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

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ARTICLE INFO

Article history: Received 3 September 2009 Received in revised form 22 November 2009 Accepted 24 November 2009

Keywords: Informed choice Informed decision making Prostate cancer Prostate Risk Indicator PSA test Screening

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. Population-based screening on PCa remains controversial although it has shown to reduce PCa mortality by 20% in a randomised screening trial (ERSPC). 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 uncertainty⁷ 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 Question-

naire 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.

We measured informed choice, i.e. knowledge, attitude towards undergoing a PSA test and intention to have a PSA test, before and after men were provided with the leaflet including the risk indicator.

2.3.2.1. Knowledge. To assess whether respondents had relevant knowledge on PCa we included 21 items covering disease and symptoms, diagnostic process, treatment and side-effects of treatment (Appendix B). Response options were true, not true, and don't know. Per correct answer, one point was added to the total 'Knowledge of PCa' score. We defined relevant knowledge as sufficient if 15 knowledge items (70%) were correctly answered.

Additionally, respondents were asked in both questionnaires to give a self-perceived risk estimation of having PCa. In Questionnaire 2 respondents were also asked to report the individualized risk as estimated by the risk indicator. Marteau considers risk perception of the condition being screened for as part of the knowledge element. However, the reported self-perceived risk and the individualized risk estimation by the risk indicator cannot be scored as 'correct' or 'incorrect' and were thus not integrated in the 'knowledge' score.

2.3.2.2. Attitude. The attitude towards undergoing a PSA test was measured by an attitude scale based on the Theory of planned behaviour¹⁷ and adapted from Marteau's multidimensional measure for informed choice.¹⁴ It contained four items, e.g. I consider having a PSA test a good idea–not a good idea, harmful–not harmful, scored on a seven point scale. Scores were transformed to a scale ranging from 0 to 100. Scores equal to or lower than 50 indicate a negative attitude; scores above 50 indicate a positive attitude towards PSA screening.

2.3.2.3. Intention. We did not study actual participation in PSA screening and thus do not know if choices were behaviourally implemented. Instead we used the reported intention to have a PSA test.

2.3.3. Psychological measures

Both questionnaires consisted of the following validated self-reported psychological measures:

- (1) The Short form health survey (SF-12) was used to measure generic health related quality of life. 18 The 12 items are used to construct physical and mental component summary measures (PCS-12 and MCS-12) that are scored using norm-based methods, where the mean and standard deviation (SD) are 50 and 10 in the general US population. A one-point difference can be interpreted as one-tenth of a SD. 19
- (2) The validated Dutch translation of the State Trait Anxiety Inventory (STAI-6),²⁰ was used to measure generic anxiety. This scale contains six items, e.g. feeling calm, relaxed or worried. Scale scores range from 20 to 80, scores above 44 indicate a high level of anxiety.²¹

Questionnaire 2 also included the following items:

- (1) The Prostate Cancer Anxiety subscale, one out of three subscales of the validated Dutch translation of the Memorial Anxiety scale for Prostate Cancer (MAX-PC).²² Eight of the 11 items were used, for example, being scared of having PCa, not wanting to deal with feelings about PCa. Item scores were transformed to ranges of 0 to 33, with higher scores indicating more PCa-specific anxiety.
- (2) The validated Dutch translation of the Decisional Conflict Scale (DCS), ²³ was used to measure the level of decisional conflict about having a PSA test or not, containing three subscales. The first subscale 'Uncertainty' (three items) refers to the level of uncertainty a patient experiences about making a health care decision. The second subscale 'Factors contributing' (nine items) relates to, e.g. feeling supported in decision making and values. The third subscale 'Effective decision making' (four items) measures the extent a man perceives the decision as effective, based on information and personal value. Scores range from 0 to 100, with scores above 37.5 indicating a decisional conflict.²⁴

2.4. Statistical analysis

The statistical analysis included descriptive statistics. Men who completed both questionnaires were compared with men who only completed Questionnaire 1 to assess potential selection bias. The χ^2 test was used for categorical variables and unpaired t-test for continuous variables.

To compare the outcomes of the sequential questionnaires of each participant, the Wilcoxon Signed Rank test was used for categorical variables and the paired t-test for continuous variables. Regulations for missing items in the STAI-6, MAX-PC, DCS and attitude towards PSA screening were conducted according to the guidelines of the SF-36 Health Survey Manual.²⁵

Correlations between the risk estimations as calculated by the risk indicator versus scores of the attitude towards undergoing a PSA test, the intention to have a PSA test and PCa specific anxiety, respectively, were calculated. The Spearman's rho was used for the categorical variable and the Pearson correlation for continuous ones.

Analyses were performed using SPSS (version 15.0, SPSS Inc., Chicago, IL). P-values less than 0.05 were considered statistically significant.

3. Results

3.1. Respondents' characteristics

In July 2008, 2000 questionnaires were sent to men aged 55–65, of which 1,027 (51%) were completed and returned. Two hundred and ninety eight men were classed as ineligible since they had previously been PSA tested (n = 282), had been diagnosed with PCa (n = 14) or were outside the required age range (n = 2). Subsequently the leaflet and Questionnaire 2 were

sent to the remaining 729 eligible men, of whom 601 men completed Questionnaire 2 (82%) (Fig. 1).

Table 1 shows the characteristics of the participants who completed both questionnaires (n = 601). Their mean age was 59.5 years (SD 2.9), 244/601 (41%) had an intermediate education and 187/601 (31%) were highly educated, 506/601 (85%) were married, 342/601 (58%) had a job and 169/601 (28%) were retired. The average number of comorbid conditions was less than one, but ranged between zero and six. This cohort did not differ significantly from the 128 men who only completed Questionnaire 1.

3.2. Informed choice

Significantly more men met the requirements of informed choice, 81/535 men (15%) at the first versus 174/522 men (33%) at the second assessment (p < 0.001). These men had adequate knowledge and their intention to have a PSA test or not reflected their attitudes towards the PSA test (Table 2).

3.2.1. Knowledge

Men's knowledge on PCa increased significantly for 16 of the 21 questions and for the total scores. Significantly more men were classified as having sufficient relevant knowledge (284, 50% versus 420, 77%, p < 0.001) (Table 3).

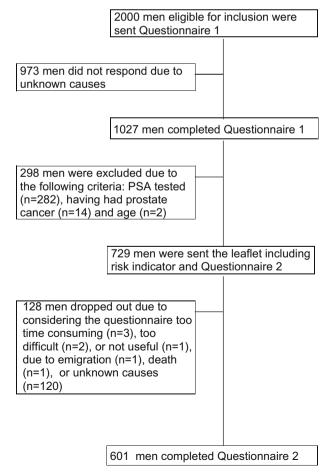


Fig. 1 - Profile of study population.

The self-perceived risk estimation of having PCa decreased significantly (p < 0.001), with 383 (71%) estimating their risk to have PCa as \leq 15% before versus 458 (90%) after receiving the leaflet. Men who intended to undergo PSA screening estimated their risks on having PCa as higher than men who did not (25% versus 13% with an estimated risk of \geq 15%, respectively). Risk estimations as calculated with the risk indicator did not differ significantly from self-perceived risk estimations at the second assessment (p = 0.19). The intention to have a PSA test and PCa-specific anxiety were associated with higher levels of estimated risk as calculated by the risk indicator (r (512) = 0.202, p < 0.001, and r (512) = 0.133, p = 0.003, respectively).

3.2.2. Attitude

The number of men with a positive attitude towards undergoing a PSA test decreased significantly (437, 78% versus 415, 72%, p < 0.001, Table 4).

3.2.3. Intention

At the second assessment more men reported the intention to have a PSA test (86, 14% versus, 126, 21%, p < 0.001, Table 4). The number of men with a positive attitude and the intention to have a PSA test increased as well (67, 16% versus 104, 27%).

3.3. Psychological measures

At the second assessment mental health had increased and generic anxiety had decreased significantly (Table 5). The number of men with 'high-anxiety' decreased from 74 (12%) to 40 (7%). The average score of the PCa specific anxiety (MAX-PC) was low; the majority of men had no PCa specific anxiety (512, 89%). Furthermore, the low average decision conflict score (DCS) indicated that the majority of men did not have a decisional conflict about having a PSA test or not (350, 65%). The scores of the subscale 'uncertainty' showed that 363 men (65%) were certain about their choice of having a PSA test or not.

Five hundred and eighty one men (97%) reported to have read the leaflet completely, of whom 553 men (92%) indicated to have understood the information.

4. Discussion

After providing information on PCa and individualized risk estimates with a prostate risk indicator, the number of men with sufficient relevant knowledge on PCa improved significantly and their intention to have a PSA test or not better reflected their attitude towards the PSA test. The number of men who met the requirements of informed decision making increased significantly as well.

The concept of informed choice as defined by Marteau and (adaptations of) her attitude scale have to our knowledge not yet been applied to assess the impact of an intervention on numbers of informed choices in PSA screening. Although we found that the rate of informed choices increased from 15% to 33%, the majority of men still made an uninformed choice. This was mainly due to value-inconsistency, for

Table 1 – Characteristics of the participants.			
	Men who completed Questionnaire 1 and 2 n = 601	Men who only completed Questionnaire 1 n = 128	p-Value
Age (year)			0.187
Average (SD, range)	59.5 (2.9, 55–65)	59.2 (2.6, 55–64)	
Educational level (%)			0.360
Low	169 (28)	44 (34)	
Intermediate	244 (41)	49 (38)	
High	187 (31)	35 (27)	
Marital status (%)			0.950
Married or cohabiting	506 (85)	107 (84)	
Single	93 (16)	20 (16)	
Employment status (%)			0.049
Paid job	342 (58)	86 (68)	
Unpaid job	84 (14)	18 (14)	
Retired	169 (28)	23 (18)	
Comorbidity			0.902
Average number of conditions (range)	0.8 (0–6)	0.8 (0–4)	

Table 2 – Aspects of an informed choice before and after receiving the leaflet, i.e. sufficient adequate knowledge, attitude towards having a prostate specific antigen test (PSA) and intention to have a PSA test.

	Intention to have a PSA test		Total
	Yes	No	
Before receiving the leaflet, n = 601			
Sufficient adequate knowledge, ^b positive attitude	28 ^a	182	210
Insufficient adequate knowledge, positive attitude	37	176	213
Sufficient adequate knowledge, b negative attitude	6	53 ^a	59
Insufficient adequate knowledge, negative attitude	3	50	53
Total	74	461	535
After receiving the leaflet, $n = 601$			
Sufficient adequate knowledge, b positive attitude	76 ^a	228	304
Insufficient adequate knowledge, positive attitude	18	58	76
Sufficient adequate knowledge, ^b negative attitude	9	98 ^a	107
Insufficient adequate knowledge, negative attitude	8	27	35
Total	111	411	522

^a Men in these categories meet the predefined criteria of an informed choice.

Table 3 – Frequencies with percentage of sufficient relevant knowledge and the mean of total knowledge score and per knowledge category, i.e. the average number of items that was answered correctly before and after receiving the leaflet.

	Before n = 601	After n = 601	p-Value
Sufficient relevant knowledge	284 (50%)	420 (77%)	<0.001
Total knowledge score (range 0–21)	13.5	16.2	< 0.001
Disease and symptoms (range 0–9)	5.9	7.3	< 0.001
Diagnostic process (range 0–5)	3.6	4.3	< 0.001
Treatment (range 0–4)	2.4	2.8	< 0.001
Side-effects of the treatment (range 0–3)	1.7	1.8	0.150

instance having a positive attitude towards PSA screening but no intention to undergo it. No intention to have a PSA test was related to a low risk estimation of having PCa as calculated by the risk indicator. Since in this study men were both informed about PCa (screening) and provided with an individualized risk estimation of having PCa, we cannot formally

^b Sufficient adequate knowledge: at least 15 out of 21 correctly answered knowledge questions.

Table 4 – Considerations, intention and attitude towards the prostate specific antigen (PSA) test and self-perceived risk of prostate cancer by respondents before and after receiving the leaflet, and risk estimation as <u>calculated by the risk indicator.</u>

	Before n = 601	After n = 601	p-Value
Considering to have a PSA test (%)	134 (22)	154 (26)	0.052
Attitude towards undergoing a PSA test Negative attitude (%) Positive attitude (%)	124 (22) 437 (78)	161 (28) 415 (72)	0.008
Intention to have a PSA test within 3 months (%)	86 (14)	126 (21)	<0.001
Self-perceived risk of having prostate cancer by respondents (mean, SD, range) Risk between 0–25%	14.1 (16.0, 0–100) 450 (83)	9.8 (11.6, 0–50) 448 (90)	<0.001
26–50% 51–75% 76–100%	84 (16) 3 (1) 4 (1)	49 (10)	
Risk estimation of having prostate cancer as calculated by the risk indicator (mean, SD, range) Risk between		10.5 (10.6, 0–80)	
0–25% 26–50% 51–75%		482 (94) 21 (4) 5 (1)	
76–100%		4 (1)	

Table 5 – Average scores (SD) of Short form health survey (SF-12) and State Trait Anxiety Inventory (STAI-6) before and after receiving the leaflet and Memorial Anxiety scale for Prostate Cancer (MAX-PC) and the Decisional Conflict Scale (DSC) after receiving the leaflet.

	Before n = 601	After n = 601	p-Value
SF-12 Generic Health Status (range 0–100, higher scores indicate better health)			
Physical health (PCS-12)	50.4 (9.1)	51.5 (7.4)	0.572
Mental health (MCS-12)	52.1 (9.9)	53.0 (9.0)	0.005
STAI- 6 Generic Anxiety score (range 20–80, higher scores indicate more anxiety)	33.3 (9.6)	30.9 (8.2)	< 0.001
MAX-PC Subscale Prostate cancer anxiety (range 0–33)		4.5 (5.3)	
DCS Decision conflict Scale total score (range 0–100)		32.8 (12.6)	
Three subscales			
Uncertainty		40.1 (21.7)	
'Factors contributed'		33.0 (12.7)	
Effective decision making		27.3 (14.0)	

separate the effect of providing information from that of providing individualized risk estimates rather than average risks. It seems plausible however, that providing decision-relevant knowledge such as individualized risk estimates will influence individuals' attitude towards having PSA screening.

The number of men who intended to have a PSA test increased while the number of men with a positive attitude decreased. A possible explanation is that men were better informed about the pros and cons of PSA screening after the intervention, resulting in some men in an attitude that turned negative (22/601, 6%) and in others in an intention to have a PSA test (40/601, 7%). However, a large number of men still had a positive attitude towards PSA screening without the intention to have PSA screening (252/601, 42%).

Volk and colleagues and Gattellari and colleagues assessed the impact of decision aids on knowledge, intention and uptake of PSA screening in randomized designs. Gattellari and colleagues found improved knowledge and a reduced interest in PSA screening. ²⁶ Volk and colleagues concluded that intervention subjects were more knowledgeable of prostate cancer screening than were control subjects and that the decision aid appeared to promote informed decision making. ²⁷

Several limitations are worth mentioning. The non-response on Questionnaire 1 of 49%, although found more often in questionnaire studies in the general population, may have biased the study findings. Only the age of the non-respondents was known and that did not differ significantly from the respondents' age.

In the Netherlands it is forbidden by law to offer PSA tests within a screening context. This had two consequences for our study. Firstly, we could not follow-up on identifying who actually had the PSA test. If a man wanted to have a PSA test after he participated in our study, he needed to go to his general practitioner and ask for it. Since it is unknown to us who these general practitioners are, we could thus not assess whether choices were behaviourally implemented. Instead we used the reported intention to have a PSA test to assess informed choice. However, due to all kind of barriers people can be prevented to perform their intended behaviour, resulting in differences between intended choice and the final behaviour.28 Secondly, we did not want to give the respondents in our study the impression that they should have an opinion about PSA testing and that they should consider having such a test themselves. Therefore the DCS and MAX-PC were included only in Questionnaire 2.

Furthermore, we used a non-validated questionnaire on PCa knowledge. Different measures have been developed, but have limited validity and reliability.²⁹ The advantage of our knowledge measure, that overlaps with the validated 10-item PROCASE Knowledge Index,³⁰ is that it contains items about the process of screening, PCa and treatment for PCa. We defined sufficient relevant knowledge as 15 or more (70%) correct answers. This is an arbitrary choice. If a cut off point of 17 correct answers had been used, the results would still have shown an increase in the number of informed choices. Defining sufficient relevant knowledge is a general problem of informed decision making: 'what is it they need to know and whose business is it to decide that'.³¹

Pros of our study include the large number of respondents and the use of validated measures to assess generic health related quality of life, anxiety, PCa-specific anxiety, and attitude towards screening, as was recommended by Edwards and colleagues.³²

Although the number of men making informed choices about PSA screening increased after the intervention, further improvement is still needed. Providing decision-relevant knowledge such as individualized risk estimates may be a useful addition to Marteau's concept of informed choice. We recommend further research, preferably in a randomized design, into providing individualized risk estimations rather than average risks on attitudes towards the PSA test and on the intention to undergo it by comparing groups receiving the leaflet with versus without the risk indicator. Furthermore, we recommend further research into the assessment of attitude towards individuals' own participation in screening rather than general attitudes towards a screening test.

5. Conclusions

The leaflet including a risk indicator enhanced knowledge about pros and cons of PSA screening and PCa, made men less positive towards screening, enhanced informed decision making, and did not adversely affect men in terms of causing anxiety or negatively influencing mental health. After the intervention most men reported no decisional conflict about having a PSA test or not.

The leaflet including a risk indicator promises to be a useful tool for shared decision making on PSA screening of physicians and patients.

Conflict of interest statement

None declared.

Acknowledgements

We are grateful to the men of the population of Dordrecht, the Netherlands, for participating in the study. We thank the Regional Public Health Service of Department Southern South-Holland Province for their friendly cooperation. We gratefully acknowledge the Prostate Cancer Research Foundation (SWOP) and Physico Foundation, the Netherlands, for funding our study.

Appendix A. Summary of the pros and cons of prostate specific antigen (PSA) screening (www.uroweb.org)

Arguments for PSA screening

If the result of the PSA test is favourable this will calm down my worries.

The PSA test can help to find prostate cancer (PCa) at an early stage and before it leads to complaints.

If as a result of a positive PSA test I undergo successful treatment I may have a better chance of cure and may live longer.

If the treatment is successful in an early stage, I may be spared the late symptoms of PCa such as spread of the tumour to other parts of my body (metastases).

Arguments against PSA screening

If my PSA value is elevated and further study does not show PCa I will have undergone medical testing for nothing and this will have caused unnecessary anxiety.

The PSA test can miss PCa. After a normal result I may feel relieved for no good reason or may still remain worried. An elevated PSA test may detect a slow growing tumour which would otherwise never have given me any trouble. I may be confronted with the possible complications of the treatment of PCa.

Appendix B

See Table B.1.

Table B.1 – 21 statements to assess respondents' knowledge of prostate cancer.

Statements

Disease and symptoms (nine items)

The prostate is located in the belly^a

Prostate cancer (PCa) is the second leading cause of cancer death among men^a

The chance to be diagnosed with PCa declines with aging

A man with early-stage PCa has a slow urinary stream

PCa does not necessarily cause symptoms^a

Urinary problems of old men are caused by benign prostate hypertrophya

Through a prostate biopsy PCa's can be found that would never have caused complaints^a

The 'old man ailment' is an early stage of PCa

Someone who has the 'old man ailment' does not get PCa

Diagnostic process (five items)

If the prostate specific antigen (PSA) test is favourable, it is not necessary to assess the PSA test ever again If the PSA test result is unfavourable, a prostate biopsy is necessary to know whether there is PCa or not PCa can be diagnosed early by a PSA test and if indicated a prostate biopsy a

Using a PSA test PCa will always be found

If the test results of the prostate biopsy are favourable, i.e. no cancer, it is not necessary to repeat the biopsy

Treatment (four items)

Early-stage PCa is responding well to treatment^a

In most cases, metastatic PCa cannot be curatively treated^a

After surgery or radiotherapy, PCa will always be gone

In case of a small prostate tumor, found by PSA testing and biopsy, the doctor may recommend not to treat the tumor but to repeat PSA tests regularly^a

Side-effects treatment (three items)

Urinary incontinence may occur after surgery or radiotherapy of (early detected) PCa^a

Prostatectomy may cause side-effects, for example erectile dysfunction^a

Radiotherapy to treat PCa, does not cause side-effects

REFERENCES

- 1. Karim-Kos HE, de Vries E, Soerjomataram I, et al. Recent trends of cancer in Europe: a combined approach of incidence, survival and mortality for 17 cancer sites since the 1990s. Eur J Cancer 2008;44(10):1345–89.
- Schroder FH, Hugosson J, Roobol MJ, et al. Screening and prostate-cancer mortality in a randomized European study. New Engl J Med 2009;360(13):1320–8.
- 3. Draisma G, Boer R, Otto SJ, et al. Lead times and overdetection due to prostate-specific antigen screening: estimates from the European Randomized Study of Screening for Prostate Cancer. J Natl Cancer Inst 2003;95(12):868–78.
- Cooperberg MR, Broering JM, Kantoff PW, Carroll PR. Contemporary trends in low risk prostate cancer: risk assessment and treatment. J Urol 2007;178(3 Pt 2):S14–9.
- Schroder FH. Review of diagnostic markers for prostate cancer. Recent Results Cancer Res 2009;181:173–82.
- Thompson IM, Pauler DK, Goodman PJ, et al. Prevalence of prostate cancer among men with a prostate-specific antigen level < or =40 ng per milliliter. New Engl J Med 2004;350(22):2239–46.
- Evans R, Edwards AG, Elwyn G, et al. "It's a maybe test": men's experiences of prostate specific antigen testing in primary care. Br J Gen Pract 2007;57(537):303–10.
- 8. Rai T, Clements A, Bukach C, et al. What influences men's decision to have a prostate-specific antigen test? A qualitative study. Fam Pract 2007;24(4):365–71.
- Schroder F, Kattan MW. The comparability of models for predicting the risk of a positive prostate biopsy with prostate-

- specific antigen alone: a systematic review. Eur Urol 2008;**54**(2):274–90.
- Kranse R, Roobol M, Schroder FH. A graphical device to represent the outcomes of a logistic regression analysis. Prostate 2008;68(15):1674–80.
- Driscoll DL, Rupert DJ, Golin CE, et al. Promoting prostatespecific antigen informed decision-making. Evaluating two community-level interventions. Am J Prev Med 2008;35(2):87–94.
- 12. Watson E, Hewitson P, Brett J, et al. Informed decision making and prostate specific antigen (PSA) testing for prostate cancer: a randomised controlled trial exploring the impact of a brief patient decision aid on men's knowledge, attitudes and intention to be tested. Patient Educ Couns 2006;63(3):367–79.
- Rimer BK, Briss PA, Zeller PK, Chan EC, Woolf SH. Informed decision making: what is its role in cancer screening? Cancer 2004;101(5 Suppl.):1214–28.
- 14. Marteau TM, Dormandy E, Michie S. A measure of informed choice. *Health Expect* 2001;4(2):99–108.
- 15. Steyerberg EW, Roobol MJ, Kattan MW, et al. Prediction of indolent prostate cancer: validation and updating of a prognostic nomogram. *J Urol* 2007;177(1):107–12 [discussion 112].
- Prostate Risk Indicator, paper version level 1 and 2.
 Rotterdam. The Netherlands: Publication of Stichting Wetenschappelijk Onderzoek (SWOP); July 2008.
- 17. Connor MNP, editor. Predicting health behaviour. Buckingham: Open University Press; 1996.
- Ware Jr J, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Med Care 1996;34(3):220–33.

^a Indicates a correct statement.

- Ware JEKM, Turner-Bowker DM, Gandek B. How to score version 2 of the SF-12 Health Survey. Boston (MA): QualityMetric Incorporated; 2002.
- van der Bij AK, de Weerd S, Cikot RJ, Steegers EA, Braspenning JC. Validation of the Dutch short form of the state scale of the Spielberger State-Trait Anxiety Inventory: considerations for usage in screening outcomes. Community Genet 2003;6(2):84–7.
- 21. Spielberger CD, Vagg PR. Psychometric properties of the STAI: a reply to Ramanaiah, Franzen, and Schill. *J Pers Assess* 1984:48(1):95–7.
- van den Bergh RC, Korfage IJ, Borsboom GJ, Steyerberg EW, Essink-Bot ML. Prostate cancer-specific anxiety in Dutch patients on active surveillance: validation of the memorial anxiety scale for prostate cancer. Qual Life Res 2009;18(8):1061–6.
- Koedoot N, Molenaar S, Oosterveld P, et al. The decisional conflict scale: further validation in two samples of Dutch oncology patients. Patient Educ Couns 2001;45(3):187–93.
- Centre OHD. User manual decision conflict scale(s). In: Ottawa Health Decision Centre at the Ottawa Health Research Institute, University of Ottawa; 2006.
- 25. Ware JEJSK, Kosinski M, Gandek BG. SF-36 health survey: manual and interpretation guide. Boston (MA): The Health Institute, New England Medical Center; 1993.

- Gattellari M, Ward JE. Does evidence-based information about screening for prostate cancer enhance consumer decisionmaking? A randomised controlled trial. J Med Screen 2003;10(1):27–39.
- Volk RJ, Spann SJ, Cass AR, Hawley ST. Patient education for informed decision making about prostate cancer screening: a randomized controlled trial with 1-year follow-up. Ann Fam Med 2003;1(1):22–8.
- 28. Jepson RG, Hewison J, Thompson AG, Weller D. How should we measure informed choice? The case of cancer screening. *J Med Ethics* 2005;**31**(4):192–6.
- 29. Rees C, Abed R, Sheard C. Development of a reliable and valid questionnaire to test the prostate cancer knowledge of men with the disease. Patient Educ Couns 2003;51(3): 285–92
- Radosevich DM, Partin MR, Nugent S, et al. Measuring patient knowledge of the risks and benefits of prostate cancer screening. Patient Educ Couns 2004;54(2):143–52.
- 31. Green JM, Hewison J, Bekker HL, Bryant LD, Cuckle HS. Psychosocial aspects of genetic screening of pregnant women and newborns: a systematic review. *Health Technol Assess* 2004;8(33):iii. ix–x, 1–109.
- 32. Edwards A, Unigwe S, Elwyn G, Hood K. Effects of communicating individual risks in screening programmes: Cochrane systematic review. *BMJ* 2003;**327**(7417):703–9.