# Informed decision making on PSA testing for the detection of prostate cancer: An evaluation of a leaflet with risk indicator

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ABSTRACT

Background: Population-based screening for prostate cancer (PCa) remains controversial. To help men making informed decisions about prostate specific antigen (PSA) screening a risk indicator (www.uroweb.org) was developed. This risk indicator is embedded in a leaflet that informs men about the pros and cons of PCa screening and enables calculation of the individual risk of having a biopsy detectable PCa.

Aim: To assess the effect of providing a leaflet including individualized risk estimation on informed decision making of men, i.e. knowledge about PCa and PSA screening, attitude towards undergoing a PSA test and intention to have a PSA test.

Methods: An intervention study among 2000 men, aged 55–65 years, randomly selected from the population registry of the city of Dordrecht, the Netherlands, in 2008. Men were sent a questionnaire on knowledge of PCa, attitude and intention to have a PSA test. Men without a history of (screening for) PCa were sent the leaflet and Questionnaire 2 within 2 weeks after returning Questionnaire 1. Validated health and anxiety measures were used.

Results: One thousand and twenty seven of 2000 men completed Questionnaire 1 (51%), of whom 298 were excluded due to a history of (screening for) PCa. Of the 729 remaining men, 601 completed Questionnaire 2 as well. At the second assessment significantly more men met the requirements of informed decision making (15% versus 33%, $p < 0.001$), more men had relevant knowledge (284/601, 50% versus 420/601, 77%, $p < 0.001$) and the intention to have a PSA test had increased ($p < 0.001$).

Conclusions: Providing information on PCa screening combined with individualized risk estimation enhanced informed decision making and may be used for shared decision making on PSA screening of physicians and patients.

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## 1. Introduction

Prostate cancer (PCa) is the most common malignancy in men, with the third cause of death in Europe in 2006.[1] Population-based screening on PCa remains controversial although it has shown to reduce PCa mortality by 20% in a randomised screening trial (ERSPC).[2] This mortality reduction was associated with a high risk of overdiagnosis, i.e. detection of cancers that in the absence of screening would not have been diagnosed within the person's lifetime. Between 27% and 56% of all cancers detected in the screening arm of ERSPC (section Rotterdam, the Netherlands) can be classified as potentially indolent, for which invasive treatment may not be necessary.[3,4]

While lacking more specific biomarkers, the most commonly used screening tool for PCa is the prostate specific antigen (PSA) test, despite its known weaknesses resulting in false-positive and false-negative results.[5,6] The false-positive results create uncertainty[7] and 'unnecessary' additional testing.[2] At the same time men are encouraged to consider PSA screening by media reports, social network, experiences with PCa of friends and family.[7,8] A possible way out of this dilemma is the use of multivariable prediction models or nomograms.[5] They can improve the diagnostic value of PSA screening by increasing its relative specificity by adding other potential predictive risk factors to the decisional process.[5,9] Based on the screening data from the ERSPC (section Rotterdam, the Netherlands) a multivariable model was developed and translated into a user friendly instrument.[10] This 'Prostate Risk Indicator®' (PRI®) provides balanced information on the pros and cons of having a PSA test for PCa and enables men and their physicians to calculate the risk of having biopsy detectable PCa. This may support men making informed choices about having a PSA test or not.[11–13]

The purpose of this intervention study was to assess the effect of providing a leaflet with individualized risk estimation on informed decision making of men. We used Marteau's definition of an informed choice, i.e. 'a choice, that is based on relevant knowledge, consistent with the decision maker's value and behaviourally implemented'.[14]

In this study the following hypotheses were tested:

– The number of men who are able to make an informed choice on PSA screening will increase after the provision of a leaflet including an individualized risk estimation.
– The leaflet with risk indicator will have no impact on the generic health related quality of life and the generic anxiety of men.

## 2. Materials and methods

### 2.1. Study population and procedure

For this study, a random sample of 2000 men, age 55–65 years from the population registry of the city of Dordrecht, the Netherlands, were sent a letter with information about the study and a questionnaire (Questionnaire 1) on PSA screening, in July 2008. Men who returned the completed Questionnaire 1 were sent a paper version of the PRI® including information about PCa and the pros and cons of PCa screening and a risk indicator to calculate their own estimated risk of having PCa. This paper version will be referred to as 'leaflet'. The leaflet and Questionnaire 2 were sent within 2 weeks after men returned Questionnaire 1. Men with a history of PCa or PSA screening were excluded from the second assessment. Actual decisions on PSA screening and PSA test results were not studied.

### 2.2. Intervention

The PRI® is based on the screening results of 6288 men participating in the initial screening round of the ERSPC section Rotterdam, the Netherlands. The PRI® as a whole exists of balanced evidence based information about the prostate, PCa, incidence, symptoms, the PSA test and further research tests which may be carried out, a list of pros and cons of PSA screening (Appendix A) plus 6 decision levels (www.uroweb.org).[15] Level 1 uses information on family history, age and urinary function to calculate a rough estimation on the probability of having a biopsy detectable PCa. In the study described here the leaflet including the information and level 1 of the risk indicator were evaluated.[16] This leaflet is an extended version of earlier consumer information about prostate cancer screening published by the Dutch Cancer Society. An independent organisation tested the leaflet with a target population which was not involved in this study. Results showed that the provided information was balanced and accurate.

### 2.3. Questionnaires

#### 2.3.1. Respondents' characteristics
Questionnaire 1 contained items on age, education, marital status, employment status, and co-morbidity. Educational level was classified as low (no education, primary school or lower education), intermediate or high (higher education or university degree). Employment status was classified as paid job, unpaid job or retired. The unpaid group existed of men who did not work due to health problems, were jobless, looked after the children, did the housekeeping or had voluntary jobs. The prevalence of co-morbidity was assessed using a standard list of 11 chronic diseases, including asthma, hypertension, diabetes, and cancer. Men were asked which disease(s) they currently were experiencing or had experienced during the past year.

#### 2.3.2. Informed choice
We used Marteau's definition of an informed choice, i.e. 'a choice that is based on relevant knowledge, consistent with the decision maker's value and behaviourally implemented'.[14] This implies that an informed choice to undergo a screening test occurs when an individual has relevant knowledge about the test, has a positive attitude towards undergoing a test, and does undergo it. If an individual has relevant knowledge about the test, has a negative attitude, and does not undergo it, he also makes an informed choice. All other combinations reflect uninformed choices.