0)	32 (5.4)	0.002

Bold lines highlight significant differences in the proportion of patients eliciting the given reason. [a]A patient could give several reasons to explain his decision on prostate cancer screening.

RESULTS

From November 2012 to February 2013, 1192 patients agreed to participate. Of these, 22 (1.8%) were ineligible, leaving 1170 patients who were randomised: 588 in the intervention group and 582 in the control group (Figure 1).

Participants' mean age was 61 years (standard deviation 6.4 years). In total, 709 (60.6%) patients had a history of PSA testing and 113 (9.7%) had a family history of prostate cancer (not first-degree relative) (Table 1).

There were no differences in patients' expectations for PSA screening for prostate cancer between the two groups prior to the intervention.

For the primary outcome, 123 (20.9%) patients in the intervention group and 57 (9.8%) patients in the control group did not intend to be screened for prostate cancer (difference = 11.1%, 95% confidence interval [CI] = 7.0 to 15.2, *P*<0.0001) (Table 2). In total, 331 (56.3%) patients in the intervention group and 432 (74.2%) patients in the control group wanted to undergo PSA screening for cancer. There were 2 missing data for intention to undergo screening in the intervention group and 4 in the control group (Table 2). Raw results showed a significant association between intervention and the intention not to be screened for prostate cancer (unadjusted odds ratio [OR] 2.4, 95% CI = 1.7 to 3.4, *P*<0.0001). These results were consistent when adjusted for age, history of PSA testing, and family history of prostate cancer (adjusted OR 2.6, 95% CI = 1.8 to 3.8, *P*<0.0001). When performing sensitivity analyses, excluding the missing data and patients who were unsure about PSA testing, there was no change in the nature or direction of results (Table 3).

When asked about the reasons behind their responses, patients reported several (Table 4), similar to findings in the literature.[13] The proportion of individuals expressing each underlying reason between the two arms was compared. After patients read the decision aid, the following was noted:

- a reduction in individuals expressing the idea that cancer screening would protect them from the disease (*P*<0.0001);
- an increase in those who believed that prostate cancer screening would not benefit their health (*P*<0.0001);
- an increase in those who thought prostate cancer screening may involve procedures with harmful side effects (*P* = 0.0005).

Within the intervention group, patients' intention to undergo prostate cancer

Table 5. Within-group analysis for intervention group with regard to the primary outcome: patients intention to undertake prostate cancer screening (*n* = 588)

Intention to undergo screening	Before intervention, *n*	After intervention, *n*	*P*-value
Yes	532 (90.5)	465 (79.1)	<0.0001
No	56 (9.5)	123 (20.9)	

screening before and after the intervention was compared. After receiving the information notice, there was a significant decrease in the intent to undergo prostate cancer screening (*P*<0.0001) (Table 5).

Predictors of change were sought in the decision to disfavour prostate cancer screening. Higher education level (college, or university), was associated with such change (OR 1.7, 95% CI = 1.1 to 2.6, data not shown) when compared with lower level of education (primary and/or secondary school).

On the contrary, neither family history of prostate cancer (OR 0.82, 95% CI = 0.42 to 1.6), nor previous testing for prostate cancer (OR 0.92, 95% CI = 0.58 to 1.4) were associated with change of decision (data not shown).

DISCUSSION

Summary

This study has shown that a two-page decision aid using visual representations reduced the proportion of patients intending to undergo prostate cancer screening. In this study, within the intervention group, there was an association between higher-level educational (college) and change of decision concerning prostate cancer screening.

Strengths and limitations

This study has several limitations. The intervention aimed to provide patients with evidence-based knowledge on prostate cancer screening. According to the theory of reasoned action, knowledge influences attitude.[14] Attitude, combined with social norms, determines intention, which is the immediate precursor of behaviour. As this is a general model, more studies are required to evaluate whether changes in patients' knowledge about PSA screening actually result in changes in their behaviour and in the process of care.

In addition, the primary outcome measure assessed the intent to undergo screening right after the patient read the decision aid. It is possible that the effect of the decision aid might not last long, although it is unlikely that the intervention could have a paradoxical effect, with there being a reduction in the intent to undergo screening initially and a later increase in the intention to undergo screening.

The efficacy of the intervention was assessed without taking into account any patient–physician discussion that could have taken place afterwards. Although international guidelines concur that prostate cancer screening is not recommended in the general population, a large number of GPs and urologists still prescribe these tests to patients, believing that it is more beneficial than harmful for patients to undergo PSA testing.[15,16]

A cluster analysis by GP was not undertaken as the randomisation was done at the patient level and patients' intent was evaluated before any interaction took place.

This study had a randomised design. The decision aid contained only evidence-based informations. It was tested and adapted according to the comments of a sample of patients. The study was pragmatic, conducted in conditions close to daily practice. The authors believe that the study offers useful informations and a simple tool for GPs who want to help patients to make an informed decision on prostate cancer screening.

Comparison with existing literature

The results concur with those from the literature: several studies have evaluated different decision aids in primary care contexts and reported positive effects on patients' knowledge and a negative effect on the intention to undergo screening for prostate cancer and/or actual prostate cancer screening.[13,17,18] These studies also showed a reduction in screening rates.

In line with these studies, the intervention used in this study helped to clarify the idea that screening did not protect from cancer and that prostate cancer screening could involve procedures with harmful side effects.

Implications for practice

Although there are various decision aids (print, video, and web application), available to help patients make a decision on whether or not to be screened for prostate cancer,[19,20] only 25% of physicians use them in practice. Among various barriers elicited for their use, physicians mentioned the lack of time and resources.[21] There is a need for an efficient and simple-to-use decision aid that could be integrated in the medical visit without disrupting the consultation.

This pragmatic study proved that it was possible to integrate such an intervention in the context of daily routine, without disrupting physician activities: physicians recruited patients during their usual consultations but patients read the information notices outside of the physician's office in the waiting rooms.

Although the decision aid was developed to be read without the presence of a physician, clinicians are encouraged to directly discuss this topic using the visual representations of the aid with those patients who are likely to have a lower level of education; this would ensure their comprehension of the benefits and limits of prostate cancer screening. All patients, independently from their characteristics, should receive appropriate information, adapted to their capacities. Further studies should focus on decision aids aimed at patients who have a lower level of education.

Overall, the efficacy of a simple, easy-to-use, decision aid that impacted on patients' intention to undergo prostate cancer screening in primary care practices in France was demonstrated. The decision aid can allow both patients and physicians to understand the complexities of prostate cancer screening by providing them with up-to-date information about the benefits and risks of screening. This could reduce overdiagnosis and prevent patients from undergoing unnecessary tests or harmful treatment. A two-page decision aid using visual representations to help patients decide whether or not to undergo prostate cancer screening was developed and tested. The intervention reduced the proportion of patients intending to undergo prostate cancer screening when compared with those receiving usual care.

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Ethical approval

This study was approved by the ethics committee of Paris Descartes University on 4 June 2012 and registered under reference number 2012 05 01.

Provenance

Freely submitted; externally peer reviewed.

Competing interests

The authors have declared no competing interests.

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Appendix 1. Characteristics of participating physicians (*n* = 86)

Characteristic	Value
Female sex, *n* (%)	43 (53%)
Experience, years (mean range)	22 (1–36)
Setting, *n* (%)	52 (60.5%)
Urban	52 (60.5%)
Part rural	20 (23.2%)
Rural	9 (10.5%)
Missing data	5 (5.8%)
Teacher in medical school, *n* (%)	47 (54.6)
Consultation duration, minutes, *n* (%)	
15	20 (23.2)
20	44 (51.2)
25	9 (10.5)
30	8 (9.3)
Missing data	5 (5.8)
Family history of prostate cancer, *n* (%)	16 (19.7)
Personal history of prostate cancer, *n* (%)	1 (1.2)
Favourable to prostate cancer screening for asymptomatic patients, *n* (%)	
Yes	18 (20.9)
No	60 (69.8)
I don't know	1 (1.2)
Missing data	7 (8.1)
Explains prostate cancer screening controversy to patients, *n* (%)	
Systematically	56 (65.1)
Sometimes	24 (27.9)
Never	1 (1.2)
Missing data	5 (5.8)
Orders PSA testing for asymptomatic patients, *n* (%)	
High risk patients only	58 (67.4)
On patients' demand	1 (1.2)
Physician's judgement (excluding high risk patients)	15 (17.4)
Systematically	6 (7.0)
Never	1 (1.2)
Missing data	5 (5.8)

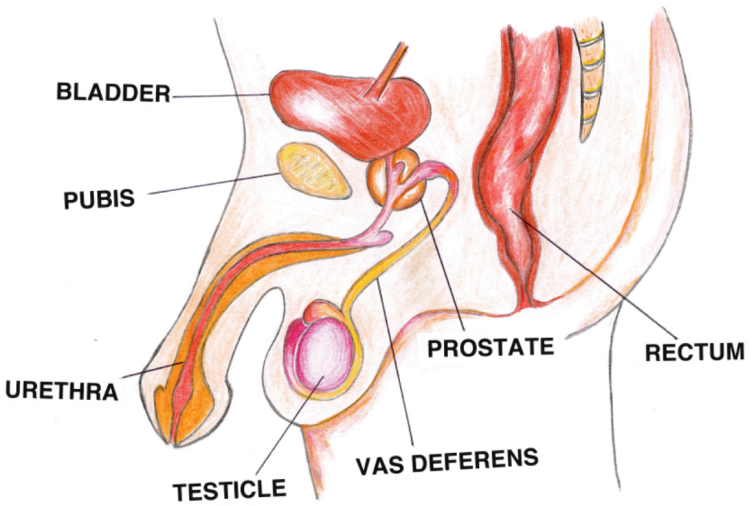
PSA = prostate-specific antigen.

Appendix 2. Decision aid.

INFORMATION NOTICE REGARDING PROSTATE CANCER SCREENING THROUGH QUANTITATIVE ANALYSIS OF THE PSA

What are the prostate and PSAs ?

The prostate is a small gland situated just underneath a man's bladder. It produces secretions as part of sperm as well as other substances; one of these substances is called PSA (Prostate Specific Antigen). With age, cancer can develop in the prostate and increase the quantity of PSA present in the blood. But **PSA levels can be high when cancer is not present or normal when cancer is present: the reliability of prostate cancer screening using PSA is therefore limited.**



Why should you inform yourself about PSA screening?

Some doctors offer an early screening for prostate cancer through a regular analysis of PSA levels, but this screening is controversial and is not recommended by French or International Health Authorities.

This is why PSA screening is controversial: **when a man is over fifty years of age it is very common to have malignant cells in the prostate. The vast majority of men with these malignant cells will not suffer from them, as they will never grow into a symptomatic cancerous disease.**

Finding these cells during a screening can lead to heavy treatments like surgery or radiotherapy. Common side effects of these treatments include impotence and/or incontinence (in more than half of the men treated). It is possible, yet exceptional, for more serious complications to occur (blood poisoning).

To this day, **scientific studies have not demonstrated that prostate cancer screening increases life expectancy.** Indeed if we compare a group of screened patients with a group of unscreened patients, we notice that there is no difference in the overall mortality between the two groups after a few year's monitoring (please check the figure at the back of this page).

What is our advice for you?

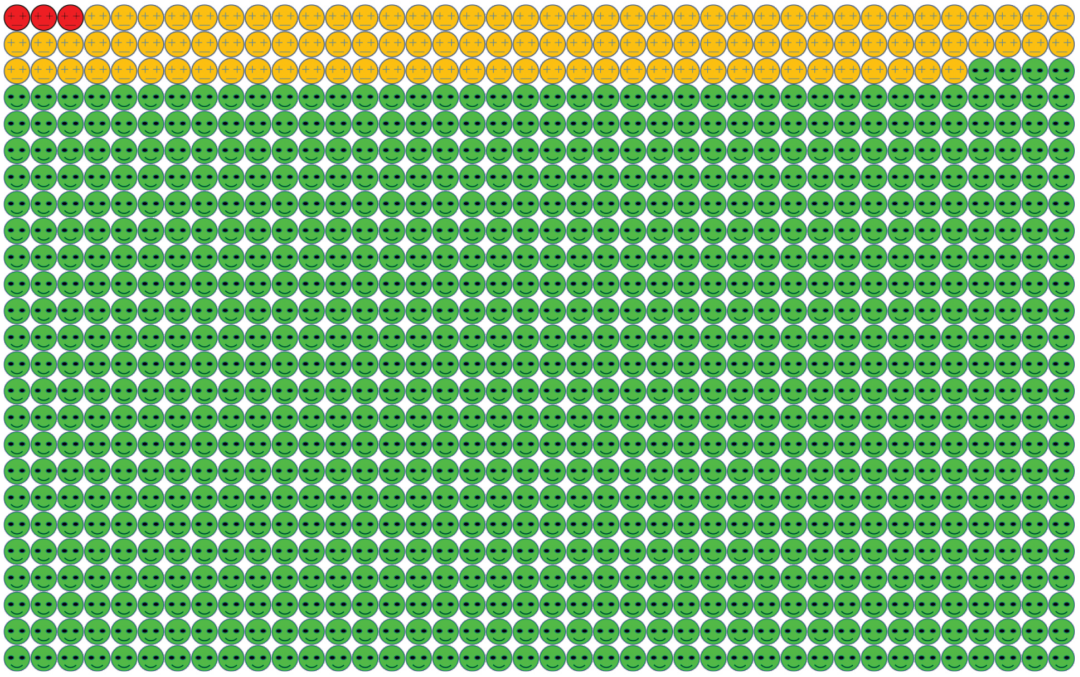
Currently this prostate cancer screening is not recommended by the Health High Authority, the National Institute for Cancer, or the College of General Medicine. It is recommended by the French Association for Urology.

The comparison between the hypothetical advantages of this screening and the known risks of the treatments associated to it explains why it is necessary to be informed. Once you're informed, the choice is yours. Should you wish it, we can talk about it together during your next appointment.

Appendix 2 continued. Decision aid.

Here are the results of a very large study spanning over 9 years. It monitored 2 groups of men aged 55 to 69: one group was offered a regular PSA quantitative analysis (the SCREENED GROUP) and one group wasn't (the CONTROL GROUP). The figure shows the situation at the end of the study.

SCREENED GROUP: after 9 years, out of 1.000 men, 3 had died of prostate cancer ; 113 had died of other causes ; 884 were alive .



CONTROL GROUP: after 9 years, out of 1.000 men, 4 had died of prostate cancer ; 113 had died of other causes ; 883 were alive .