A DECISION AID FOR AN INFORMED CHOICE WHEN PATIENT ASKS FOR PSA SCREENING
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FRANÇOISE MAMBOURG, LAURENCE KOHN, JO ROBAYS, SABINE JANSSENS, MICHEL ALBERTIJN, MAGALI RONSMANS, CHRIS DE LAET
A decision aid for an informed choice when patient asks for PSA screening

Françoise Mambourg (KCE), Laurence Kohn (KCE), Jo Robays (KCE), Sabine Janssens (BSM Management), Michel Albertijn (Tempera), Magali Ronsmans (BSM Management), Chris De Laet (KCE)

Raf Mertens (KCE)

Gigi Veereman (KCE), Anja Desomer (KCE)

Bram Spinnewijn (Domus Medica), Luc Lefèbvre (SSMG), Annelies Engelen (KULeuven), Filip Ameye (AZ Maria Middelaars), Anne Boucquiau (Fondation contre le cancer), Erik Briers (Europa Uomo), Hans Neefs (VLK), Vera Nelen (Provinciaal Instituut voor Hygiène), Thierry Pontus (SBU), Karin Rondia (Fondation contre le cancer), Alain Servaes (patient), Joke Vanderhaegen (KULeuven)

Willem Oosterlinck (UZ Gent), Patrik Vankrunkelsven (CEBAM), Jacques Cornuz (CHU Lausanne, Switzerland)

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Membership of a stakeholder group on which the results of this report could have an impact: Filip Ameye, Erik Briers, Rudi Bruyninckx, Jacques Cornuz, Thierry Pontus, Alain Servaes

Owner of subscribed capital, options, shares or other financial instruments: Patrik Vankrunkelsven

Fees or other compensation for writing a publication or participating in its development: Yvan Leunckens, Bram Spinnewijn

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Payments to speak, training remuneration, subsidised travel or payment for participation at a conference: Filip Ameye, Willem Oosterlinck, Thierry Pontus, Bram Spinnewijn

Presidency or accountable function within an institution, association, department or other entity on which the results of this report could have an impact: Filip Ameye

Ine Verhulst

Nathalie da Costa Maya (CDCS asbl)
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<th>ABBREVIATION</th>
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<tr>
<td>ADT</td>
<td>Androgen Deprivation Therapy</td>
</tr>
<tr>
<td>BAU</td>
<td>Belgian Association of Urology</td>
</tr>
<tr>
<td>BVU</td>
<td>Belgische Vereniging voor Urologie</td>
</tr>
<tr>
<td>Domus Medica</td>
<td>Dutch Belgian GP Scientific Organisation</td>
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<tr>
<td>DRE</td>
<td>Digital Rectal Examination</td>
</tr>
<tr>
<td>ERSPC</td>
<td>European Randomized Study on Screening for Prostate cancer</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>GMD+/DMG+</td>
<td>Global medical report containing a list of preventive acts</td>
</tr>
<tr>
<td>HAS</td>
<td>Haute Autorité de Santé, France</td>
</tr>
<tr>
<td>IDM</td>
<td>Informed Decision Making</td>
</tr>
<tr>
<td>MA</td>
<td>Meta-analyse</td>
</tr>
<tr>
<td>PC</td>
<td>Prostate Cancer</td>
</tr>
<tr>
<td>PLCO</td>
<td>Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial</td>
</tr>
<tr>
<td>PPV</td>
<td>Positive Predictive Value</td>
</tr>
<tr>
<td>PSA</td>
<td>Prostate Specific Antigen</td>
</tr>
<tr>
<td>SBU</td>
<td>Société Belge d'Urologie</td>
</tr>
<tr>
<td>SDM</td>
<td>Shared Decision Making</td>
</tr>
<tr>
<td>SR</td>
<td>Systematic Review</td>
</tr>
<tr>
<td>SSMG</td>
<td>Société Scientifique de Médecine Générale</td>
</tr>
<tr>
<td>TRUS</td>
<td>Transrectal Ultrasound Examination</td>
</tr>
<tr>
<td>USPTSF</td>
<td>United States Preventive Services Task Force</td>
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1 INTRODUCTION

This report was aimed to be an update of a previous KCE report (KCE report 2006) published in 2006. At publication time of this previous KCE guideline, authors have planned an update. This should take place after the publication of the results from two large randomised control trials: The European Randomized Study on Screening for Prostate cancer (ERSPC) and The Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO-USA). Those publications were followed by numerous discussions and many more controversies. Some guidelines updates as the USPTSF guideline (2012) and the HAS scientific review were published afterwards. Both reports recommend against the routine use of PSA-based screening for prostate cancer and underlined the necessity to provide information based on benefit and harms of this screening to the clinicians and their patients. Providing information based on screening benefit and harms to the men concerned by this issue was one of the recommendations retained in KCE 2006 report. This recommendation was in accordance with the Belgian law on patients’ rights which states the right to information.

Meanwhile, it was decided to add to the Global Medical File used by the general practitioners (GP) to centralise patient’s data (named GMD/DMG+ in Belgium), a new part dedicated to prevention. The content of this new part was fixed by a scientific group issued from the Quality Council of the National Institute for Health and Disability Insurance (named NRKP/CNPQ in Belgium). This group stated that there was sufficient evidence to exclude the PSA-based screening for prostate cancer of the list of actions promoted by this GMD+/DMG+. Consequently, Belgian GPs do not have to propose this test if the patient does not express concern on PSA test or on prostate cancer screening. Furthermore, the PSA test for screening in men without any risk factor was not yet reimbursed in Belgium since 1 Augustus 2012. Due to those two facts, general practitioner’s (GPs) were more and more put in face to explain this decision and the two Belgian GP scientific organisations (Domus Medica and Société Scientifique de Médecine Générale-SSMG) became both asking partners for a tool to support shared decision making (SDM) usable during GPs consultations.
Consequently, after updating the previous KCE report (KCE report 31, 2006), this study aims to develop messages on the outcomes of the prostate specific antigen (PSA)-based cancer screening. Those messages are developed in collaboration with the Belgian (GP) scientific organisations and should allow GP to clarify the issues surrounding PSA screening with their patients.

Those messages apply to men older than 50 years of age without family history of prostate cancer. They do not include the use of the PSA test for monitoring in men who have been diagnosed with prostate cancer.

This report contains following chapters:

- Chapter 2: Update of the previous report
- Chapter 3: Theory of risk communication and shared decision making
- Chapter 4: Quantification of screening benefit and harms
- Chapter 5: Elaboration of the SDM tool

The description of the specific methodology used for each chapter takes place in the beginning of this chapter.

2 UPDATE OF THE PREVIOUS REPORT

2.1 Methodology

2.1.1 Literature search

A literature review was developed as an update of KCE report 31. The search was done in March 2013 for meta-analyses (MA) and systematic reviews (SRs) published after 2005 in Medline (through OVID), EMBASE and the Cochrane Database of Systematic Reviews (Appendix 1.1.2). The search was limited to articles published in English, Dutch and French. In general, systematic reviews not reporting the search strategy and/or the quality appraisal of the included studies were excluded. All searches were run in March 2013.

The identified studies were selected based on title and abstract. For all eligible studies, the full-text was retrieved. In case no full-text was available, the study was not taken into account for the final recommendations.

We did not update the most recent review as its search date was recent and the fact that it is unlikely that other RCT’s can be identified, as RCT’s for PSA screening need a large sample size and need a long follow-up.

2.1.2 Quality appraisal

The quality of the retrieved SRs and MA was assessed using the checklists of the Dutch Cochrane Centre (www.cochrane.nl). All critical appraisals were done by a single KCE expert (Appendix 1.4.1).

2.1.3 Data extraction

For each publication, the search date, publication year, included studies and main results were extracted and summarized in data extraction tables. Data extraction tables are provided in Appendix 1.5.
2.2 Results

2.2.1 Systematic reviews

We found four SR.\textsuperscript{6, 7, 8, 9} The quality of the systematic review published by Lumen \textsuperscript{7} was assessed as moderate (only two databases were searched) and not included in this review. The three others were assessed as high quality.\textsuperscript{6, 8, 9} Chou performing one SR underlined that the 2 largest and highest-quality trials (ERSPC, 2009 and PLCO, 2009) reported conflicting results. The ERSPC trial found PSA screening every 2–7 y to be associated with decreased risk for death from prostate cancer in her “core” group (men aged 55–69 y) after 9 y (relative risk (RR), 0.80 [95% CI, 0.65–0.98]). The PLCO trial found no effect after 10 years (RR, 1.1 [95% CI, 0.80–1.5]).\textsuperscript{6}

Djulbegovic performed one meta-analysis including six RCT’s with a total of 387 286 participants. She noted that all trials had one or more substantial methodological limitations. Meta-analysis results showed that screening was associated with an increased probability of receiving a diagnosis of prostate cancer (RR 1.46, [95% CI, 1.21 to 1.77; P<0.001]) and stage I prostate cancer (RR 1.95, [95% CI, 1.22 to 3.13; P=0.005]). Effect of screening on death from prostate cancer was no significant (RR 0.88, [95% CI, 0.71 to 1.09; P=0.25]). Although this review is of high quality, there was considerable heterogeneity among the trials included in the specific mortality reduction outcome (I\textsuperscript{2}=55%, χ\textsuperscript{2}=8.89; P=0.06).\textsuperscript{8}

Illic et al. (2013) did an update of 2010 Cochrane review and pooled five studies (n= 341 342). As for the others authors, both the ERSPC and the PLCO studies were assessed as at low risk of bias, whilst the Norrkoping, Quebec, and Stockholm studies were assessed as of high risk of bias. Meta-analysis of PLCO data and data from the ‘core age group’ of the ERSPC study produced a RR of 0.94 [95% CI, 0.65 to 1.35] for prostate cancer-specific mortality.\textsuperscript{9}

However, the pooled studies in the meta-analysis are inconsistent, on the one hand, the ERSPC study shows a modest effect on cancer specific mortality but on the other hand the PLCO study does not. There are also large methodological differences between the studies, the most notable differences are the large differences in screening uptake (both in intervention and control group), screening frequency and screening method.

The Cochrane\textsuperscript{a} handbook states that if there is considerable variation in results, and particularly if there is inconsistency in the direction of effect, it may be misleading to quote an average value for the intervention effect. Therefore we consider pooling of inconsistent results in Illic et al. (2013) inadequate. Due to the fact that the search strategy and quality appraisal were adequate we decided to take both of these over and to base our conclusion on the two high quality trials.

2.2.2 Randomized controlled trials

Two studies were assessed as having at low risk of bias. We give a more detailed description explaining the strengths and limitations and explore the reasons for the conflicting results. A formal quality appraisal of the retrieved RCT’s was done in the Cochrane review,\textsuperscript{3} results of their formal appraisal is presented in Appendix.

The Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO-USA)\textsuperscript{3} study randomized 76 685 men aged 55 to 74 years (cancer free) across 10 study centres in the USA (United States of America). Participants in the screening group were offered annual PSA testing for six years and annual digital rectal examination (DRE) for four years. In the 38 343 men assigned to screening overall adherence to screening was 85% for PSA and 86% for DRE. Both participants and health-care providers decided upon the method of evaluating abnormal screening results. Primary outcome was prostate cancer mortality. The study reported on a 10- to 13-year follow-up of 76 693 men aged 55–74 y. Study showed no difference in prostate cancer–specific mortality at 13year (rate ratio, 1.09 [95% CI, 0.87 to 1.70]). The main limitation of this study was the high rate of contamination in the control group (up to 52% by 6 years). Furthermore, approximately 44% of men in each group had undergone ≥1 PSA test before trial entry.\textsuperscript{3, 10}

The European Randomized Study on Screening for Prostate cancer (ERSPC)\textsuperscript{2} started in July 1994 as a randomized, multi-centre trial across nine European countries (The Netherlands, Belgium, Sweden, Finland, Italy, Spain, Switzerland, Portugal, and France). France and Portugal were finally excluded because the follow-up time was too short). Each country used different recruitment and randomization and screening procedures. At

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\textsuperscript{a} \url{http://handbook.cochrane.org/}
the study involved 182,160 men between the ages of 50 and 74 years, with a predefined core age group of 162,388 men aged 55 to 69 years. Primary outcome of the trial was prostate cancer mortality. The screening group (55-69 y) defined as “core age group” and after a median follow-up of 11 years, the reduction in prostate cancer related mortality was 21% (rate ratio, 0.79 [95% CI, 0.68 to 0.91]). Besides the intention-to-screen analysis, they performed a hypothesis-generating secondary analysis, which was limited to men who actually underwent screening and was corrected for selection bias to show the effect among screened men, with this method they found a reduction of 29%. In this study, the proportion of over diagnosis was estimated by the author to be approximately 50% of screen detected cancers. At 11 years of follow-up, 1055 men would need to be invited (NNI) for screening. 37 supplementary cancers (due to over-diagnosis) would need to be detected (NND) in order to prevent one death from prostate cancer.

In the different centers a wide variation of the screening procedures were applied: use of PSA alone or in combination (with DRE and TRUS), use of different PSA cut-off points (3 or 4 ng/mL) and use of different screening intervals (from 2 years in Finland to 4 years in others countries and 7 years for the first round in Belgium).

The effect reported in the study should therefore be considered to be the result of an individual based meta-analysis of studies that show heterogeneous results.

In order to illustrate and explore this point we performed a fixed effect (random effect gives the same result) inverse variance meta-analysis with pooling the reported rate ratio’s and their confidence interval in the individual countries contributing to the study. The resulting pooled rate ratio is exactly the same as the effect reported in the ERSPC paper. The ERSPC paper used a Poisson regression model stratified by center, applied to the individual data.

As a result, the important heterogeneity, coming from the different effects observed in the counties that contributed to the study becomes apparent. On the one hand, most of the observed reduction in the study comes from the large reductions seen in Sweden and to a minor degree in the Netherlands, rate ratio’s in both countries were already statistically significant by themselves. On the other hand, Finland, the center contributing the largest number of participants and providing 48% of the statistical weight, shows a risk ratio of only 0.89 [95% CI, 0.72 to 1.10] (not statistically significant). Consequently, the 3 largest centers show conflicting results.

Note that the low I² value reported here merely reflects the fact that the estimations in some countries is based on small sample sizes, have low precision with very large confidence intervals and artificially lower the I² value (as one degree of freedom is subtracted per study added). This dependence on the precision of the underlying individual studies limits the validity of I² as a measurement of heterogeneity.

Table 1 – Fixed effect inverse variance meta-analysis pooling the reported risk ratio’s of the individual countries contributing to the ERSPC study

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>log[Rate Ratio]</th>
<th>SE</th>
<th>Weight</th>
<th>Rate Ratio IV, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>-0.1508</td>
<td>0.267</td>
<td>6.8%</td>
<td>0.86 [0.49, 1.51]</td>
</tr>
<tr>
<td>Finland</td>
<td>-0.1165</td>
<td>0.1082</td>
<td>48.0%</td>
<td>0.89 [0.72, 1.10]</td>
</tr>
<tr>
<td>Italy</td>
<td>-0.1508</td>
<td>0.3192</td>
<td>5.5%</td>
<td>0.86 [0.46, 1.61]</td>
</tr>
<tr>
<td>Netherlands</td>
<td>-0.3425</td>
<td>0.1589</td>
<td>22.3%</td>
<td>0.71 [0.32, 0.97]</td>
</tr>
<tr>
<td>Spain</td>
<td>-0.7655</td>
<td>1.2379</td>
<td>0.4%</td>
<td>0.210 [0.19, 24.33]</td>
</tr>
<tr>
<td>Sweden</td>
<td>-0.5798</td>
<td>0.1978</td>
<td>14.4%</td>
<td>0.56 [0.38, 0.83]</td>
</tr>
<tr>
<td>Switzerland</td>
<td>-0.1165</td>
<td>0.4618</td>
<td>2.6%</td>
<td>0.89 [0.36, 2.20]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td></td>
<td></td>
<td></td>
<td>100.0% 0.79 [0.68, 0.92]</td>
</tr>
</tbody>
</table>

Test for overall effect: Z = 3.13 (P = 0.002)

2.3 Discussion

The two high quality studies provide conflicting results and therefore we consider that pooling these inconsistent studies inappropriate. Moreover, the ERSPC study should rather be considered as an individual based meta-analysis of disparate studies with very heterogeneous results. Several explanations for these discrepancies were put forward. One obvious explanation is differences in PSA screening rates in the intervention and control group. However, this does not explain all heterogeneity, e.g. in the PLCO study this cannot explain away the excess mortality observed in the data. Haines et al., put forward a hypothesis that attributes these divergent results to imbalances in the use of androgen deprivation therapy (ADT) between the intervention and control arm. In the European trials far more patients received hormonal treatment in the
control than the prostatectomy arm, whereas hormonal therapy in the US trial was balanced between arms.

Due to all these uncertainties, inconsistencies and discrepancies an effect cannot be confirmed nor ruled out and estimates of the reductions in prostate cancer-specific mortality attributable to PSA screening range from 0 to 50%.

2.4 Key messages

- There is considerable inconsistency between the two large fair quality RCT’s (ERSPC¹¹ and PLCO¹⁰), there is also important inconsistency between centres within the ERSPC trial.

- PLCO (USA) found no statistically significant difference in prostate cancer–specific mortality at 13 years (rate ratio 1.09 [95% CI, 0.87 to 1.70]).

- ERSPC(Europe) found that screening was associated with reduced prostate cancer–specific mortality compared with no screening in a subgroup of men aged 55 to 69 years after a median follow-up of 11 years (rate ratio 0.79 [95% CI, 0.68–0.91]).

- ERSCPC is a multicentre study conducted in different countries in Europe and there is considerable statistical, clinical and methodological heterogeneity and inconsistency among the different countries included in the study.

- Due to all these inconsistencies, estimates of the reductions in prostate cancer–specific mortality, attributable to PSA screening, range from 0 to 50%.

3 RISK COMMUNICATION AND SHARED DECISION MAKING

3.1 Introduction

Patients have to make informed decision related to their health. Informed decision making (IDM) “occurs when an individual understands the disease or condition being addressed and also comprehends what the clinical service involves, including its benefits, risks, limitations, alternatives, and uncertainties; has considered his or her own preferences, as appropriate; believes he or she has participated in decision making at a level that he or she desires; and makes a decision consistent with those preferences” (Rimer et al., 2004¹⁴; p.1216).

This is not always so. Patients often place undue weight on potential benefits of screening while underestimating potential limitations.¹⁴ Clear information is particularly required in decision such PSA screening to facilitate informed choice. Indeed, there is no clear “reduction” in prostate cancer morbidity or mortality. Furthermore, the consequences of the screening can lead to embarrassing negatives consequences, i.e. repeated biopsies, incontinence and impotence, risk of which men may not be aware. These uncertainties contribute to the difficulty of weighing the benefits and harms of screening for prostate cancer using PSA test (named here PSA prostate cancer), a test widely available and frequently recommended and ordered by physicians.¹⁴

Informed decision making goes together with risk understanding. Patients are often not knowledgeable well enough about health statistics and risks to fully grasp this information. Unfortunately, also doctors often fail to fully understand this information and many misunderstandings on the interpretation of risk parameters exist.

The goal of this chapter is to give theoretical guidelines to the elaboration of the tool to support discussion between GPs and patients about PSA screening. We also aim to give some insight on the concept related to informed and shared decision making. Firstly, we will thus address the difficulties of understanding the risk statistics in patients and physicians and how the understanding of the risks could be improved by an adequate communication on the risk. We will secondly discuss how to go from IDM
to Shared Decision Making (SDM): what is SDM, why SDM aimed to achieved, what are the barriers and facilitators of SDM and what could be done to implement SDM in clinical settings.

3.2 Risk understanding and communication

3.2.1 Introduction

To adequately communicate to a patient the risks and benefits of specific therapies or interventions, such as screening, requires that the medical professional fully understands the concepts. Previous research has shown that there are many misunderstandings in both patients and physicians, among others about relative and absolute risks, positive predictive values etc., which leads to confusion. Strategies are known to improve the understanding of the probabilities. This section will address these aspects.

3.2.2 Methodology

We have searched in several databases for systematic reviews on risk communication in the context of another research on information of women about breast cancer screening. Detailed methodology could be found in the scientific report of the study. We consulted also work of the Harding Centre for Risk Literacy at the Max Planck Institute for Human Development in Berlin (http://www.harding-center.de/).

3.2.3 Patients’ understanding of risk statistics

Research has shown that in the general population, and therefore also in patients, the statistical literacy, or rather ‘numeracy’ is poor in general, including numeracy for health statistics. Galesic et al. studied the statistical numeracy in the general population in Germany and the US by evaluating the correct answers to some basic statistical questions. The statistical literacy was somewhat better in the German population but was overall low in both populations, even on the rather simple questions of this survey. For example on the question of expressing 1 per 1000 as a percentage only 24% of the Americans and nearly half of the Germans answered correctly. Moreover, the proportion of answering correctly was obviously very much related to education levels. This is also reflected in the way patients perceive their individual health risks. In a study in 9 European countries it was found that around 90% of men and women largely overestimated the mortality reduction by PSA or mammography screening respectively, or did not know.

Although one of the reasons for these misunderstandings is obviously related to insufficient statistical education, the main reason is poor communication from the medical community. It has been argued that the main problem is the fact that probabilities for a single event often fail to mention what the probability refers to: number of patients, number of times an event occurs, during which timeframe, etc.

3.2.4 Physicians’ understanding of risk statistics

Intuitively one would assume that physicians understand health risk statistics much better since they have all taken statistical courses during their medical education. However, research has shown that many physicians poorly understand some of the key concepts. One of the reasons is that very often in statistical teaching; the emphasis is on frequent inference theories based on probabilities, putting most emphasis on chance distributions, p-values and the central limit theorem. Less emphasis is given to teaching how to interpret the results, although this would generally be more useful to physicians and more intuitive.

Survival versus mortality

Research in medical practice confirms this. In a RCT, 300 US primary care physicians were given the key characteristics of two hypothetical screening tests. In one group the results were described as 5-year survival rates and early detection rates while in the other group the same results were described as decreased cancer mortality and increased incidence of the disease. Primary care physicians were more enthusiastic about the screening test describing the 5-year survival rates and early detection rates (irrelevant evidence) than about the test supported by relevant evidence (cancer mortality reduced from 2 to 1.6 in 1000 persons). The authors concluded that most physicians mistakenly interpreted improved survival and increased disease detection as evidence that screening saved lives, although in practice there was no reduced mortality. A test in 65 German physicians in internal medicine provided similar results; 79% judged screening for prostate cancer with PSA testing efficient when results were presented as survival rates, but only 5% when the same results were presented as mortality rates.
Lead-time bias and over-diagnosis

The two main reasons for this misinterpretation of survival rates are called 'lead-time' bias and over-diagnosis. Lead-time bias refers to the fact that early diagnosis of a cancer that would normally have been diagnosed several years later will automatically lead to a longer 5-year survival even when patients die at the same moment. Over-diagnosis refers to the fact that a large group of patients may have a non-progressive disease that would never have been diagnosed during their lifetime without screening, thereby artificially inflating the success of treatment.

Sensitivity, specificity and positive predictive value

Another problem is the blind reliance on screening characteristics such as sensitivity and specificity. Often physicians consider a high sensitivity and specificity as evidence for an efficient screening test and many overestimate the accuracy of a positive test. However, they fail to understand that the main parameter for efficiency is the prevalence of the condition in the screened population. In one study, 160 gynecologists that were given key screening performance parameters for mammography screening (prevalence, sensitivity and specificity) were afterwards asked to estimate the probability that a screen positive woman has indeed breast cancer. The majority of those gynecologists grossly overestimated the probability of cancer and answers ranged from 1% to 90% while the right answer was 10%.

For example, a screening test with a sensitivity and specificity of 95%, in a population with a disease prevalence of 10% would lead to 9500 individuals per 100 000 being correctly diagnosed as having the disease and 4500 with a false positive diagnosis. The same test but in a population with a disease prevalence of only 1% this would lead to 950 correct diagnoses but to almost 5000 false positives (see table 2 below), meaning that out of almost 6000 persons with a positive test result only 16% would truly have the disease, a metric which is called the positive predictive value (PPV).

<table>
<thead>
<tr>
<th></th>
<th>Disease</th>
<th>No disease</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEST +</td>
<td>9500</td>
<td>4500</td>
<td>14000</td>
</tr>
<tr>
<td>TEST -</td>
<td>50</td>
<td>85500</td>
<td>86000</td>
</tr>
<tr>
<td>Total</td>
<td>10000</td>
<td>90000</td>
<td>100000</td>
</tr>
</tbody>
</table>

Table 2 – Two by two tables showing the influence of disease prevalence on screening performance (same hypothetical test with 95% sensitivity and specificity) in a population of 100 000 persons

Relative risks versus absolute risks

A third problem that jeopardizes the correct interpretation of results is the general use of relative risks to describe positive results in medical research, peer reviewed articles and risk communication. When a 50% decrease in relative risk is reported this sounds far more impressive than for example reporting a decrease of the absolute risk from 2 to 1 case per 10 000. Presenting the absolute rather than the relative risks would help both the medical and the lay public to correctly interpret results leading to a more transparent communication.

3.2.5 How to improve risk understanding?

Information on risk required to use understandable data, understandable as well by the physicians than by the patients. The previous chapter indicated how relative the understanding on risk by both protagonists is when classical ways to present statistics are used.

In 2013, we had search for what information must be presented in decision aid and how to present it, caring for a maximum of neutrality. This was carried out for a study on the informed choice on breast cancer screening. Because our findings are also useful for the current project, we report them in the next sections. We consider these findings as guidelines for developing a tool to improve risk understanding.
The content of the information required for an informed decision making

In order to elaborate the content of messages aiming to feed a tool to support shared decision making in PSA screening decision, we referred to the International Patient Decision Aid Standards (IPDAS) criteria that refer to the type of information that needs to be included in an effective decision aid. IPDAS is an internationally-recognised scheme to improve the quality and effectiveness of patient decision aids. This organisation develops criteria to which effective decision aids should adhere.\(^b\)

IPDAS criteria useful for informing men about PSA screening and what concrete information is therefore required are presented in the next table:

\(^b\) [http://ipdas.ohri.ca/IPDAS_checklist.pdf](http://ipdas.ohri.ca/IPDAS_checklist.pdf)
### Table 3 – IPDAS criteria and information on PSA screening

<table>
<thead>
<tr>
<th>IPDAS criteria</th>
<th>Information related to PSA screening required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of the condition (health or other) related to the decision.</td>
<td>What is prostate cancer?</td>
</tr>
<tr>
<td>Description of the decision that needs to be considered.</td>
<td>What is PSA screening?</td>
</tr>
<tr>
<td>Listing of the options (health care or other).</td>
<td>Screening or not screening for prostate cancer with PAS?</td>
</tr>
<tr>
<td>Description of what happens in the natural course of the condition (health or other) if no action is taken.</td>
<td>Mortality by prostate cancer.</td>
</tr>
<tr>
<td>Information about the procedures involved (e.g. what is done before, during, and after the health care option).</td>
<td>Information on the screening process, biopsies and surgery.</td>
</tr>
<tr>
<td>Information about the positive features of the options (e.g. benefits, advantages).</td>
<td>Information on reduction of the mortality and morbidity due to prostate cancer.</td>
</tr>
<tr>
<td>Information about negative features of the options (e.g. harms, side effects, disadvantages).</td>
<td>Information on overdiagnosis, on overtreatment, on harm effects of biopsies and surgery (incontinence, impotence, anxiety).</td>
</tr>
<tr>
<td>Information about outcomes of options (positive and negative) includes the chances they may happen.</td>
<td>Probabilities on reduction of the mortality or morbidity due to prostate cancer, on earliest diagnose, overdiagnosis, on overtreatment, on harm effects of biopsies and surgery (incontinence, impotence, anxiety).</td>
</tr>
<tr>
<td>Information about what the test is designed to measure.</td>
<td>Description of what is PSA.</td>
</tr>
<tr>
<td>Description of possible next steps based on the test results.</td>
<td>Information on biopsie and surgery, watchfull waiting or active surveillance.</td>
</tr>
<tr>
<td>Information about the chances of disease being found with and without screening.</td>
<td>Probabilities of prostate cancer diagnose with and without PSA screening.</td>
</tr>
<tr>
<td>Information about detection and treatment of disease that would never have caused problems if screening had not been done.</td>
<td>Probabilities of mortality with and without PSA screening.</td>
</tr>
</tbody>
</table>
The format of the information required for a neutral and understandable information on the risks

Based on a review of the literature on risk communication carried out for the study on information about breast cancer screening,\textsuperscript{15} we have identified criteria that participate in understandable, balanced and neutral messages:

- Expressing messages in absolute numbers
- Presenting messages using the same denominator i.e. 1000 people
- Presenting both gain and loss information in the same visual, offering by this way the possibility to compare the positive and negative features of the available options.
- Showing negative and positive feature of the options with equal detail
- Specifying time frame, the same for the different options
- Using the same scale for all visuals
- Avoiding to use narratives

3.3 From Informed Decision Making towards Shared Decision Making

3.3.1 Introduction

In this section we will define the notion of SDM and explore what are the notable barriers and facilitators to its implementation in current practice. We will also review the effectiveness of the interventions that have been already tried in order to improve this implementation.

3.3.2 Methodology

First, we used systematic reviews related to SDM we have by chance identified in our previous breast cancer screening report. Next, we carried out specific search strategies to identify any other relevant systematic review and update it with a specific search on papers focusing in PSA screening.

We searched in: MEDLINE, PreMEDLINE, Embase, Psychinfo and Sociological abstract databases. We completed our search with hand searching.

Detailed search strategies are presented in appendix (see Appendix 3.1)

We included only studies published in English, French or Dutch from 2002 until end of 2013. We kept for further full text review only systematic reviews where methodology reported a search in at least two databases. Because of the slight number of hits and the descriptive goal of this part of the report, we did not add any other criteria for inclusion.

We finally used 11 reviews on SDM, published between 2004 and 2013. They are from good to moderate quality (assessed by AMSTAR) (see 0).

3.3.3 What is “shared decision making” and what is the aim of SDM?

There is increased emphasis on client centred care. It is more and more expected that patients are involved in making health decisions.\textsuperscript{22} In this context, “Shared decision making (SDM) connotes a process in which physicians and patients share in the decision-making process, which is conducted through one or more face-to-face encounters.” (Rimer et al.,\textsuperscript{14} p.1216)

The aim of SDM is to empower the patient but also to:

- Provide patient-centered care
- Comply with legal and ethical patient rights
- Be responsive to patients’ desire to be involved
- Remain accountable for screening and treatments used
- Improve patient satisfaction with the decision-making process
- Potentially improve patient health outcomes

SDM could be nourished by IDM interventions. The interventions show consistent evidence that IDM interventions improved knowledge, beliefs, risk perceptions, or a combination of these. Nevertheless, little evidence araised about whether these interventions result, among other, in participation in decisions\textsuperscript{23} and few study have actually adressed patient/clinician communication subsequent to the use of a decision aid.\textsuperscript{24}
It is thus not because IDM intervention, such as decision aid, are introduce in clinical pathways that they automatically lead to SDM. And IDM interventions are not the only ones that could be used. Stacey et al. identified in 2008 several approaches, such as patient education material, prompt sheets, consultation planning, decision aids and decision coaching.

In 2010, Stacey et al. conducted an analysis of existing conceptual models of SDM based on 23 papers. We report here the different concepts they identify in SDM models:

<table>
<thead>
<tr>
<th>Table 4 – Concepts found in SDM models</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Main themes</strong></td>
</tr>
<tr>
<td><strong>Features of SDM process</strong></td>
</tr>
<tr>
<td></td>
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<td></td>
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<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Individuals involved in SDM</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Factors influencing the SDM process</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Outcomes of SDM</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

Source: Stacey et al., 201027; p. 169

3.3.4 **Shared decision making in PSA screening**

In the particular context of prostate cancer and older patients, Vedel et al. report that physician initiate screening more often than patients, while patient are often requesting repeat PSA testing. This type of consultation is reported to be longer by primary practitioners. In the patient point of view, the fact that physician recommend or not having PSA testing predict the effective testing. The sole fact to discuss it is also a predictor of being screened.

SDM, and more particularly SDM on PSA screening, could have impact on the final decision: a decreased intention to undergo screening was noted in 13 decision aids: 8 of these dealt with prostate cancer screening, and 3 studies shows increase in screening and 3 others a decrease.

3.3.5 **Barriers and the success factors to the implementation of shared decision making**

Gravel et al. reviewed 28 studies and identify several barriers to implementation of SDM in clinical setting: the most often reported are:

- Time constraints
- Lack of acceptability due to patient characteristics
- Lack of applicability due to the clinical situation

Reported facilitators are:

- Provider motivation
- Positive impact on the clinical process
- Positive impact on patient outcomes

These results are confirmed by the update by Légaré et al. published in 2008.
More recently, Elwyn summarized the existing literature and pointed out that barriers lie in physician attitudes and their need for more training. Clinicians do not always trust or agree with the content of decision aid. Several are convinced that patients did not want to decide themselves when facing difficult diagnoses. The existence of competing information is also a barrier to the implementation of SDM.  

3.3.6 Effectiveness of interventions to improve SDM

As we just see it, adopting SDM strongly depend on physician goodwill. Several authors search for guide to improve their participation. Interventions that can lead to it are decision aids, educational meeting, distribution of educational material to physicians, audit, feedback, risk communication training, SDM training. Stacey et al. report that some interventions, like educational training workshops on SDM and tools to screen for decisional conflict, are considered by enthusiast physicians to be able to overcome some of the known barriers. Nevertheless, in their systematic review aiming to assess effectiveness of intervention to improve healthcare professional adoption, Legaré et al. declared that they are not able to draw firm conclusions about the most effective types of intervention. They have analysed 5 RCTs comparing single intervention or multifaceted interventions to usual care, or other multifaceted intervention. More recently, Elwyn et al. hoped to make recommendation on how best to implement decision aid into practice. Here again, they have to conclude that, based on published studies, it is too early for such recommendations.  

Next to physicians, patients are also actors of SDM. In order to increase patient participation in SDM, we selected two systematic reviews. Firstly, Stacey et al. identified usual patient education material as non-adequate. However, question prompt sheets, and consultation planning are effective interventions to facilitate patient involvement in the medical consultation, in the context of cancer treatment or screening. Patient decisions aids and decision coaching facilitate patient's role in SDM.  

Secondly, Legaré et al. conclude that, from the patient perspective, multifaceted interventions that include educating health professionals about sharing decisions with the patients and patient-mediated interventions (i.e. decision aids) appear to be promising.  

4 QUANTIFICATION OF THE BENEFIT AND HARMS OF THE SCREENING

4.1 Introduction

The focus of this project is notably to provide specific and statistically-sound material on prostate cancer screening outcomes. Consequently, we need to quantify the benefit and harms of PSA-based screening for the Belgian population. For this purpose, KCE methodology implies to use results issued from good quality randomized control trials. Although not reflecting all the uncertainty around the effect of PSA, the KCE team decided to select the European study (ERSPC) alone as it was conducted in the European context, including Belgium. The effect shown in that trial is modest at best, and there is considerable heterogeneity among countries in this multicentre study. This implies that there is considerable uncertainty around the numbers that are presented. Furthermore, as ERSPC study included men in the age-group 55-69y, our results are focused on this age-group. The alternative however, using the PLCO study that does not show an effect at all, is problematic and it is not really useful to present concrete numbers based on no effect at all, simply stating that there is no proven effect would suffice here. The information to practitioners should mention this limitation clearly.

4.2 Methodology

As explained above, our main source is the ERSPC study. For some outcomes, we searched for more details in ERSPC related publications. So, for false positive results (see point 2.3.3.1), we used the analysis done by Kilpelainen et al. 2011. For lead time (see point 2.3.3.4), we used the analysis done by Finne et al. 2010. For overdiagnosis we applied the 40% modeled estimate from the ERSPC of Heijnsdijk et al. applied to the Belgian incidence data. For harms (see point 2.3.3.3), we used the Göteborg trial whose results are included in the ERSPC study but is conducted and reported separately and contains more information on harms.
We applied data from the ERSPC study on the Belgian mortality and cancer data. Main data sources were: Belgian Cancer Registry (BCR), Belgian life table and Statbel.

The Belgian Cancer Registry Foundation is a public institution which collects data concerning new cancer cases in Belgium and makes up statistics from these data (http://www.kankerregister.org/). We used data from the year 2010. The Directorate General Statistics and Economic Information (DGSEI) is in charge of the national (official) statistics in Belgium. This Directorate published the Belgian life table and the mortality statistics (http://www.statbel.fgov.be/).

4.3 Results

4.3.1 Burden of prostate cancer in the age-group 55-69 years

We present the burden of the prostate cancer (PC) for 100 000 men aged from 55 to 69 years as actually shown in BCR (2010). The observed incidence of PC is 6325 cases per year for 100 000 men aged from 55 to 69 years. The PC related mortality is compared with the main others mortality causes in the age-group.

<table>
<thead>
<tr>
<th>Cause</th>
<th>100 000 men aged 55-69 years</th>
<th>100 000 men aged 70-79 years</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>All cause</td>
<td>19 310</td>
<td>33 596</td>
<td>StatBEL life table (2010)</td>
</tr>
<tr>
<td>Prostate cancer</td>
<td>32†</td>
<td>1097</td>
<td>BCR (2008) applied to life table</td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td>4011</td>
<td></td>
<td>StatBEL cause of mortality applied to life table</td>
</tr>
<tr>
<td>Other cancers</td>
<td>7258</td>
<td></td>
<td>BCR (2008) applied to life table</td>
</tr>
<tr>
<td>Violent causes</td>
<td>1133</td>
<td></td>
<td>StatBEL cause of mortality (2008) applied to life table</td>
</tr>
</tbody>
</table>

*data observed in BCR (2008) applied to life table. Data shown in material includes PC deaths in the 15 following years.
4.3.2 Screening related benefit

4.3.2.1 Prostate cancer specific mortality

To present the effect of screening on the PC specific mortality, we have estimated the number of deaths from prostate cancer per 100 000 men over 15 years in two groups. First group (named: "no screening group") included 100 000 men in the age-group 55-69 followed over 15 years and not screened for prostate cancer, second group (named "screening group") included 100 000 comparable men screened for prostate cancer. All results are presented for 100 000 men in this chapter, but in the information designed for the patients results will be presented per 1000. As the study only has a follow-up time of 12 years and the intervention would be already regular screening during 15 years (age-group 55 – 69), the information that the study provides needs to be extrapolated far beyond the actual data and meaningful figures, needed to inform the decision aid, can only be estimated making use of strong assumptions. Those assumptions have a large impact on the estimated effects and a lot of caution is needed interpreting our estimations.

Following assumptions are used to produce the estimates.

- The reduction seen in the ERSPC study is a valid estimate of the effect of screening.
- The effect observed in the study can be extrapolated to estimate the effect of regular screening during 15 years.
- The effect is constant over the time period.
- There is a time lag of 7 years, as seen in the study.
- The effect starts 7 years after the beginning of the screening and last up to 7 years after the screening. This may inflate the effect somewhat, as prostate cancer related mortality increases with age and no gradual waning of the effect is assumed. On the other hand, this approach may underestimate the effect, as the 29% reduction was measured over the whole period, including the 7 years lag without an effect. There is no way to make out what the real impact of these assumptions is and how they cancel each other out.

- The overall effect seen in the ERSPC study applies to the Belgian context, even if considerable heterogeneity was observed within the European study.

We use the estimate of the effect adjusted for non compliance as reported in the study what is 29% ([95% CI, 14 to 42]; P = 0.001). Furthermore, we use the Belgian life table (2010) to adjust for competing mortality. Other causes of death were taken from StatBEL causes of mortality (2008), applied to the Belgian life table to adjust for competing mortality.

<table>
<thead>
<tr>
<th>Number of deaths caused by prostate cancer</th>
<th>Screening group</th>
<th>No screening group</th>
</tr>
</thead>
<tbody>
<tr>
<td>578</td>
<td></td>
<td>813</td>
</tr>
</tbody>
</table>

4.3.2.2 Metastatic disease from prostate cancer

We applied directly the 50% reduction in metastatic disease seen in the intervention group compared to the control group in the ERSPC. As we do not have information on metastatic disease in Belgium, as the data from the Belgian Cancer Registry only report the Stages I – IV, we assume a comparable proportion as in the ERSPC study. Metastatic disease constituted 9% of all cancers in the ERSPC study.

<table>
<thead>
<tr>
<th>Number of metastatic diseases caused by prostate cancer</th>
<th>Screening group</th>
<th>No screening group</th>
</tr>
</thead>
<tbody>
<tr>
<td>285</td>
<td></td>
<td>569</td>
</tr>
</tbody>
</table>
4.3.3 Screening related harms

Screening related harms are false positive results (followed by unnecessary biopsies), and over diagnosis.

4.3.3.1 False positive results

For proportion of false positive (unnecessary biopsies) per screening round, we used the numbers presented the secondary analysis of the European ERSPC study done by Kilpelainen et al. 2011. We used the numbers of the first round, overall numbers of second round and third round were comparable, but based on fewer numbers because of drop out. Proportions differ however in an important way between countries, ranging from 5 to 20%. We do not used specific results Belgian data difficult to interpret due to repeated changes in the screening protocol. Furthermore, it is unclear what the correct proportion may be actually in Belgium in a routine setting, as no Belgian routine data are available.

4.3.3.2 Overdiagnosis

For overdiagnosis we applied the 40% modeled estimate from the ERSPC of Heijnsdijk et al. to the Belgian incidence data. We did not use a direct measure such as the rate ratio for prostate cancer as measured directly in the RCT as this does not take in account the lead time effect and compensatory drop that is expected, as earlier found cancer do not appear in the statistics in later years. As there is no information on what the implications are of PSA screening on overdiagnosis in Belgium, we not adjust. Adjusting would lead to a lower estimate of prostate cancer in the non-intervention group and a somewhat reduced harm caused by overdiagnosis. Differences would probably be small however, especially in the light of the considerable uncertainty that there is around the real % overdiagnosis. So, we used the Belgian incidence data as they are for the moment, even if over-diagnosis is already partly reflected in those data. It is also important to note that the follow-up time in the ERSPC is actually too short to reliably measure the degree of overdiagnosis due to lead time effects, it remains very unclear what the actual degree of overdiagnosis really is.

<table>
<thead>
<tr>
<th>Table 8 – Screening related harms for 100 000 men</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
</tr>
<tr>
<td>False positive results per screening round</td>
</tr>
<tr>
<td>Over diagnosis for the whole screening period followed over 15 years</td>
</tr>
</tbody>
</table>

4.3.4 Treatment related harms

To estimate the number of patients that undergo prostatectomy, active surveillance and radiotherapy, we proposed to the Belgian Urologist Association to use a Belgian publication. Following this publication, 80% of patients undergo prostatectomy, 10% active surveillance and 10% radiotherapy. We received no comment on this proposition. Consequently, we used data found in the cited publication. Afterwards, treatment related harms were applied to patients in both groups (screening and not screening group), side effects are proportional to those.

4.3.4.1 Prostatectomy

To estimate the harms caused by prostatectomy we followed Carlsson et al., who found that in the Göteborg trial, who is also included in the ERSPC trial, 79.1% of preoperatively potent men in the screening-group and 90.7% in the control-group became impotent or sexually inactive 18 months postoperatively, whereas 14.3% of screened men and 20.5% of controls were considered postoperatively incontinent.

To apply those results to the Belgian population, we assume that 30% of the men were not preoperatively potent, following the proportion presented by Carlsson et al. Note that it is unclear to which degree these estimations are valid in the Belgian context. Furthermore, as the prostate cancer incidence, the mortality reduction observed in the Göteborg trial is more

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important than the overall reduction in ERSPC. Only 49% of diagnosed prostate cancer underwent surgery in the intervention group and 38% in the control group. The rate ratio of dying from prostate cancer was 0.56 (95% CI 0.39–0.82; p=0.002) in the screening group compared with the control group. A secondary analysis showed that the rate ratio of death from prostate cancer for attendees compared with the control group was 0.44 (95% CI 0.28–0.68; p=0.0002).

Table 9 – Estimated side effects of prostatectomy

<table>
<thead>
<tr>
<th>100 000 men, age-group 55 – 69 followed over 15 years</th>
<th>Screening group</th>
<th>No screening group</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persons who became impotent or sexually inactive 18 months postoperatively after prostatectomy</td>
<td>3967</td>
<td>3188</td>
<td>Carlson et al., 2011 applied to the Belgian situation would be</td>
</tr>
<tr>
<td>Persons who became incontinent after prostatectomy</td>
<td>2125</td>
<td>1518</td>
<td>Carlson et al., 2011 applied to the Belgian situation would be</td>
</tr>
<tr>
<td>Persons with intestinal problems after prostatectomy</td>
<td>1063</td>
<td>759</td>
<td>KCE report</td>
</tr>
</tbody>
</table>

4.3.4.2 Radiotherapy

The ERSPC study did not measure directly the harms related to radiotherapy. For harms related to radiotherapy we used the KCE report of 2006. There 60% of men became impotent and 30% had bowel dysfunction, albeit temporary.

Table 10 – Estimated side effects of radiotherapy

<table>
<thead>
<tr>
<th>100 000 men, age-group 55 – 69 followed over 15 years</th>
<th>Screening group</th>
<th>No screening group</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persons who became impotent or sexually inactive 18 months after radiotherapy</td>
<td>372</td>
<td>266</td>
<td>KCE report 2006</td>
</tr>
<tr>
<td>Persons with rectal problems after radiotherapy</td>
<td>266</td>
<td>199</td>
<td>KCE report 2006</td>
</tr>
</tbody>
</table>
4.3.4.3 Active surveillance
For harms related to active surveillance, we mentioned the risk of anxiety linked to the repeated biopsy and uncertainty.

4.3.4.4 Lead time
It is also necessary to take into account lead time as screening related harms.

Lead-time is defined as the time by which screening advances the diagnosis compared with absence of screening. Finne pooled results issued from ERSPC partners in The Netherlands, Sweden, Finland, Italy and Belgium. Using a serum PSA cut-off of 4 ng/ml, he estimated the mean lead-time in the whole study population as 6.8 years [95% CI, 6.4 to 7.3]. The shortest mean lead-time (4 years) was estimated for Belgium. This is related to the fact that screening had a relatively low detection rate, while prostate cancer incidence in the control arm was higher than that for the other centers. The high incidence in the control arm may be related to the volunteer-based design. This design may have led to recruitment of high-risk men and/or contamination. Indeed, contamination due to unorganized screening in the control arm may increase the prostate cancer incidence in the control arm. This assumption is corroborated by the fact that the rates in the control arm in these countries are well above national incidence rates.

As one round of prostate cancer screening can advance clinical diagnosis by 4-8 years, cancers diagnosed after screening would be treated earlier than cancers diagnosed after symptoms. Consequently patients diagnosed after screening would suffer longer from treatment related side effects.

5 ELABORATION OF A TOOL TO SUPPORT SDM

5.1 Introduction
This chapter aims to describe the process used for produce SDM tool to decide on a PSA testing for prostate cancer screening. This tool must be usable by every Belgian GP in the SDM process.

The process followed four steps:
1. Development of a first draft
2. Preliminary assessment of the whole tool by representative of scientific associations of GPs
3. Test for GPs acceptability and readability of this material
4. Test of the usability of the SDM during appointment

5.2 Methodology

5.2.1 First step
The development of the first draft was done in French after KCE team brainstormed on its potential general design. It appeared that, next to information to share with patients, providing GPs up-to-date technical background information on the all process (including the outcomes) of PSA prostate cancer screening may be useful. First raison therefore was the large among of scientific publications and advance in prostate cancer management recently published. Second reason was that due to discrepancies of (continued) medical education, Belgian GPs knowledge on PSA screening may vary. Uniform knowledge on PSA screening process and outcomes was considered as a basic requirement to achieve a successful SDM with the patient. Consequently, the KCE team decided to develop a tool in two parts:

- An introductive part dedicated to practitioners
- A ‘decision aid’ part aimed to be discussed with the patient during the SDM process.
The first part was developed by KCE team and based on some guidelines\(^1\), \(^3^7\) \(^3^8\) and on others reference documents.\(^3^9\) A first assessment of scientific exactitude of the text was done by the chairman of the Oncology College (section urology) of the Federal Public Service of Public Health.

The second part was first developed on the basis of instructions issued from chapter 3 for its content and format (see point 3.2.5). The data presented were issued from the quantification of benefit and harms of PSA screening described in chapter 4. As the advantages and disadvantages of participating in this screening are based on ERSPC study what has included men aged 55-69 years old, information provided in the SDM material are focused on this age-group. It was decided to submit this part first to the representative of the GPs associations and secondly to GPs.

### 5.2.2 Second step

A preliminary assessment of the whole tool written in French was done by three GPs representatives of the Dutch-speaking scientific association of GPs (Domus Medica) and three GPS representative of French-speaking scientific association of GPs (SSMG). This assessment aimed to assess acceptability and understandability of the document.

We send them a first draft a few days before we met them. For practical reasons, we carried out face-to-face individual interviews with the representatives of Domus Medica and in group interview with the representatives of the SSMG. Modifications and precisions issued from those assessments were afterwards applied to the draft. The draft was also submitted to the three Belgian urological associations (BAU, SBU Belgian Society of Urology/Société belge d’Urologie, and BVU) chairman’s. The second version was translated in Flemish by a professional translator and reviewed by a representative of Domus Medica and a communication expert of the KCE. French and Dutch-speaking versions were finally both submitted to a stakeholder’s panel (listed in the colophon) and discussed during two meetings organized at 10-03-2013 and at 11-12-2013.

Modifications and precisions discussed during those meetings were afterwards applied to the draft. Seen the remarks of this preliminary assessment and additional comments of specialists, the project opted to a designed leaflet made by a graphic designer specialized in health communication. Obviously, the design followed the guiding principles for decision aid as described in chapter 3. We developed this material on the same way as material developed for informing women on breast cancer screening issues.\(^1^5\)

### 5.2.3 Third step

This part tested GPs’ acceptability and readability of the SDM tool. As this tool contains a wide description of the complete screening process, a good comprehension of this may be crucial in the GP-patient communication. KCE team judged that a way to assess this was to perform a comprehension test of this section by the GP alone. The value and comprehension of the SDM tool was tested in sixteen face-to-face interviews with GPs. Well in advance of the interview (two weeks beforehand), each GP received a copy of the SDM tool with the accompanying request to read the tool carefully in preparation for the interview.

The interview consisted of two parts (see Appendix 4.1.1):

1. A comprehension test on the section of the SDM tool that is directed at the patients, i.e. the material to be presented to the patient;
2. A questionnaire on PSA screening in general, discussing:
   2.1. How a (demand for) PSA screening is handled by the GP;
   2.2. The attitude of the GP towards the use of the SDM tool in a consultation;
   2.3. The merits and the possible use of this tool;
   2.4. The impact on a consultation, should the tool be used;
   2.5. A review of each page of the SDM tool;
   2.6. The perceived neutrality of the tool (towards screening).

The interviews were preceded by a preliminary test with two GPs (one Dutch-speaking and one French-speaking). Those two GPs did not point out any flaws in the interview questionnaire, nor did they have any fundamental comments on the SDM tool. As a result, the questionnaire was maintained without changes and adaptations of the SDM tool were limited to a number of minor - mostly editorial - changes.

Following this preliminary test of the questionnaire and the SDM tool, fourteen GPs were interviewed. As the two preliminary interviews were
based on an identical questionnaire and an almost identical tool, the results of these two test interviews are included in the analysis, resulting in a set of sixteen interviews. All in all, sixteen GPs agreed to participate in the study. Each one agreed to:

1. An introductory interview (face-to-face) on their views and practice regarding PSA screening, the use of decision aids and their first impressions of the SDM tool. The comprehension test was also part of this introductory interview (described here as the third step);
2. Use the SDM tool with four patients who asked for PSA screening or expressed concerns on prostate cancer (described in the fourth step);
3. A concluding interview (face-to-face) on the experiences of the GP with the SDM tool (described in the fourth step).

To be noted is that all GPs put themselves forward to participate in the study, answering to an invitation by Domus Medica (Dutch-speaking part of Belgium) or Société Scientifique de Médecine Générale (French-speaking part of Belgium). Given this self-nomination, the sample of sixteen GPs obviously cannot be seen as representative. A selection bias might even be expected, as GPs with for instance an interest in PSA screening or decision aids might be more motivated to apply. All in all, twenty Dutch-speaking and thirty four French-speaking GPs expressed an interest in participating. The number of applications in both parts of the country thus exceeded the number of GPs needed for the test. The selection of participants distributed GPs evenly:

- between the Dutch- and French-speaking parts of Belgium
- between the urban and rural parts of the country
- between male and female GPs

All of these criteria could influence the attitude and willingness of (older) male patients to discuss prostate cancer. When a choice remained between candidates, an optional fourth criterion was regional distribution, aiming to spread the participating GPs over the country.

Of the sixteen GPs participating, eight were French-speaking and eight Dutch-speaking. Seven GPs were women, nine were men. Five GPs maintained their practice in or close to a main city (Gent, Charleroi, Liège, Brussels), while the other eleven practised in smaller cities or rural communities. All in all, GPs from eight Belgian provinces participated. A balanced distribution of the participating GPs was thus achieved.

The interviews with GPs were held in the second half of October and in November 2013, after two preliminary test interviews were concluded at the end of September 2013. The large majority of the sixteen interviews went smoothly. Three interviews posed some difficulties: two GPs had not read the SDM tool before the interview; and one GP invited a co-worker to participate in the interview. These three interviews were continued, due to the time restraints involved in rescheduling the appointments, and that because the presence of an extra GP added considerable experience, the participation of an extra GP was allowed by the interviewer. However, in these three interviews, the comprehension test was omitted, as the preparatory reading was missing or a combined interview does not allow for individual answers. Most interviews took 30 to 45 minutes, with all interviews ending within an hour.

5.2.3.1 The comprehension test

The first part of the interview in this third step was a ‘comprehension test’. The test aimed to establish the readability of the section of the SDM tool with material to be presented to the patient. The test was designed to measure whether GPs:

1. Could easily look up and find specific patient-oriented information on PSA screening;
2. Correctly understood and reproduced the content of the SDM tool.

The comprehension test consisted of ten open-ended questions on the data presented in the patient section. An example of such a question is: “Compare the mortality rate for men with and without screening.” Being a comprehension test, the questions either measured the correct comprehension of the information or were formulated in such a way that a GP was almost obliged to search for the correct answer in the text. For instance, most questions asked for precise figures or definitions. This also allows for a clear demarcation between wrong and right answers.
A comprehension test can be compared to an open book examination. The interviewee is allowed and even encouraged to find the correct answer in the SDM tool, as the test measures whether a person can find information (as opposed to memorising it).

The test focused on establishing whether the information and figures that will be used in patient contacts are clear and unambiguous. No questions were asked on the section of the SDM tool that provides the GPs with technical background information on PSA screening.

Most GPs answered swiftly and precisely the questions in the comprehension test (see Appendix 4.2), resulting in a mean score of 7.5 out of 10. Apart from one GP scoring 2.5 (and thereby lowering the mean score considerably), all GPs attained at least 5/10 and ten out of thirteen GPs scored seven or more correct answers (out of ten). All questions were correctly answered by a (large) majority of GPs, apart from one question in which the majority of the answers were judged as insufficiently detailed. To this question (which men of 55-69 years does PSA screening target?), most GPs answered ‘all’ or they gave only part of the correct answer (men without complaints regarding urinary passages and without any symptoms related to the prostate).

Most of the faulty or incomplete answers to the questions originated in the desire of the GPs to provide a swift answer, from memory and without checking the correct answer (even though they were allowed and even encouraged to do so). Some doctors might have interpreted the comprehension test subconsciously as questioning their professional abilities. This tendency to answer from memory often led to partial answers. When a GP looked up an answer in the text, the answer was invariably correct.

Because, with the effective use of the SDM tool, the GP would be showing specific pages and information to the patient, most of the incomplete answers would not be given in a real world consultation, as the correct information is prominently displayed on the page showed. Thus, the SDM aimed for use with the patients was judged as clearly formulated and posing no fundamental comprehension problems for the GPs.

5.2.3.2 A first appraisal of the SDM tool by the GPs

Reliable content of the material – None of the sixteen GPs made fundamental remarks opposing the content of the SDM tool. All GPs agreed with the content, often stating voluntarily that the added value of PSA screening is dubious.

All GPs viewed the tool as well developed and presenting scientific reliable material. Younger GPs often mentioned that they received similar information during their training and that the tool provided hardly any new knowledge. More mature GPs occasionally claimed that the tool does contain new information, referring mostly to details.

Two (minor) criticisms were expressed more than once. The text:

- Is limited to men of 55-69 years old and offers no information for 70+ men, while several interviewees said that there were demands originating from this age group;
- Neglects to mention the possibility of a false negative biopsy, which is a negative screening result while prostate cancer is actually present. Several GPs referred to similar actual cases that they had encountered.

The GPs viewed the tool as neutrally formulated on the decision to screen or not (9 doctors) or discouraging PSA screening (7 doctors). All seven doctors who felt that the tool ‘discouraged screening’ explained this by referring to the figures in the document and claiming that these figures implicitly advise against PSA screening. No GP mentioned an explicit or implicit bias towards or against PSA screening in the editorial content or word choice of the document.

Helping the patient to decide – The GPs valued the endeavour to inform patients about PSA screening and to involve patients in the decision to screen or not. They welcomed the neutral yet clear-cut form of the tool.

The GPs stated that one advantage of the tool is that it helps GPs to give objective advice on PSA screening, supporting advice not to screen with convincing statistical proof.
Some GPs refrain from explicitly discouraging PSA screening, supporting the view that any final choice on whether to be screened should be made by the patient. They welcomed the SDM tool, as it was seen as helping patients to decide.

**A practical aid while discussing PSA screening** – The SDM tool fills a void, as hardly any tools or visual aids exist in the area of discussing PSA screening and prostate cancer with a patient. Not one of the sixteen GPs used anything more than an elementary drawing of the prostate during conversations on PSA screening.

Moreover, the use of the tool assures a GP that all important issues regarding PSA screening will be addressed during a consultation.

**A difficult fit with the consultation** – Not all GPs were keen to use the instrument. Ten out of sixteen claimed that they would use the SDM tool in their conversations with patients on PSA screening. Four stated that they would not use the tool (one had doubts; one did not answer). All objections refer to two drawbacks:

- *The information presented is complex.* Each of the GPs expressed fear that the instrument and the information it contains is too complex for (a large part of) their patient base. For instance, the graphs comparing the impact of screening versus no screening are judged to be confusing and difficult to understand. The GPs stress that they prefer (very) elementary diagrams and graphs that are easy to understand;

- *A time-consuming process.* Most GPs fear that, due to the complex format, the proper use of the SDM tool will require too much time. Estimates range from an additional five to more than ten minutes. This additional time would exceed the time slot of a regular consultation. This was felt to be particularly relevant, as many patients bring up (vague) prostate issues in a consultation dedicated to another medical problem.

Noteworthy is the fact that the concern about the amount of additional time needed to walk through the SDM tool was also expressed by GPs who claim that they value a high level of information and consultation with their patients, who claim to use other decision aids, and who extend the time span of their consultations.

Several GPs pointed to a separate, preventive consultation as the natural habitat for the SDM tool on PSA screening. However, such preventive consultations are also already filled with other issues.

Some presented the idea of a dedicated consultation on prostate cancer, offering plenty of time to discuss the screening and walk through the SDM tool. One difficulty might be that the content of the SDM tool points to a decision not to screen. This might become a counter-intuitive situation for the GP and their patient: an additional consultation is proposed (and paid for), of which the result would be ‘do nothing’.

**Other remarks on the SDM tool** – During the interviews, several other remarks surfaced:

1. *Proposing other statistical and graphical representations.* Several GPs assumed that the use of bar graphs and percentages would increase the comprehensibility of the SDM tool (instead of the current visuals, which do not use percentages and graphs). However, most of these suggestions are contrary to the literature on visualisation and neutral information;

2. *Adding a drawing of the prostate,* as many patients have no idea what the organ looks like and how it functions;

3. *Reducing the number of references to death.* GPs fear that the frequent mention of death and the chance of death may shock and preoccupy patients, meaning that other information is not or is incompletely absorbed by the patient.

**An additional (and separate useable) resume** – Several GPs proposed adding to (or even replacing) the SDM tool with a much shorter summary note, which the patient can take home with him. This resume should limit itself to a number of key messages. It allows a patient to review the conversation with his GP and how they came to the decision (not) to screen. Such a summary would also be useful in terms of informing other family members, especially as GPs fear that many patients are not able to reproduce a faithful account of their conversation with the doctor. One GP warned of a situation whereby a patient arrives home after a visit to his GP, with a confusing narrative on the considerable possibility that he may be a victim of prostate cancer, yet that his doctor advises him to do nothing.
Some GPs positioned this summary note as a primary health care instrument, informing patients on the advantages and disadvantages of PSA screening before the actual consultation on PSA screening. In this view, a GP would opt to use the SDM tool only when a patient has follow-up questions after reading the summary document.

5.2.4 Fourth step

This step tested the usability of the SDM tool during consultation. The sixteen GPs, who had evaluated the acceptability and readability of the SDM tool during the third step were given eight weeks (between December 9th 2013 and January 31st 2014) to use the patient ‘decision aid’ part of the SDM tool with patients who asked for a PSA testing or expressed concerns about prostate cancer.

Each GP had already agreed to carry out the test in the preceding step and had been informed about the following conditions:

- use the SDM tool with at least four patients asking for a PSA testing or expressing concerns about prostate cancer;
- fill out a ‘patient form’ after each test (Appendix 5.1) as a record of the test;
- discuss the experience with the SDM tool in a face-to-face interview.

Two sets of the SDM tool were sent by post to the GPs. Each part of the SDM tool (the introductory part dedicated to practitioners and a ‘decision-aid’ part aimed at the patient) was presented in the form of a spiral-bound booklet in landscape format. A covering letter reminded GPs of the goal, process and deadlines relating to the test. Six ‘patient forms’ for the GPs to fill out after each test were also enclosed.

Several phone contacts were planned with the participating GPs to follow the development of the test and to organize the concluding face-to-face interviews.

After receiving the SDM tool, one GP decided not to carry out the test with the patients after all; two doctors became ill and dropped out of the study, two GPs did not have the opportunity to use the SDM tool and another doctor feared causing anxiety if the tool was used and therefore resolved not to use it during consultation. Therefore, an extra GP was included in the study, and the co-worker of a participating GP, who had already attended the comprehension test, was also asked to test the SDM tool.

All in all, twelve GPs (seven French-speaking and five Dutch-speaking, five women and seven men) used the SDM tool with their patients. Forty-three patient forms were filled out during and/or after the consultation (one GP, who filled out six patient forms, tested the tool with four more patients but did not complete a form for them). In all consultations, except one, the matter of PSA testing and/or prostate cancer was addressed by the patients themselves. Two GPs notified their patients that the use of the SDM tool was part of a study in which they were participating.

The concluding face-to-face interviews (see Appendix 5.2) took place at the end of January and during February 2014. During the interviews, which took between 20 and 45 minutes, following topics were discussed:

1. how the testing had gone;
2. how the GP had used the SDM tool;
3. how patients had reacted towards the SDM tool;
4. how the GP evaluated the SDM tool;
5. GPs suggestions and remarks.

5.2.4.1 Overall impressions of the use of the SDM tool with patients during consultation

Mixed opinions - Seven GPs considered the test to be a positive to partly positive experience and were willing to use the tool in the future, should it become available. On the other hand, five GPs expressed negative feelings about it (three of them will certainly not use the tool in the future, one had not made up his mind and one did not express an opinion). It appears that doctors who ‘believed’ in the instrument and were keen to use it beforehand, were (very) positive about the test. The same is true for GPs who explicitly communicated the official point of view (PSA testing is discouraged) and used the tool to provide objective justification for their advice. Those who were less eager at the moment of the comprehension test are now unenthusiastic about the tool. They confirmed the objections previously mentioned during the comprehension test, namely the complexity of the tool (found to be too long and inadequate for use during
a consultation and not appreciated by their patients), and the number of references to death.

“Il est peu agréable d’entendre les conclusions sur la mort ou les effets indésirables.”

“La présentation de l’outil produit un malaise.”

Two doctors suggested (again) that it would be better if the tool were replaced by a ‘take home’ folder which could be handed to the patient before/to prepare for a consultation on PSA testing.

Some patients favour the doctor’s advice – Some GPs consider the experience to be negative because, despite their efforts to explain the tool, patients, although they might listen politely, are more interested in the doctor’s advice, than in charts that they do not necessarily understand:

“Wat je (als huisarts) vertelt is belangrijker dan het visuele.”

“Allé, zeg jij maar wat ik best doe.”

Others appreciate being involved in the decision-making process - The satisfied GPs mention no major problems. They regard the tool as a practical aid while discussing PSA testing with patients (who appreciate being involved in decision-making and being taken seriously) and a great added value for their consultation:

“C’est un excellent support pour fournir des explications.”

The accurateness of the figures impresses the patients and shows a scientific-based opinion which makes it possible for the GP to overcome the emotional impact surrounding cancer.

Influence of patients’ profile - Several doctors have the feeling that (some of) their patients are not able to either receive and interpret the information, or make objective comparisons (for example: they fear the patient might attach great importance to survival statistics and dismiss side effects such as incontinence). Several believe that a certain socio-professional level is required to perceive the pertinence of the tool.

It also appears that patients can be influenced to undergo PSA testing by other (specialised) doctors. The emotional state of the patient also plays an important part in the patient’s interest in the tool.

Using the tool can be tricky - One GP, who decided not to carry out any test because of the fear that discussion of the SDM tool with patients might induce anxiety and confusion, said it was not possible for her to find a valid way of introducing the SDM tool in a consultation:

“Ik kon dit niet doen zonder angst te induceren. Terwijl je als huisarts angst moet wegnemen.”

This doctor declared that the tool was far too complicated and felt uncomfortable with the fact that, whilst a doctor is supposed to discourage PSA testing, there is no alternative to offer to the patient. Another doctor had a similar experience when one of his anxious patients believed that he was one of the ‘red’ men in the chart (that is, suffering from prostate cancer).

Several other doctors pointed out that it took them some time to assimilate the tool and be able to use it:

“Finalement, c’est peut-être moi qui ai plus difficile à bien maîtriser les schémas que les patients à les comprendre.”

“...toch niet simpel om te begrijpen of uit te leggen trouwens.”

The SDM tool is not too time-consuming – On average, it took the GPs 10 minutes to use the SDM tool. This was less than the GPs expected, and even if with most patients, the time spent was longer than for a usual consultation, this time was mostly seen as positive for the quality of the consultation:

“Cela ne prend pas beaucoup de temps, le support est efficace si on utilise les blocs appropriés.”

Discouraging PSA testing is not easy – Several doctors stated that the use of this kind of tool is contradictory with current health policy practices such as preventive healthcare and (breast) cancer screening:

“C’est difficile de faire marche arrière après avoir conseillé au patient pendant des années de faire le dépistage.”

“L’utilisation de l’outil va à l’encontre de la politique des dépistages systématiques organisés dans certaines provinces.”
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Information on PSA screening

“En tant que médecin, on se sent un peu seul à diffuser cette information dans le discours ambiant.”
“...sommige huisartsen reageren erg emotioneel en houden vast aan PSA-screening, tegen beter weten in.”

5.2.4.2 Use of the SDM tool by the GPs

As mentioned previously, the twelve participating doctors used the SDM tool with forty-three patients (see detailed file in Appendix 5.3). Those patients were aged 50 to 78 (average age of 62) and three-quarters of them had a high education level (last years of secondary school and or university or similar education). This can be explained by the fact that certain GPs said that they had chosen the patients with whom they wanted to use the tool.

“Cette présentation statistique n’est pas facilement compréhensible ou intégrable par un homme simple. Et s’il est cultivé, il n’aimera pas être réduit à une occurrence statistique.”

Patients came to consultation for different reasons and three-quarters of them had already undergone at least one PSA testing in the past:

- A general check-up (26 patients);
- Other reasons (13 patients);
- Cancer screening (4 patients).

All the doctors used the ‘patient section’ of the tool, and two of them also used one page of the practitioner’s part (page 6 ‘balance of screening’):

“Blad zes is een prima overzicht, dat zou in het patiëntendeel moeten”

Whereas one doctor chose to share the whole SDM tool with his patients, all the others made a selection depending on the patient’s profile. GPs showed mainly the charts on the right-hand pages of the tool, but half of them also used the explanations on the left-hand side. All the pages of the ‘patient section’ were shown:

- Causes of death among men aged 55 to 69 (p.13): used 30 times
  Overall positive comments
  - Used with younger patients
  - Used to introduce the subject
  - Very useful to relativize the problem, to show the impact is lesser than other diseases.

- What will happen in the 15 years to come (p.15) : used 29 times
  Positive, but also negative comments
  “Illustre bien le propos: 8 décès sans dépistage contre 6 avec.”
  “Trop compliqué à comprendre et à expliquer et chiffres pas assez marquants.”

- Consequences of lead time (p.16) : used 25 times
  Positive, but also negative comments
  “Is de samenvatting van de boodschap.”
  “Il est très difficile pour les patients de comprendre la notion d’avance au diagnostic.”

- Long term effects (two years after treatment) (p.17): used 29 times
  Positive, but also negative comments
  - Used with elder patients
  - Might have less impact, patients might agree to suffer the sequels
  “Difficile à comprendre et chiffres pas assez significatifs.”

- Short-term effects of PSA testing (p.19): used 16 times
  Is considered to be interesting complementary information

The use of the tool requires (a little) more time, as GPs took 3 to 30 minutes to use the tool (with an average of 10 minutes) and is therefore usable during consultation. Nine doctors found the exercise not time consuming at all and stated it does not take more or less time. The time impact is clearly influenced by the questions the tool raises with the patients. In any event, the use of the tool clearly impacts the consultation favourably (when the GP is motivated by the use of the tool, and finds it challenging to involve the patient in the decision-making process) or unfavourable (when the doctor does not believe that their patient is interested and/or capable of understanding the information contained in the tool; or if the doctor finds the tool inappropriate). Obviously, the
‘positive’ GPs are willing to continue to use the tool if made available (for example to show a patient that it is not necessary to panic when his PSA level is raised), whereas the others prefer not to use it in the future.

“... maar niet systematisch. Het is vooral leuk om bij de hand te hebben. Als tijdens een gesprek een grote interesse bij patiënt blijkt dan kan de tool aanvullend werken. Bijvoorbeeld als de patiënt twijfelt.”

“J’apprécie beaucoup l’outil. Cela ne prend pas beaucoup de temps et il est important de pouvoir expliquer clairement au patient, il prend part à la décision.”

“Het goed gebruiken vergt veel tijd en het instrument is te rationeel opgebouwd. Het is gemaakt voor rationeel, bijna wetenschappelijke mensen.”

“Cela prend beaucoup de temps et d’énergie pour retenir l’attention du patient qui veut simplement savoir s’il a ou non un cancer.”

5.2.4.3 Appraisal of the SDM tool by the patients

Even the GPs who expressed mixed feelings towards the SDM tool declared that the patients were positive overall towards the tool and that they showed interest. Only ten patients expressed negative reactions. Those patients were not very receptive to cancer prevention, or not interested in statistics:

“Le patient me déclare qu’il fait aussi le dépistage de sa prostate en passant chaque année dans les cars provinciaux et qu’il a bien l’intention de continuer !”

“Le patient déclare « c’est de la statistique... tout dépend d’un échantillon et des populations choisies ! Je ne peux accepter cette sélection statistique.”

“Dit is veel te moeilijk.”

Personal experiences and/or emotional distress can also influence the patient’s attitude toward the tool as many patients know about prostate cancer and the alarm that goes with cancer and therefore screening worries them:

“Le patient m’explique qu’un de ses amis très proches s’est vu dépister son cancer de la prostate suite au PSA. Il veut donc aussi pouvoir en bénéficier (réaction émotionnelle).”

“De vrees voor ‘kanker’ was te groot. De emotionele druk van het woord was te groot voor deze patiënt en oversteeg de rationaliteit.”

The same is true for the patient’s profile. One GP feared that a patient with a low educational level would not understand the tool and was very surprised that the patient turned out to be very receptive:

“Finalement, c’est peut-être moi qui ai plus difficile à bien maîtriser les schémas que les patients à les comprendre.”

But other doctors remained convinced of the importance of the patient’s socio-professional profile:

“Cela nécessite d’avoir un certain niveau socioprofessionnel pour comprendre l’intérêt du document.”

Showing the tool went particularly smoothly when the patients had (excellent) mathematical training or a higher education:

“Très habitué professionnellement à interpréter des statistiques bancaires”

“Zeker bij hoger opgeleide patiënten werkt de tool goed.”

Most patients were curious and listened attentively. Some patients were seduced by the statistical accuracy of the tables presented, and felt flattered to be shown this data. Others were puzzled, unsettled or even stunned. Thanks to the complementary explanations of their doctor, they all tried and were able to understand the tool.

“Les patients apprécient qu’on les implique dans la décision, ils sont satisfaits d’être pris au sérieux.”

“De patiënt verschoot wat van de tool; ze zijn dat niet gewoon. De interesse groeit doorheen gebruik.”
The use of the tool clearly had an impact on the consultation, as 39 patients (out of 43) made a decision regarding PSA testing. The GPs had the impression that their explanations contributed to the decision in the case of half of the patients. We know that 15 patients decided to undergo PSA testing and 12 patients decided not to be screened (although 8 of them had planned to do so when arriving at the consultation). Some GPs believe the tool helped (those) patients to make an informed decision:

“Cela a réellement influence la décision des patients, car ils étaient initialement tous demandeurs du PSA.”

“Les patients étaient surprise et satisfaits de recevoir une information aussi complète. Ils se demandent si c’est utile d’être encore dépistés.”

“Koos voor geen screening, terwijl hij binnenstapte met de vraag om te screenen. De mening draait 180 graden dus.”

Whereas others stated that the use of the tool made no difference:

“Patiënt had al van tevoren beslist, uitleg veranderde er niets aan.”

“Ondanks volledige uitleg en correcte inschatting wou hij toch de test.”

One of the doctors, who addressed the subject of PSA testing himself, found the tool counterproductive, as it led the patient to ask to be screened:

“Patiënt laat zich nu testen omdat ik erover begon.”

Two other GPs feared that the patient might turn to another doctor, or other public health services, which do not try to convince them not to be screened.

“Si je ne leur prescris pas le dépistage, ils risquent d’aller voir un de mes confrères, ou encore, aller au car de dépistage.”

“De patiënt gaf toe om niet te screenen maar het zou me niet verwonderen moest hij meteen naar een andere huisarts gaan om alsnog een screening te krijgen.”

Some doctors felt disappointed when, despite them explaining the tool, the patient nevertheless decided to be screened:

“Je n’ai pas pu le convaincre.”

“De patiënt stapte binnen met het idee om PSA screening te vragen en bleef bij die mening. Ondanks de tool en het advies, vroeg hij uiteindelijk toch om een PSA screening.”

5.2.4.4 Further remarks and suggestions

At the end of the face-to-face interview, GPs were asked to share some final remarks and suggestions, some of which had already been mentioned during step three:

1. Integrate information for 70+ men

   “Zeker toevoegen: wat na 70 jaar? Nu stopt de tekst daar. Maar voor prostaatpatiënten is die 70 jaar vrij dichtbij. Die zijn minstens 50 jaar en al snel ouder dan 60. Ze zitten allemaal in hun hoofd met dat ze 80 en ouder gaan worden. Die willen dan ook weten wat er na 70 jaar gebeurt.”

2. Develop an additional (and separately useable) summary (see step three)

3. Develop a free dedicated consultation on prostate cancer (see step three)

Other suggestions were put forward by GPs motivated by the use of the tool:

1. Incorporate the emotional state of the patient in the SDM tool

   The current tool is too rational and scientific and does not take into account the emotional state of the patient nor answer his needs. When a patient comes asking about PSA testing, he often is not ready to listen to the pros and cons of screening. The reason which brings him to a consultation (cancer of a close relative) makes the conversation emotionally difficult for the patient and the doctor.
2. **Build a 360° communication strategy**

*Use multiple diffusion channels*

The tool should be made available to every Belgian GP in the SDM process. As not all GPs are affiliates of Domus Medica or Société Scientifique de Médecine Générale, it is important to spread the tool through other distribution channels. Specialised doctors (for example cardiologists) should also receive the tool, as they sometimes routinely suggest PSA testing when they recommend a blood test. The tool should be available for use on smart phones and screens.

*Make a video carrying the same messages*

This situation deserves a less traditional and rational approach. It is time to think in terms of ‘advertisement’ and take into account emotional involvement and empathy.

*Organise annual local information sessions about PSA testing*

Ideally, all GPs from the same town should be present to show the men that there is a shared vision regarding this matter. This kind of meeting is more neutral than individual consultations.

*Involve the wives of 50+ men*

And invite them to those meetings! In GPs’ experience, wives are far more concerned about their husbands’ health than the husbands themselves.

*Ik had vroeger 65 folders staan over een typisch mannelijk probleem. Er zijn toen 3 folders door mannen meegenomen en 62 door vrouwen.*

3. **Use role plays to train GPs to handle these conversations**

In medical school, or through continuous training. Several GPs expressed their discomfort in using the tool. As one of them mentioned, doctors learn how to announce to a patient that he has cancer, but not how to explain to a patient that he might have cancer, and is advised to do nothing about it.

5.3 **Results**

We describe here the final versions of the tool after performing the four steps described above. As explained above, the successive versions of the tool contained two parts: a part designed for practitioners and the SDM material as such designed for discussion between patient and practitioner.

5.3.1 **Part dedicated to practitioners**

This part (see Information on [http://kce.fgov.be/fr/node/2418/](http://kce.fgov.be/fr/node/2418/)) has two goals: firstly to update practitioners’ knowledge on prostate cancer screening outcomes with actual research findings and secondly to give them some definitions usable to respond to potential patient’s questions. It describes:

- The scope and the rationale of the document.
- Some scientific considerations on the two large RCT’s (PLCO and ERSPC) performed on PSA-screening.
- Elementary knowledge on prostate cancer (PC) epidemiology (mortality, morbidity).
- The definitions of men who are ‘at elevated risk for PC’ are given.
- The potential consequences of the PSA screening, chronologically: biopsy and commonly accepted initial PC managements as active surveillance, watchful waiting, radical prostatectomy, radiotherapy (external beam and interstitial) and their potential side-effects.

As active surveillance is in Belgium a relatively new management strategy, a summary of her indications (PC risk category) and modalities is mentioned. Some definitions as lead-time and over-diagnosis/over-treatment in PC screening are added. As lead-time and over-diagnosis/over-treatment are relatively new and complex knowledge, they are illustrated by two graphics issued from the scientific literature. A table showing potential rate of benefit and harms of regular screening of a cohort of thousand men followed from 55 to 69 years of age concludes this part. It is followed by a glossary.
5.3.2  **Part to be discussed between patient and practitioner**

This part (see Information on [http://kce.fgov.be/fr/node/2418/](http://kce.fgov.be/fr/node/2418/)) consists in the SDM tool as such, designed to be use in practitioner/patient interaction.

The first left page contains an introductory text for practitioner with some definitions usable in patient contact (what is PSA and what means an high PSA test result?) and the first right page shows a anatomic representation of prostate as it was suggested during the second step of GPs test.

In the next pages, the right page present the information especially designed for men, while the left page “in mirror”, presents explanations usable by the practitioner.

The following figures are presented in the tool and discussed hereafter:

- The risk of dying for men aged 50-69 years.
- Long term outcomes of PSA-screening or not screening.
- Harms of PC management, two years after.
- Consequences of PSA screening in the next months.

5.3.2.1  **Risk of dying for men aged 50-69 years**

5.3.2.2  **Long term outcomes of PSA-screening or not screening**

This figure shows a side by side comparison of the situation of 1000 men in PSA screening group versus 1000 men not in PSA screening group.

Outcomes shown are for both groups:

- Number of men having a prostate cancer and among them:
  - the number of men suffering from harms related to PC management (two years after this management): major change in the sexual function, incontinency, anxiety due to repeated biopsies if active surveillance and digestive disorders
  - the number of men without any sequel after PC management.
- Number of men without prostate cancer.

5.3.2.3  **Harms of PC management**

Like the previous ones, this figure shows a side by side comparison of the situation of 1000 men in PSA screening group versus 1000 men not in PSA screening group.

Outcomes shown are for both groups:

- Men who died due to prostate cancer
- Men having a prostate cancer but yet alive after 15 years, including the number of men suffering from PC metastasis in this group

For men in the screening group, additional outcomes shown are:

- The number of men receiving an over diagnose of PC
- The number of men who are living thanks to PSA screening.
APPENDIX 1  UPDATE OF THE PREVIOUS REPORT

Appendix 1.1  Review of clinical studies

Appendix 1.1.1.  PICO

- **Patient**: men without prostate cancer symptom and without particular risk of prostate cancer
- **Intervention**: screening
- **Comparison**: usual care
- **Outcomes**: mortality (all causes and specific), morbidity (Harms)

Appendix 1.1.2.  Systematic reviews (SRs) and meta-analyses (MA)

A broad search of electronic databases (Medline, EMBASE, Cochrane Database of SRs) was conducted in March 2013.
### Appendix 1.2 Search for SR and MA

**Search questions**

Benefit and harms of PSA screening for prostate cancer

**Note**

Specific search for systematic reviews and meta-analysis
Update of KCE report 31 (search date 2005).

**Keywords**

Prostatic neoplasms (MESH) and mass screening (or early detection) (MESH)

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<td>21</td>
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<tr>
<td>3. (methodol$ or systematic$ or quantitativ$).ti,ab,sh. (499224)</td>
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<tr>
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<td>11. Letter.pt. (454859)</td>
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<td>12. Historical article.pt. (119600)</td>
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<td>13. Review of reported cases.pt. (0)</td>
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<td>14. Review,multicase.pt. (0)</td>
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<td>15. or/10-14 (671198)</td>
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<tr>
<td>16. 9 not 15 (140150)</td>
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<td>prostate cancer'/exp AND 'cancer screening'/exp AND ([meta analysis]/lim OR [randomized controlled trial]/lim OR [systematic review]/lim) AND ([dutch]/lim OR [english]/lim OR [french]/lim) AND [male]/lim AND [humans]/lim AND [embase]/lim AND [2005-2013]/py</td>
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</tbody>
</table>

<table>
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<th>1</th>
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</thead>
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<td>(Prostatic neoplasms) and (mass screening) from 2005 to 2013 in Cochrane Reviews</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 1.3.1. Flow diagram for systematic reviews (SR) and meta-analyses (MA)

Appendix 1.4 Quality Appraisal
Appendix 1.4.1. Systematic reviews and meta-analyses

<table>
<thead>
<tr>
<th>Items</th>
<th>Chou</th>
<th>Djulbegovic</th>
<th>Illic</th>
<th>Lumen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Search date</td>
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<td>July 2010</td>
<td>November 2012</td>
<td>April 2011</td>
</tr>
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<td>PSA based screening</td>
<td>PSA based screening</td>
<td>PSA based screening</td>
<td>PSA based screening</td>
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<td>Yes</td>
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<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>3</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>4</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>+/-</td>
</tr>
<tr>
<td>5</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>6</td>
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<td>Yes</td>
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<td>No</td>
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<td>9</td>
<td>Yes</td>
<td>No</td>
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<td>No</td>
</tr>
<tr>
<td>Comment</td>
<td>Did not pool for the correct reasons</td>
<td>Inadequate pooling</td>
<td>Inadequate pooling</td>
<td>Inadequate pooling</td>
</tr>
</tbody>
</table>

Legend of items 1 to 9 of the quality appraisal:
1. Is de vraagstelling adequaat geformuleerd?
2. Is de zoekactie adequaat uitgevoerd?
3. Is de selectieprocedure van artikelen adequaat uitgevoerd?
4. Is de kwaliteitsbeoordeling adequaat uitgevoerd?
5. Is adequaat beschreven hoe data-extractie heeft plaatsgevonden?
6. Zijn de belangrijkste kenmerken van de oorspronkelijke onderzoeken beschreven?
7. Is adequaat omgegaan met klinische en statistische heterogeniteit van de onderzoeken?
8. Is statistische pooling op een correcte manier uitgevoerd?
9. Zijn de resultaten van de systematische review valide en toepasbaar?
### Appendix 1.4.2. Randomized Controlled Trials

**Risk of Bias for ERSPC²**

Risks were presented as presented in the Cochrane review⁸

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk of bias</td>
<td>The study was a multi-centre trial across 9 European countries that randomly assigned men to screening or control groups, “Within each country, men were assigned to either the screening group or the control group... on the basis of random number generators.”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk of bias</td>
<td>Method of concealment was not described in the publication. It was also unclear whether method of concealment differed among study sites given that different randomization procedures were implemented across the different sites, “…randomization procedures differed among countries and were developed in accordance with national regulations.”</td>
</tr>
<tr>
<td>Blinding (performance bias and detection bias) All outcomes</td>
<td>Low risk of bias</td>
<td>It is not possible to blind participants and clinicians to the screening intervention. Causes of death were evaluated in a blinded manner. Causes of death were obtained from registries and individual chart reviews. A committee analysed causes of death at each centre, with an independent data and safety committee reviewing the trial. There was no information on blinding for other outcome measures (e.g. diagnosed cancers) “Causes of death were evaluated in a blinded fashion... or on the basis of official causes of death. The causes were classified by the independent committees.”</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk of bias</td>
<td>Data from the Portugal study centre were excluded from all analyses due to discontinuation. Data from the France centre of the trial were not included in mortality analyses due to short duration of follow-up, and were not included in primary analyses of additional outcomes - although data were provided. “The primary analysis was planned at the outset on the basis of follow-up of at least 10 years, which was reached with data through 2008. The current analyses include follow-up data through 2008...regarding the core age group analysis.”</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk of bias</td>
<td>Objectives of the ERSPC include cancer specific mortality and quality of life outcomes. Mortality is reported but quality of life is not descriptively reported in this publication. Measures relating to quality of life are currently being reviewed and will</td>
</tr>
</tbody>
</table>
form the basis of future publications, “…an evaluation of the effect on quality of life is pending”

Other bias
- Unclear risk of bias

Main data analysis is based on the core age group (55-69 years). There are differing age groups across the 8 reported sites. “The benefit of screening was restricted to the core age group of subjects who were between the ages of 55 and 69 years at the time of randomizations”

**Risk of Bias for PLCO³**

Risk were presented as presented in the Cochrane review.⁹

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation</td>
<td>Low risk of bias</td>
<td>Individual randomization was performed within blocks stratified according to centre, age and sex. Although the method used to generate allocation sequence was not mentioned in the trial report, it was provided in an earlier publication (PLCO - Prorock). “The randomization scheme uses blocks of random permutations of varying lengths and is stratified by SC (study centre), gender and age. Random assignment is implemented using compiled software and encrypted files loaded on SC microcomputers.”</td>
</tr>
<tr>
<td>Allocation concealment</td>
<td>Low risk of bias</td>
<td>Concealment was achieved through a central system. “As each person is successfully randomized into the trial, data including name, gender, date of birth and study arm are automatically stored in encrypted data tables.”</td>
</tr>
<tr>
<td>Blinding (performance bias)</td>
<td>Low risk of bias</td>
<td>It is not possible to blind participants and clinicians to the screening intervention. Data on diagnosed cancers and mortality were obtained by patient reported questionnaire and followed up by telephone (unblinded). This data was supplemented by linkage to the National Death Index. Death certificates were obtained to confirm deaths and determine cause. Possible cancer-specific deaths were reviewed by blinded reviewers. “Reviewers of these deaths were unaware of study-group assignments for deceased subjects.”</td>
</tr>
<tr>
<td>Incomplete outcome data</td>
<td>Low risk of bias</td>
<td>Data on mortality and diagnosis are available for the 10-year follow-up, but follow-up data on 13-year outcomes are not complete. “As of December 31, 2009 (the cut-off date for this analysis), the vital status of 92% of the trial participants was known at 10</td>
</tr>
</tbody>
</table>
Information on PSA screening

Selective reporting (reporting bias)  
- Low risk of bias
  Study protocol is available and the study’s pre-specified outcomes have been reported. Outcomes, such as harms, are to be reported in future publications “...there is evidence of harms, in part associated with the false-positive tests, but also with the over-diagnosis inseparable from PSA screening, especially in older men.”

Other bias  
- High risk of bias
  Data were analysed according to the intention-to-screen principle. Data on contamination were also provided (estimated to be 40-52%).

Appendix 1.5  Data extraction table

Appendix 1.5.1. Specific mortality reduction

Table 11 – Systematic review and meta-analysis

<table>
<thead>
<tr>
<th>I Study ID</th>
<th>II Method</th>
<th>III Population</th>
<th>IV Intervention</th>
<th>V Results</th>
<th>VII Critical appraisal of review quality</th>
</tr>
</thead>
</table>
| Chou 6     | SR to update the 2002 and 2008 U.S. Preventive Services Task Force evidence reviews on screening (and treatments for prostate cancer: not useful here)  
Funding: Agency for Healthcare Research and Quality (AHRQ)  
Search date: July 2011  
Database: MEDLINE (2002 to July 2011) and the Cochrane Library Database (through second quarter of 2011).  
Study designs: 5 RCT’s, only 2 fair- | Men without prostate cancer in USA (PLCO, 2009), Europe (ERSPC, 2009), Göteborg (subgroup of ERSPC) and Nörrkoping (Sweden).  
Sample sizes ranged from 9026 to 182 160 and maximum follow-up from 11 to 20 years (median, 6 to 14 years). | PSA based prostate cancer screening.  
The ERSPC trial varied in recruitment and randomization procedures, screening intervals, and PSA cut points among study centres. There were greater use of active treatments and more frequent screening intervals in the PLCO trial than the ERSPC trial. | PSA-based screening identifies more prostate cancers, but most trials found no effect on risk for death from prostate cancer. However, the 2 largest and highest-quality trials reported conflicting results. The ERSPC trial found PSA screening every 2–7 y to be associated with decreased risk for death from prostate cancer in a pre-specified subgroup of men aged 55–69 y after 9 y (RR, 0.80 [95% CI, 0.65–0.98]; absolute risk reduction, 0.07 percentage point), but | High quality review but consistency is low (inconsistent results between highest quality trials) so they adequately choose not to pool the results. |
The PLCO trial had a relatively high rate of previous PSA testing (44%) and contamination in the control group (50% received ≥1 PSA test). A fair-quality study from 1 centre participating in the ERSPC trial reported better results than the overall ERSPC analysis, with substantial overlap in patient populations. Three poor-quality screening trials did not find PSA-based screening associated with decreased risk for death from prostate cancer.

| Study designs: 6 RCT’s were included for specific mortality: | 387,286 participants (men without prostate cancer) randomized to either prostate cancer screening or no screening | All but one study (Norrköping that initially used only DRE) included measurement of PSA as a screening test in all participants. In the ERSPC the screening method differed by participating country and was mostly based on PSA. Finally, in the | With the inverse variance method, the calculated relative risk was 0.88 (0.71 to 1.09; \( P = 0.25 \)) when analysed in an intention to screen analysis. | High quality review but there was considerable heterogeneity among the trials included in the specific mortality reduction outcome (I² = 55%, \( \chi^2 = 8.89 \); \( P = 0.06 \)). Inadequate pooling of conflicting results |

Djulbegovic *  
SR and meta-analysis of RCT’s  
Funding: not reported  
Search date: July 2010  
Database: Medline, Embase, CENTRAL, abstract proceedings, and reference list.
ERSPC (2009), PLCO (2009), the Götenborg trial, which included participants previously reported in the ERSPC trial, Nörrkoping (Sweden), French ERSPC and Quebec 2004.

Götenborg study screening was based on PSA testing alone, and participants received a digital rectal examination only if the test result was abnormal.

<table>
<thead>
<tr>
<th>Study designs: 5 RCT’s were included for specific mortality: ERSPC (2012), PLCO (2012), Nörrkoping (Sweden), Stockholm and Quebec 2004.</th>
<th>341,342 participants (men without prostate cancer) randomized to either prostate cancer screening or no screening.</th>
</tr>
</thead>
</table>
| Following screening procedures, individually or in combination, were included: • digital rectal examination (DRE); • prostate-specific antigen (PSA) test (including total, velocity, density, and percentage free and complex) • trans-rectal ultrasound (TRUS)-guided biopsy. | Meta-analysis of the five included trials identified the risk ratio of prostate cancer-specific mortality to be 1.00 (95% CI 0.86 to 1.17).

A meta-analysis incorporating the ‘core age group’ in the ERSPC study identified the RR of prostate cancer specific mortality to be 1.00 (95% CI 0.83 to 1.19). |

Both the ERSPC and the PLCO studies were assessed as at low risk of bias, whilst the Nørrkoping, Quebec, and Stockholm studies were assessed as high risk of bias. Meta-analysis of the two low risk of bias studies produced a RR of 0.96 (95% CI 0.70 to 1.30). Using data from the ‘core age group’ of the ERSPC study produced a RR of 0.94 (95% CI 0.65 to 1.35).

We consider this pooling of inconsistent results as inadequate though it is also unclear how they apply GRADE, as results are inconsistent and, even under the assumption that pooling would be valid, do not exclude a clinically relevant effect.
<table>
<thead>
<tr>
<th>I Study ID</th>
<th>II Population</th>
<th>III Sample</th>
<th>IV Intervention</th>
<th>V Follow-up</th>
<th>VI Results</th>
<th>VII Limitations</th>
<th>VIII Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ERSPC 2012</strong>&lt;sup&gt;2&lt;/sup&gt;</td>
<td>Men in 7 European countries enrolled 1991–2003.</td>
<td>182 160 men aged 50–74y; 162 388 men in predefined “core” subgroup age 55–69y. 82 816 assigned to screening; 82% had ≥1 PSA test during trial. 99 184 assigned to control group; based on single site, screening in controls: -20%</td>
<td>Variable by centres  Most centres performed PSA every 4 y; some also used DRE or TRUS (as Belgium) PSA cut points were 2.5–10.0 µg/L; 3.0 µg/L most often used; some ancillary testing with lower PSA values, Positive screening result led to biopsy; treatments according to local policies and guidelines.</td>
<td>Median follow-up: 11 y</td>
<td>Reduced prostate cancer–specific mortality in core” subgroup: rate ratio: 0.79 (CI, 0.68–0.91); NNS 1055; NNT 37</td>
<td>Inconsistencies in screening intervals and PSA thresholds among study centres. Methods of allocation concealment not described. Differences in exclusion of men by age between centres. Exclusion of data from 2 study centres (Portugal and France, which would bring the number of participating countries to 9) Inadequate reporting of attrition.</td>
<td></td>
</tr>
<tr>
<td><strong>PLCO 2012</strong>&lt;sup&gt;3&lt;/sup&gt;</td>
<td>Men enrolled at 10 study centres in the United States 1993–2001</td>
<td>76 693 men aged 55–74y 38 343 men assigned to screening; overall adherence to screening was</td>
<td>Annual PSA for 6y Annual DRE for 4y PSA cut point&gt; 4.0 µg/L Positive PSA or DRE result</td>
<td>13 years</td>
<td>No difference in prostate cancer–specific mortality at 13y: rate ratios: 1.09 [CI, 0.87–1.70].</td>
<td>High rate of contamination in control group (up to 52% by 6 y). Approximately 44% of men in each group had undergone ≥1...</td>
<td></td>
</tr>
<tr>
<td>Information on PSA screening</td>
<td>KCE Report 224</td>
<td></td>
<td></td>
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<td>-----------------------------</td>
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<tr>
<td>85% for PSA and 86% for DRE</td>
<td>referred to patient’s primary care physician for management</td>
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<tr>
<td>38 350 men assigned to usual care; 52% had ≥1 PSA test during trial.</td>
<td>PSA test before trial entry</td>
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APPENDIX 3 RISK COMMUNICATION AND
SHARED DECISION MAKING

Appendix 3.1  Search strategies

Appendix 3.1.1. Medline

**Attitude of Health Personnel*/Multimedia (1087055) 44833
*Decision Making/Multimedia (63) 27607
*Physician-Patient Relations/ or *Professional-Patient Relations/Multimedia(238481) 36891
*Cooperative Behavior/Multimedia (1420) 10825
Patient Participation/Multimedia (9506) 17800
2 or 3 or 4 or 5 88020

Shared decision making.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier] 1920
6 or 7 88696

Cancer screening.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier] 16433
8 and 9 504

Limit 10 to ((dutch or english or flemish or french) and (meta-analysis or "review" or systematic reviews) and last 10 years) 52

Appendix 3.1.2. Embase

#6 5 AND [review]/lim AND ([dutch]/lim OR [english]/lim OR [french]/lim) AND [embase]/lim AND [2003-2013]/py
#5 3 AND 4
#4 'cancer screening'/exp
#3 1 OR 2
#2 'medical decision making'/exp/mj OR 'clinical decision making'/exp/mj OR 'patient decision making'/exp/mj OR 'decision making'/exp/mj OR 'physician attitude'/exp/mj OR 'doctor patient relation'/exp/mj OR 'interpersonal communication'/exp/mj
#1 'shared decision making'

Appendix 3.1.3. Psychinfo

*Health personnel attitudes 7266
*Decision making 22990
*Client participation 751
*Cooperation/ or *interpersonal interaction 10441

Shared decision making.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures] Multimedia(63)
Cancer screening 2143
1 or 2 or 3 or 4 or 5 Multimedia(63) 41187
6 and 7 184
Limit 8 to ((dutch or english or french) and last 10 years) 179

Meta-analysis.mp. or review.pt. or search: tw.Multimedia(131807)
9 and 10 5
## Appendix 3.2 Selected studies

### Table 13 – Description of the design of systematic reviews included

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Objective</th>
<th>Number of studies included</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Briss et al., 2004</td>
<td>Whether IDM interventions: (1) promote understanding of cancer screening, (2) facilitate participation in decision making about cancer screening at a level that is comfortable for individuals; or (3) encourage individuals to make cancer-screening decisions that are consistent with their preferences and values.</td>
<td>15</td>
<td>IDM or SDM Interventions</td>
<td>Knowledge, beliefs, and perceptions of risk about the disease or condition(s) + options for prevention or early detection Participation in decision making at the level desired for a particular decision at a point in time. Facilitation of decision making consistent with individual preferences and values, through improved knowledge and more accurate beliefs and perceptions combined with more active participation in the decision-making process. Greater implementation of policies that promote and facilitate SDM. Improvement in provider knowledge and self-efficacy about, attitudes toward, and intentions to perform SDM. Improvement in provider participation in SDM. Improved outcomes for individuals as a result of desired changes in provider and system approaches. Adherence to decisions. Actual use of screening tests or rates of follow-up of abnormal tests. Match between individual circumstances and decisions individual levels of decisional conflict. Satisfaction with either the decision-making process or the decisions reached. Health outcomes or fit between the types of health outcomes achieved and individual preferences. Harms or unintended consequences of these programs.</td>
</tr>
<tr>
<td>Edwards et al., 2009</td>
<td>To review the literature to identify external influences on information exchange and shared decision-making in healthcare</td>
<td>7</td>
<td>Information exchange component of shared decision-making (i.e. the giving and receiving of information by either the</td>
<td></td>
</tr>
<tr>
<td>Author, year</td>
<td>Objective</td>
<td>Number of studies included</td>
<td>Intervention</td>
<td>Outcomes</td>
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<td>-------------</td>
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</tr>
<tr>
<td>Gravel et al., 2006</td>
<td>Systematic review on the barriers and facilitators to implementing shared decision-making in clinical practice as perceived by health professionals.</td>
<td>31</td>
<td>healthcare practitioner and the patient or both</td>
<td>Perceived barriers and facilitators to implementing shared decision-making in the practice</td>
</tr>
<tr>
<td>Légaré et al., 2008</td>
<td>To update a systematic review on the barriers and facilitators to implementing shared decision-making in clinical practice as perceived by health professionals.</td>
<td>38</td>
<td></td>
<td>Perceived barriers and/or facilitators to shared decision-making.</td>
</tr>
<tr>
<td>Légaré et al., 2010</td>
<td>To determine the effectiveness of interventions to improve healthcare professionals' adoption of SDM.</td>
<td>5</td>
<td>Any type of intervention that aimed to improve healthcare professionals' adoption of shared decision making.</td>
<td>Objective measure of the adoption of SDM by healthcare professionals Third-observer instruments like OPTION (a scale that measures the extent to which clinicians involve patients in decision-making tasks), the Decision Support Assessment Tool (DSAT), or the Informed and Shared Decision Making instrument.</td>
</tr>
<tr>
<td>Légaré et al., 2012</td>
<td>The effectiveness of interventions to improve health professionals’ adoption of shared decision making in routine clinical practice, as seen</td>
<td>21</td>
<td>Interventions to improve health professionals’ adoption of shared decision making.</td>
<td>Health professionals’ adoption of shared decision making as reported by patients in a self-administered questionnaire.</td>
</tr>
<tr>
<td>Author, year</td>
<td>Objective</td>
<td>Number of studies included</td>
<td>Intervention</td>
<td>Outcomes</td>
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<td>-------------</td>
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</tr>
<tr>
<td>Vedel et al., 2011</td>
<td>(1) to examine PCPs' self-reported practices and point of view concerning prostate cancer screening with PSA tests, and (2) to assess older patients' points of view regarding PSA testing.</td>
<td>20</td>
<td>Self-reported practices and attitudes of PCP with regard to the use of PSA test + older patients' point of view regarding PSA testing.</td>
<td>Building a theoretical organizing framework for evaluation of studies.</td>
</tr>
<tr>
<td>Jimbo et al., 2013</td>
<td>Understanding the impact of the decision aid on patient's attributes, shared decision-making, and patient/clinician concordance</td>
<td>79 (35 on at least PSA)</td>
<td>Intervention with DA</td>
<td>Building a theoretical organizing framework for evaluation of studies. Adaptation of the Integrative Model of Behaviour by Frosch et al., which combines the 4 theories most frequently applied in health behaviour research within the past 30 years (Theory of Reasoned Action, Theory of Planned Behaviour, Health Belief Model, and Social Cognitive Theory). Combination of measurable constructs of behaviour (attitudes, perceived social norms, self-efficacy, and behavioural intention) to the actual behaviour. AND how the subsequent patient/clinician discussion ensues in terms of shared decision-making and patient/clinician concordance (match between the patient's preferred screening option and the clinician's recommended option). Focus on understanding the impact of the decision aid on patient's attributes, shared decision-making, and patient/clinician concordance.</td>
</tr>
<tr>
<td>Author, year</td>
<td>Objective</td>
<td>Number of studies included</td>
<td>Intervention</td>
<td>Outcomes</td>
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<tr>
<td><strong>Stacey, 2008</strong></td>
<td>To highlight key historical changes leading to patient involvement in decision making, to summarize evidence on effective interventions to support shared decision making, to explore strategies to implement these interventions in oncology practices, and to identify future directions</td>
<td>23</td>
<td>Decisions aids focused on cancer treatment or screening decisions</td>
<td></td>
</tr>
<tr>
<td><strong>Stacey, 2010</strong></td>
<td>To conduct a detailed theory analysis of existing conceptual models of SDM to ascertain their characteristics, strengths, limitations, and extent to which the models are relevant to inter-professional practice.</td>
<td>23</td>
<td>SDM conceptual models</td>
<td></td>
</tr>
<tr>
<td><strong>Elwyn, 2013</strong></td>
<td>To search for and analyse the findings of published peer-reviewed studies that investigated the success levels of strategies or methods where attempts were made to implement patient-targeted decision support interventions into routine clinical settings.</td>
<td>17</td>
<td>Use of decision support interventions (DESI) in routine practice</td>
<td></td>
</tr>
<tr>
<td>Author, year</td>
<td>Results of the review</td>
<td>Author’s conclusions</td>
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<td>Briss et al., 2004</td>
<td>The interventions were generally consistent in improving individuals’ knowledge about the disease, accuracy of risk perceptions, or knowledge and beliefs about the pros and cons of screening and treatment options. However, few studies evaluated whether these interventions resulted in individuals participating in decision making at a desirable level, or whether they led to decisions that were consistent with individuals’ values and preferences.</td>
<td>Current evidence is insufficient to determine the effectiveness of IDM interventions for individuals in health care settings, for community members outside of healthcare settings, or for interventions targeted to healthcare systems and providers. Although there was generally consistent evidence that these interventions improved knowledge, beliefs, risk perceptions, or a combination of these (e.g., knowledge about the disease, the test or the consequences of the test, accuracy of risk perceptions, or accuracy of beliefs), there was little evidence about whether these interventions resulted in participation in decision making at a level desired by individuals, or whether the interventions promoted decisions consistent with individual preferences and values. In addition, too few studies were available to determine the effectiveness of IDM interventions targeted to community members outside of healthcare systems or targeted to healthcare systems and providers.</td>
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<td>Edwards et al., 2009</td>
<td>In a model of external influences on information exchange within healthcare consultations, practitioner influences were: receptiveness to informed patients and patient choice, lack of knowledge of cultural difference, patient centeredness vs. stereotyping. Patient influences were: motivation to seek and engage with information; the appraisal of information before a consultation, expression of cultural identity, and ways of managing the risk of poor information. Shared influences were: differing illness notions, role expectations and language. Empowerment, disempowerment and non-empowerment were outcomes of information exchange and health literacy was a mediator of external influences and empowerment.</td>
<td>A more comprehensive conceptualisation of external influences on information use and information exchange in medical consultations is proposed. Patients’ motivation to seek information, the management of that information and its risks and information exchange in consultations can lead to empowerment. Health literacy as an influence on all these stages can be a mediator of empowerment. However, the receptiveness of healthcare practitioners to informed patients is also crucial to information exchange and empowerment.</td>
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<tr>
<td>Gravel et al., 2006</td>
<td>The three most often reported barriers were: time constraints (18/28), lack of applicability due to patient characteristics (12/28), and lack of applicability due to the clinical situation (12/28). The three most often reported facilitators were: provider motivation (15/28), positive impact on the clinical process (11/28), and Interventions to foster implementation of shared decision-making in clinical practice will need to address a broad range of factors. Very little is known</td>
<td>Interventions to foster implementation of shared decision-making in clinical practice will need to address a broad range of factors. Very little is known</td>
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<tr>
<td>Author, year</td>
<td>Results of the review</td>
<td>Author’s conclusions</td>
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<tr>
<td>Légaré et al., 2008</td>
<td>In order of frequency, the three most often identified facilitators were: motivation of health professionals (n = 22), the perception that shared decision-making will lead to a positive impact on patient outcomes (n = 16) and the perception that shared decision-making will lead to a positive impact on the clinical process (n = 15)</td>
<td>Interventions to foster implementation of shared decision-making in clinical practice will need to address a range of factors.</td>
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**Comparison 1: single intervention compared to usual care:**
One RCT statistically incompletes: impossible to judge the effect of the intervention

**Comparison 2: single intervention compared to any other single intervention**
Two RCTs. In the first one, the authors reported narratively that they did not find any differences between groups. In the second study, the author compared the Statin Choice decision aid (intervention) to the standard Mayo patient education pamphlet (control) and reported one continuous measure of the adoption of SDM using the OPTION scale. The standard effect size for this study was 1.06 (95%CI = 0.62 to 1.50) (Effects of interventions: Table 1).

**Comparison 3: multifaceted intervention compared to usual care.**
Two RCTs: in the first one, the multifaceted intervention combined an educational meeting, the distribution of educational material to physicians, and a decision aid; it was not possible to judge the effect of the intervention due to an unit of analysis error. In the second RCT they combined an educational meeting, the distribution of educational material to physicians, and audit and feedback. The standard effect size for this study was 2.11 (95%CI = 1.30 to 2.90).

**Comparison 4: multifaceted intervention compared to a single intervention**
No studies addressed this type of comparison.

**Comparison 5: multifaceted intervention compared to any other multifaceted intervention.**
One RCT compared risk communication training followed by SDM training, and SDM training followed by risk communication training. Each intervention combined an educational meeting and audit and feedback. Based on the 95% CI around the standard effect size estimate, this study did not find any statistical differences between groups on measures to assess the adoption of SDM.

In only two of the five included RCTs was a statistically significant effect size associated with the intervention to promote healthcare professionals’ adoption of SDM. No firm conclusions about the most effective types of intervention for increasing healthcare professionals’ adoption of SDM Healthcare.
### Author, year | Results of the review | Author’s conclusions
--- | --- | ---
| **SDM.** | No evidence was found of harms to patients following these interventions. | Multifaceted interventions that include educating health professionals about sharing decisions with patients and patient-mediated interventions, such as patient decision aids, appear promising for improving health professionals’ adoption of shared decision making in routine clinical practice as seen by patients.

| Légaré et al., 2012 | Only three of the 21 studies reported a clinically significant effect for the primary outcome that favoured the intervention. The first study compared an educational meeting and a patient-mediated intervention with another patient-mediated intervention (median improvement of 74%). The second compared an educational meeting, a patient-mediated intervention, and audit and feedback with an educational meeting on an alternative topic (improvement of 227%). The third compared an educational meeting and a patient-mediated intervention with usual care (p= 0.003). | This review has identified factors influencing prostate cancer screening for older adults. The results suggest that multi-component system changes at the physician and patient levels are needed in order to optimize prostate cancer screening practices in PC, particularly for older men who will not benefit from it.

| Vedel et al., 2011 | Interactions Between Patients and Physicians. Interactions between patients and PCPs are major drivers of PSA testing (10 studies). Physicians initiate screening more often than patients. Moreover, 71% of PCPs discuss PSA screening with patients. PCPs believe that after discussion patients have to decide. PCPs’ views regarding informed decision making show that PCPs want to play an important role. In addition, patient requests are also frequently a reason for ordering a PSA test. In addition, less PSA testing is associated with longer consultations for patient counseling and PCPs estimate that counselling for prostate screening increases consultation time. | This review has identified factors influencing prostate cancer screening for older adults. The results suggest that multi-component system changes at the physician and patient levels are needed in order to optimize prostate cancer screening practices in PC, particularly for older men who will not benefit from it.

Patients point of view: interactions Between Older Patients and Physicians. Four studies have shown that interactions between older patients and physicians are an important factor. A physician's recommendation is a significant predictor of having a PSA test (OR: 68 [31.2–148.9]). Discussing screening with a physician is a predictor of being screened.

Some patients request the PSA test and want to be screened even if their doctor recommend against it.

| Jimbo et al., 2013 | Few studies have actually addressed patient/clinician communication subsequent to use of a decision aid. Since the decision aids are purported to improve shared decision making, it is surprising that there are few objective data to support such claims. The studies that did measure some component of shared decision-making based | This review has identified factors influencing prostate cancer screening for older adults. The results suggest that multi-component system changes at the physician and patient levels are needed in order to optimize prostate cancer screening practices in PC, particularly for older men who will not benefit from it.

Patients point of view: interactions Between Older Patients and Physicians. Four studies have shown that interactions between older patients and physicians are an important factor. A physician's recommendation is a significant predictor of having a PSA test (OR: 68 [31.2–148.9]). Discussing screening with a physician is a predictor of being screened.

Some patients request the PSA test and want to be screened even if their doctor recommend against it.

---
their measurements on patient self-report. Unfortunately, they are not considered to be sufficiently objective, even rarer than the measurement of shared decision making was the measurement of concordance. Since shared decision-making allows for a decision to be deferred when an agreement is not met, it would be important to assess whether the decision aid led to an increase in agreement between the patient and the clinician. Current cancer screening literature, particularly that regarding colorectal cancer screening, reveals a potential negative impact shared decision-making as the clinicians increasingly prefer colonoscopy as the test of choice, to the exclusion considering patient preference. Thus, whether patients activated through decision aids could steer the clinicians toward a more shared decision-making approach increased concordance would be an important outcome measure. Positivist factors, such as the influence of media and family and the ease of the referral process subsequent testing, were addressed so rarely as to inconsequential.

Stacey, 2008

Gravel: There are several known barriers to using shared decision making in clinical practice. In a review of 28 studies, the most common barriers were health care professionals’ concerns about not having enough time, perception that patient characteristics or clinical situations were not conducive to shared decision making, view that some patients prefer a paternalistic approach without asking patients about their preferred role in decision making, and limited familiarity with shared decision making. Alternatively, some clinicians were very motivated to engage patients in shared decision making and believed that it would lead to a positive impact on the clinician-patient encounter and clinical outcomes. These clinicians also agreed that shared decision making was useful and that most patients want to participate in making decisions together with their clinicians. Interventions such as educational training workshops on shared decision making and tools to screen for decisional conflict in routine clinical practice may overcome some of the known barriers.

Interventions to facilitate patients’ participation: While usual patient education materials are not adequate, question prompt sheets and consultation planning are effective interventions to facilitate cancer patient involvement in the medical consultation, and both patient decision and decision coaching facilitate patients’ roles in shared decision making and help them achieve higher-quality decisions.

Stacey, 2010

All conceptual models included the patient and usually one health care professional identified as the physician (n = 11), a nurse (n = 4), or a healthcare professional (n = 9). As well, 3 models (20%) Among the 15 identified SDM models, most focused on the physician–patient dyad without recognizing others such as family and other healthcare
<table>
<thead>
<tr>
<th>Author, year</th>
<th>Results of the review</th>
<th>Author’s conclusions</th>
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<tr>
<td></td>
<td>identified family members as relevant in the process [3, 23, 32, 37]. Although the various models identified different healthcare professionals as potentially being involved in sharing the decision with patients, only two models (both of which were subsequent iterations of SDM models) included two professionals either concurrently or sequentially within the decision making process [22,38]. Concepts found in SDM models: Main themes / Core concepts</td>
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<td></td>
<td>Features of SDM process</td>
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<tr>
<td></td>
<td>1. Equipoise (recognize decision to be made)</td>
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<td></td>
<td>2. Knowledge transfer and exchange</td>
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<td></td>
<td>3. Expression of values/preferences</td>
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<td></td>
<td>4. Deliberation</td>
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<td></td>
<td>5. The decision</td>
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<td>6. Implementation of the decision</td>
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<td></td>
<td>Individuals involved in SDM</td>
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<td></td>
<td>7. Patient</td>
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<td></td>
<td>8. Primary practitioner</td>
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<td></td>
<td>9. Decision coach</td>
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<td></td>
<td>Factors influencing the SDM process</td>
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<td></td>
<td>10. Establishing partnership</td>
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<td></td>
<td>11. Healthcare system policies</td>
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<td></td>
<td>12. Access to health information (other than practitioner-provided)</td>
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<td></td>
<td>13. Availability of decision support interventions to facilitate SDM</td>
<td></td>
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<tr>
<td></td>
<td>14. Access to health services</td>
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<tr>
<td></td>
<td>Outcomes of SDM</td>
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<td></td>
<td>15. Patient level outcomes (e.g. understanding, satisfied with the provider/decision making process, adherence to chosen option)</td>
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<td></td>
<td>16. Relationship level outcomes (e.g. agreement)</td>
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<td></td>
<td>17. Practitioner outcomes</td>
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<tr>
<td></td>
<td>18. Healthcare system outcomes</td>
<td></td>
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<tr>
<td>Elwyn, 2013</td>
<td>The existence of barriers. The dominant theme in a majority of the studies was the existence of barriers to efficient delivery and, therefore, implementation. Stacey [32], Feibelman [34], and Frosch [24] reported professionals’ attitudes and their call for more training in how to use decision support and undertake SDM [27,30-32]. There are also reports that clinicians may not trust or agree with the content of DESIs [23,</td>
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<td>We must be careful not to equate the successful introduction of DESIs into clinical pathways as automatically leading to SDM. For instance, Frosch found that the use of a prostate specific antigen DESI ahead of a clinical encounter led to less SDM if a</td>
<td></td>
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</table>
### Results of the review

34, 38]. Some professionals were reported to hold the view that patients did not want decisional responsibility when facing difficult diagnoses [39] and that DESIs were in “competition” with other information designed for patients, suggesting that the intended aim of the DESIs, (i.e., to support patients in engaging in decisions), was not always understood [23,31,34]. Studies also reported that clinicians did not view the task of referring patients to use DESIs as part of their role, often citing competing demands and time pressure as the main reason why they could not incorporate this task into their usual practice [23,24,26,31,34,36-40]. As Bracket reports, when clinicians were responsible for identifying patients, distribution of DESIs failed because they were “distracted by other duties” [26]. Frosch [24] and Uy [25] describe two such studies, characterized essentially by implementation failure, particularly in organizations where team work was poor. One study illustrated this disinterest by using a modest financial incentive to encourage DESI distribution to patients; although effective while in operation, this strategy had no lasting impact as distribution ceased completely once the incentive ceiling had been met [25].

### Facilitators

Some studies report factors that facilitated the use DESIs. The provision of training and skills development for providers [30, 31, 35], and the identification of a clinical champion, especially in a leadership position, were important positive factors [25, 40]. However, the most often cited predictor of success was the introduction of a system where eligible patients were systematically identified [26, 40], or supported to use DESIs ahead of relevant clinical consultations [36, 37]. In other words, methods of distribution that did not to rely on clinicians to initiate access to these tools proved to be the most effective by far.

### CCL

Many of the barriers are similar to those encountered in other attempts to improve practice performance, where other competing priorities take precedence and where uncertainty about the added value of the proposed intervention favours the status quo [41].

### Author’s conclusions

patient was not in favour of screening [48]. While we can be confident that these interventions have positive results at the patient level [3], we do not as yet fully understand their impact on clinician-patient dialogue. The goal for this review was to make recommendations about how best to implement patient DESIs into practice. Having reviewed the existing studies, it seems too early for such recommendations.
Table 15 – Quality appraisal of included systematic reviews (according to AMSTAR)

<table>
<thead>
<tr>
<th>Author, year</th>
<th>a priori design</th>
<th>two independent data extractors</th>
<th>comprehensive literature search</th>
<th>publication status</th>
<th>list included excluded studies</th>
<th>characteristics included studies</th>
<th>quality assessment</th>
<th>scientific quality in formulating conclusions</th>
<th>methods to combine studies</th>
<th>publication bias</th>
<th>conflict of interest</th>
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<tr>
<td>Briss et al., 2004</td>
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<td>Yes</td>
<td>No</td>
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<td>NA</td>
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<tr>
<td>Edwards et al., 2009</td>
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<td>No</td>
<td>Yes</td>
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<td>NA</td>
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<tr>
<td>Gravel et al., 2006</td>
<td>Unclear</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
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<tr>
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<td>No</td>
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<td>Yes</td>
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<td>Légaré et al., 2010</td>
<td>Yes</td>
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<td>Légaré et al., 2012</td>
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<td>Yes</td>
<td>Yes</td>
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<td>Yes</td>
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<td>Jimbo et al., 2013</td>
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<td>Yes</td>
<td>Yes</td>
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<td>Stacey, 2008</td>
<td>Unclear</td>
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<td>No</td>
<td>No</td>
<td>No</td>
<td>Partly</td>
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<td>Elwyn, 2013</td>
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<td>Yes</td>
<td>Yes</td>
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APPENDIX 4 ELABORATION OF A TOOL

Appendix 4.1 Interview guide in-depth discussions with general practitioners - Acceptability and comprehension test

- Remercier d’accepter de participer à ce projet
- Qui sommes nous ? (présenter succinctement le chercheur et l’entreprise)
- Que faisons-nous :
  - Rappeler le contexte de l’étude du KCE (Arrêt remboursement dosage PSA + Volonté d’outiller les médecins généralistes qui doivent faire face à ce changement de procédure, pour les aider à informer les patients)
  - Projet en deux temps :
    1) Nous testons l’outil d’aide pour les médecins généralistes avec 16 médecins généralistes (1er entretien)
    2) Ces médecins utilisent l’outil en consultation avec 4 patients et nous font part de leur vécu (2e entretien)
- Rappeler les modalités de participation (2 entretiens et 4 tests avec patients)
- Expliquer utilisation des entretiens :
  - Adaptation outil ➔ Anonyme
- Questions ?

Appendix 4.1.1. test de comprehension + test d’acceptabilité

- Demander au médecin s’il a pu prendre connaissance du document (le cas échéant lui donner le temps de lire)
- Lui expliquer le fonctionnement du test
- Réaliser le test
- Avez-vous des choses à ajouter par rapport à ce qui a été dit au cours de cet entretien ?
- Demander les informations afin de compléter la fiche d’information
- Aborder la suite du projet : (Communiquer calendrier + Aborder la question du recrutement des patients)
  « Est-ce réalisable d’effectuer quatre tests en six semaines, vu qu’il est prévu de faire le test uniquement avec les patients qui posent des questions sur le PSA, sur le cancer de la prostate ou sur le dépistage en général ? »
  - Annoncer appel téléphonique
  - Envoi du document à utiliser
  - Et des fiches à compléter
- Prise de rdv pour 2ème entretien
- Remercier pour l’entretien
<table>
<thead>
<tr>
<th>Question</th>
<th>Réponse correcte</th>
<th>Localisation Bonne réponse</th>
<th>Remarques</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Que signifie ‘en bonne santé’ dans le schéma de la page 16 ?</td>
<td>Le cancer de la prostate est présent, mais ne dérange pas et l’homme n’en est pas conscient (ne le sait pas)</td>
<td>Avance au diagnostic (p.16)</td>
<td></td>
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<tr>
<td>2. Quels hommes âgés de 55 à 69 ans sont visés par le dépistage ?</td>
<td>Les hommes n’ayant ni plaintes urinaires ni symptômes relatifs à la prostate.</td>
<td>Information générale (p. 11)</td>
<td></td>
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<tr>
<td>3. Chez les hommes de 55 ans, quel est le rapport entre le nombre de décès suite au cancer de la prostate par rapport au nombre de décès pour cause de maladies cardio-vasculaires ?</td>
<td>20 pour cent 8 contre 40  Les décès pour cause de maladies cardio-vasculaires sont 5 fois plus fréquents</td>
<td>Causes de décès (p. 13)</td>
<td></td>
</tr>
<tr>
<td>4. Le dépistage découvre plus de cancers de la prostate. Pourquoi s’agit-il de ‘sur-diagnostic’ ?</td>
<td>Sans le dépistage, ces hommes n’auraient ni remarqué ni souffert de ce cancer pendant le reste de leur vie.</td>
<td>Les 15 ans à venir (p. 15)</td>
<td></td>
</tr>
<tr>
<td>5. Quelle est la proportion des hommes qui ont reçu un diagnostic de cancer de la prostate après avoir subi une biopsie ?</td>
<td>35 sur 102 / environ un tiers</td>
<td>Dosage du PSA (p.19)</td>
<td></td>
</tr>
<tr>
<td>6. Pourquoi y a-t-il plus d’effets secondaires en cas de dépistage ?</td>
<td>Le dépistage trouve plus de cancers et entraîne plus d’effets secondaires</td>
<td>Consequences (p.17)</td>
<td></td>
</tr>
<tr>
<td>7. Qu’est-ce qu’un ‘faux positif’ ?</td>
<td>Un résultat lors d’un premier test, qui s’avère erroné après d’autres examens.</td>
<td>Dosage PSA (p.19)</td>
<td></td>
</tr>
<tr>
<td>8. Pourquoi est-ce que le dépistage cause plus de désagréments aux patients souffrant du cancer de la prostate ?</td>
<td>L’avance au diagnostic cause des durées de traitement plus longues et donc plus de désagréments.</td>
<td>Consequences (p.16+17)</td>
<td></td>
</tr>
<tr>
<td>9. En résumé, quels sont les effets positifs du dépistage ?</td>
<td>2 hommes restent en vie 3 hommes au lieu de 6 ont des métastases dans les 15 ans après la découverte.</td>
<td>Les 15 ans à venir (p. 15)</td>
<td></td>
</tr>
<tr>
<td>10. Comparez le risque de mourir des hommes avec et sans dépistage.</td>
<td>8/1000 sans dépistage, 6 /1000 avec dépistage</td>
<td>les 15 ans à venir (p15)</td>
<td></td>
</tr>
</tbody>
</table>
Acceptabilité

1: La consultation et le dépistage du cancer de la prostate

1. Comment le dépistage du cancer de la prostate est-il abordé lors d’une consultation ?
   - Qui aborde le sujet ?
   - Déroulement de la conversation
   - Quelles questions les patients posent-ils à propos du dépistage du cancer de la prostate ?

2. Qu’est-ce que ce genre d’outil pourrait apporter dans le cadre de cette conversation ?
   - L’utiliseriez-vous ? Pourquoi ? Pourquoi pas ?
   - Qu’est ce qui doit changer ?

3. Comparaison de l’outil avec d’autres outils
   - Dépistage du cancer de la prostate
   - Autres sujets

4. En cas d’utilisation de l’outil, quel serait l’impact sur la consultation ?
   - Durée
   - Contenu

2: Le texte de l’outil

5. Contenu :
   - Quelle information manque dans le texte
   - Quelle information pourrait être plus succincte ?
   - Quelle information est la plus utile ?
   - Qu’est-ce qui vous aide le plus pour informer le patient ?

   - Qu’est ce qui était peu clair/confus :
     - Dans le schéma
     - Dans le texte

   - Vos patients :
     - Quelle information vous semble difficile à comprendre pour le patient ?
     - Que doit on adapter/améliorer ?

   - Vous-même :
     - Y a-t-il de l’information qui vous a surpris ? Si oui, laquelle ?
     - Quelles questions subsistent après lecture du document ?

6. Appréciation globale du document :
   - Avantages
   - Désavantages
   - Graphiques
   - Texte explicatif
   - Score global sur 10 ?
   - Qu’est-ce qui devrait changer en cas d’utilisation future de l’outil ?
3: La neutralité de l’outil de décision

7. Ce texte vous incite :

☐ A stimuler le dépistage du cancer de la prostate
☐ Déconseiller le cancer de la prostate
☐ Ni l’un ni l’autre

Pourquoi?

☐ Référence à un fait, un chiffre lequel: .................................................................
☐ Pas de référence spécifique (= contenu général du document)

Explications
...............................................................................................................................................

Remarques
...............................................................................................................................................

Formulaire à remplir par le médecin généraliste

Date de l’entretien :

Nom & Prénom :
Adresse :
Téléphone :
Mail :
Numéro de compte bancaire :

Age : ........................................ OU ☐ - de 40 ans,
☐ 41-50 ans, ☐ 51-60 ans, ☐ + de 60 ans

Pratique la médecine depuis : (indiquer année 19XX ou nombre d’années) .................................................................

...............................................................................................................................................

Type de cabinet :
☐ en solo ☐ en duo ☐ en maison médicale ☐ autre : à préciser

Notes :
.............................................................................................................................................
<table>
<thead>
<tr>
<th>vraag</th>
<th>het juiste antwoord</th>
<th>antwoord-locatie</th>
<th>opmerking</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Wat betekent ‘in goede gezondheid’ in het schema op bladzijde 16</td>
<td>De prostaatkanker is aanwezig, maar hindert niet en de man weet er niet van</td>
<td>vroegtijdige diagnose (p.16)</td>
<td></td>
</tr>
<tr>
<td>2. Op welke mannen van 55-69 jaar mikt screening?</td>
<td>Mannen zonder klachten over de urinewegen en zonder symptomen aan de prostaat</td>
<td>algemene informatie (p. 11)</td>
<td></td>
</tr>
<tr>
<td>3. Hoe verhoudt overlijden aan prostaatkanker zich tot overlijdens aan hart- en vaatziekten bij mannen van 55 jaar</td>
<td>20 procent 8 versus 40 Overlijden aan hart- en vaatziekten komt vijfmaal meer voor</td>
<td>doodsoorzaken (p. 13)</td>
<td></td>
</tr>
<tr>
<td>4. Screening ontdekt meer prostaatkankers. Waarom is dit ‘over-diagnose’?</td>
<td>Zonder de screening zouden de kanker zich nooit manifesteren</td>
<td>de volgende jaar (p. 15)</td>
<td></td>
</tr>
<tr>
<td>5. Welk aandeel van mannen krijgt na een biopsie de diagnose dat ze prostaatkanker hebben?</td>
<td>35 op 102 / ongeveer een derde</td>
<td>PSA-gehalte (p.19)</td>
<td></td>
</tr>
<tr>
<td>6. Waarom zijn er bij screening meer mannen met bijwerkingen?</td>
<td>Screening vindt meer kankers en zorgt voor meer bijwerkingen</td>
<td>Gevolgen (p.17)</td>
<td></td>
</tr>
<tr>
<td>7. Wat is een 'valse positieve'?</td>
<td>Een positieve uitkomst op een eerste test, die bij nader onderzoek verkeerd blijkt</td>
<td>PSA-gehalte (p.19)</td>
<td></td>
</tr>
<tr>
<td>8. Waarom zorgt screening voor meer ongemak bij patiënten met prostaatkanker?</td>
<td>Vroegere diagnose zorgt voor gemiddeld langere behandeltijden en dus meer ongemak</td>
<td>gevolgen (p.16+17)</td>
<td></td>
</tr>
<tr>
<td>9. Wat zijn de belangrijkste positieve effecten van screening?</td>
<td>2 mannen blijven leven 3 mannen in de plaats van 6 krijgen uitzaalingen binnen de 15 jaar na ontdekking</td>
<td>de volgende jaar (p. 15)</td>
<td></td>
</tr>
<tr>
<td>10. Vergelijk de sterftekans van mannen met en zonder screening</td>
<td>8 mannen overlijden zonder screening 6 mannen overlijden met screening</td>
<td>de volgende jaar (p. 15)</td>
<td></td>
</tr>
</tbody>
</table>
Aanvaardbaarheid

**DEEL 1: DE CONSULTATIE EN PROSTAATKANKERSCREENING**

1. Hoe komt prostaatkancerscreening ter sprake in een consultatie?
   - Wie brengt het onderwerp aan?
   - Verloop van het gesprek?
   - Gebruikt u informatie & tools daarbij? Welke, wanneer, evaluatie?
   - Welke vragen hebben patiënten over prostaatkancerscreening?

2. Zou zo'n instrument kunnen helpen tijdens zo'n gesprek?
   - Zou u het gebruiken? Waarom wel? Waarom niet?
     - Wat moet anders?

3. Vergelijking beslissingshulp met eventuele andere instrumenten over
   - Prostaatkancerscreening
   - Andere onderwerpen

4. Bij gebruik: impact op de consultatie
   - Tijd
   - Verschuiving van de inhoud van de consultatie
   - …

**DEEL 2: DE TEKST VAN DE BESLISSINGSHULP**

5. Elk hoofdstuk/bladzijde overlopen:
   - Inhoud:
     - Welke informatie ontbrak in de tekst?
     - Welke informatie mag korter in de tekst?
     - Welke informatie is het meest nuttig?
     - Wat helpt u met meeste bij het informeren van de patiënt?
   - Wat was onduidelijk & verwarrend?
     - In het schema?
     - In de tekst?
   - Uw patiënten:
     - Welke informatie lijkt u voor patiënten moeilijk om te begrijpen?
     - Wat moet er beter & anders?
   - Uzelf: was er informatie die u verraste? Zo ja: welke?
   - Welke vragen hebt u nog, na lezing?

6. Algemene oordeel over de tekst
   - Voordelen
   - Nadelen
   - Schema’s
   - Verklarende tekst
   - (Algemene) score op 10?
   - Wat moet er veranderen als u dit zou gaan gebruiken?
DEEL 3: DE NEUTRALITEIT VAN DE BESLISSINGSHULP

7. Zet de tekst u aan om:

☐ prostaatkankeronderzoek te stimuleren
☐ geen richting
☐ prostaatkankeronderzoek te ontraden

Waarom?

☐ verwijzing naar feit of cijfer, welk: ................................................................................................................................................................................................

☐ geen specifieke verwijzing (= algemene teneur van de tekst)

Verduidelijking
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### Appendix 4.2 Results acceptability and comprehension test

**Bijlage: resultaten leesbaarheidstest**

<table>
<thead>
<tr>
<th></th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
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<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Huisarts 9</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0.5</td>
<td>1</td>
<td>8.5</td>
</tr>
<tr>
<td>Huisarts 10</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0.5</td>
<td>2.5</td>
</tr>
<tr>
<td>Huisarts 11</td>
<td>0</td>
<td>0.5</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0.5</td>
<td>0.5</td>
<td>0.5</td>
<td>0.5</td>
<td>7</td>
</tr>
<tr>
<td>Huisarts 12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Huisarts 13</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Huisarts 14</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0.5</td>
<td>0.5</td>
<td>0.5</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Huisarts 15</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>Huisarts 16</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>10</td>
</tr>
</tbody>
</table>
APPENDIX 5 USABILITY OF THE TOOL

Appendix 5.1 Patient form to be filled out during the usability test of SDM tool (Fourth step)

*KCE: beslissing prostaatkankerscreening*

*Gebruik van de beslising met patiënten: evaluatiefiche*

**Ter herinnering: het instrument wordt getest met patiënten die zelf spontaan vragen stellen over PSA, screening of prostaatkanker**

<table>
<thead>
<tr>
<th>Informatie</th>
<th>aan te kruisen &amp; aan te vullen</th>
<th>memo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naam van de huisarts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leeftijd van de patiënt</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beoordeling van het sociaal-educatief niveau</td>
<td></td>
<td></td>
</tr>
<tr>
<td>van de patiënt</td>
<td>lager onderwijs</td>
<td></td>
</tr>
<tr>
<td>(opleidingsniveau of beroep)</td>
<td>lager secundair onderwijs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>hoger secundair onderwijs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>hogere studies of universitair</td>
<td></td>
</tr>
<tr>
<td>Context van de consultatie</td>
<td>algemeen nazicht</td>
<td></td>
</tr>
<tr>
<td></td>
<td>kankeropsporing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>andere</td>
<td></td>
</tr>
<tr>
<td>Voerde de patiënt al eerder een PSA-screening</td>
<td>ja</td>
<td></td>
</tr>
<tr>
<td>uit?</td>
<td>nee</td>
<td></td>
</tr>
<tr>
<td>Welke bladzijden toonde u aan de patiënt?</td>
<td>doodsoorzaken bij mannen tussen 55 en 69 jaar (blz 13)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>wat zal in de komende 15 jaar overkomen? (blz 15)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>toelichting bij het schema (blz 16)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>gevolgen op lange termijn (twee jaar na het begin …) (blz 17)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>follow-up van de screening: gevolgen op korte termijn (blz 19)</td>
<td></td>
</tr>
<tr>
<td>In het algemeen: hoe reageerde de patiënt op de schema’s?</td>
<td>positief (met interesse)</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
<td>---------------------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td>negatief (zonder interesse)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>anders: …</td>
<td></td>
</tr>
<tr>
<td>Deed de patiënt moeite om de schema’s te begrijpen?</td>
<td>ja</td>
<td></td>
</tr>
<tr>
<td></td>
<td>nee</td>
<td></td>
</tr>
<tr>
<td>Begreep de patiënt de schema’s?</td>
<td>ja, gemakkelijk</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ja, dankzij bijkomende verduidelijkingen</td>
<td></td>
</tr>
<tr>
<td></td>
<td>moeizaam</td>
<td></td>
</tr>
<tr>
<td></td>
<td>in het geheel niet</td>
<td></td>
</tr>
<tr>
<td>Het gebruik van het instrument vroeg…</td>
<td>meer tijd om uit te leggen</td>
<td></td>
</tr>
<tr>
<td>(in vergelijking met de tijd van een gewone consultatie)</td>
<td>minder tijd om uit te leggen</td>
<td></td>
</tr>
<tr>
<td></td>
<td>niet meer of minder tijd</td>
<td></td>
</tr>
<tr>
<td>Hoeveel tijd?</td>
<td>........ minutes</td>
<td></td>
</tr>
<tr>
<td>Nam de patiënt een beslissing over de PSA-test tijdens de consultatie?</td>
<td>ja</td>
<td></td>
</tr>
<tr>
<td></td>
<td>nee</td>
<td></td>
</tr>
<tr>
<td>Droeg uw uitleg bij tot die beslissing?</td>
<td>ja</td>
<td></td>
</tr>
<tr>
<td></td>
<td>nee</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ik weet het niet</td>
<td></td>
</tr>
<tr>
<td>Uw indrukken, opmerkingen en commentaar?</td>
<td>....</td>
<td></td>
</tr>
</tbody>
</table>
**Etude KCE : dépistage du cancer de la prostate**

**Utilisation de l’outil d’information auprès des patients : grille d’évaluation**

Pour rappel, l’outil est testé auprès des patients qui abordent spontanément la question du PSA, du dépistage ou du cancer de la prostate.

<table>
<thead>
<tr>
<th>Informations</th>
<th>Cocher / compléter</th>
<th>Votre mémento</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nom du médecin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age du patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evaluation du niveau socio-éducatif du patient (enseignement ou mention de la profession du patient)</td>
<td>Primaire</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Secondaire inférieur</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Secondaire supérieur</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Études supérieures / universitaires</td>
<td></td>
</tr>
<tr>
<td>Contexte de la consultation</td>
<td>Check-up général</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dépistage cancer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Autre</td>
<td></td>
</tr>
<tr>
<td>Le patient a-t-il déjà effectué des tests PSA ?</td>
<td>Oui</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Non</td>
<td></td>
</tr>
<tr>
<td>Quels visuels lui avez-vous présenté ?</td>
<td>Cause de décès des hommes 55-69 ans (p. 13)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Que va-t-il arriver dans les 15 ans à venir ? (p. 15)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Conséquences de l’avance au diagnostic (p. 16)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Séquelles à long terme (2 ans après prise en charge) (p. 17)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Suivi du dépistage : conséquences à court terme (p.19)</td>
<td></td>
</tr>
<tr>
<td>Globalement : comment le patient a-t-il réagi face aux visuels ?</td>
<td>Positivement (il s’est montré intéressé)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Négativement (pas intéressé)</td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
<td></td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Le patient a-t-il essayé de comprendre les visuels ?</td>
<td>Oui</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Non</td>
<td></td>
</tr>
<tr>
<td>Le patient a-t-il compris les visuels ?</td>
<td>Oui, facilement</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oui, grâce aux explications complémentaires</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Difficilement</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pas du tout</td>
<td></td>
</tr>
<tr>
<td>L’utilisation de l’outil demande-t-elle … (par rapport à au temps de consultation en général)</td>
<td>Plus de temps pour expliquer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moins de temps pour expliquer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pas plus ni moins de temps</td>
<td></td>
</tr>
<tr>
<td>Combien de temps ?</td>
<td>…… minutes</td>
<td></td>
</tr>
<tr>
<td>Le patient a-t-il pris une décision concernant le test PSA lors de la consultation ?</td>
<td>Oui</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Non</td>
<td></td>
</tr>
<tr>
<td>Votre explication a-t-elle contribué à cette prise décision ?</td>
<td>Oui</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Non</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ne sait pas</td>
<td></td>
</tr>
<tr>
<td>Vos impressions, remarques, commentaires ?</td>
<td>….</td>
<td></td>
</tr>
<tr>
<td>Etape</td>
<td>Contenu</td>
<td>Note/Questions</td>
</tr>
<tr>
<td>-------</td>
<td>---------</td>
<td>----------------</td>
</tr>
<tr>
<td>1. Le déroulement des tests auprès des patients</td>
<td>Remercier d’avoir accepté de tester l’outil avec les patients</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Déroulement des tests</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Demander au médecin de décrire comment se sont déroulés les tests de manière générale</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Demander au médecin de décrire comment il a utilisé l’outil :</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Uniquement la version ‘patient’/également la version ‘médecin’</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Systématiquement un visuel/utilisation des visuels en fonction des patients</td>
<td></td>
</tr>
<tr>
<td>2. L’utilisation de l’outil par le médecin</td>
<td>Demander au médecin de décrire comment il a utilisé l’outil :</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Uniquement la version ‘patient’/également la version ‘médecin’ ?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Systématiquement un visuel/utilisation des visuels en fonction des patients ?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Comment s’est-il assuré de la lisibilité de l’information ?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Est-ce que le médecin a informé le patient de ce que l’outil utilisé était encore en phase de développement ?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Quand est-ce que la fiche a été complétée (pendant consultation/après) ?</td>
<td></td>
</tr>
<tr>
<td>3. Analyse des fiches individuelles :</td>
<td>Nombre de tests effectués</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Y a-t-il des patients réunissant les conditions auprès desquels l’outil n’a pas été testé et pourquoi ?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Parcourir chacune des fiches avec le médecin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Demander au médecin de commenter le test Impression</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Comment les patients ont-ils réagi à l’outil ?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Noter auprès de combien de patients l’outil a été testé, et entendre le médecin sur le nombre de tests réalisés</td>
<td></td>
</tr>
</tbody>
</table>
6. Evaluation de l’outil

Quelles **améliorations/modifications** faut-il apporter à l’outil en vue d’une utilisation future ?

- **Quant au fond :**
  - Version patient
  - Version médecin

- **Quant à la forme :**
  - Version patient
  - Version médecin

Le médecin envisage-t-il **de continuer à utiliser l’outil** (oui/non/pourquoi, moyennant quelles modifications…)

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Quelles améliorations/ modifications</strong> faut-il apporter à l’outil en vue d’une utilisation future ?</td>
<td>Parcourir l’outil patient/et ou la version médecin</td>
</tr>
<tr>
<td>- <strong>Quant au fond :</strong></td>
<td>10’</td>
</tr>
<tr>
<td>- Version patient</td>
<td></td>
</tr>
<tr>
<td>- Version médecin</td>
<td></td>
</tr>
<tr>
<td>- <strong>Quant à la forme :</strong></td>
<td></td>
</tr>
<tr>
<td>- Version patient</td>
<td></td>
</tr>
<tr>
<td>- Version médecin</td>
<td></td>
</tr>
</tbody>
</table>

5. Clôture

Avez-vous des **choses à ajouter** par rapport à ce qui a été dit au cours de cet entretien ?

- **Aborder éventuellement la suite du projet :**
  - Rédaction d’un rapport par le KCE
  - Diffusion éventuelle de l’outil par les SSMG

**Remercier** pour l’entretien et la participation au test (de la part du KCE aussi)
### Gespreksstramien – debriefing deelnemende huisartsen

<table>
<thead>
<tr>
<th>Naam huisarts</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>datum</td>
<td></td>
</tr>
</tbody>
</table>

(bedanken)

#### 1. Het algemene verloop van de test

1.1. Hoe verliepen de tests in het algemeen?

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
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</tbody>
</table>

1.2. Hoe gebruikte de huisarts het instrument?

- [ ] alleen versie 'patiënt'
- [ ] ook de versie huisarts'

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
</tr>
</tbody>
</table>

- [ ] alles
- [ ] in functie van de patiënt

Hoe controleerde de huisarts het begrip bij de patiënt?

Wanneer vulde de huisarts de fiche in (tijdens of na de consultatie)?

#### 2. Het gebruik van het instrument door de huisarts

Het verloop van de tests: hoe gebruikte de huisarts het instrument:

- [ ] alleen het deel 'patiënt'
- [ ] ook het deel 'huisarts'?

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
</tr>
</tbody>
</table>

- [ ] alleen de publieksgerichte rechterpagina's
- [ ] ook de verduidelijking op de linkerpagina's
- [ ] ook de inleidende bladzijden

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

- [ ] alles
- [ ] in functie van de patiënt

Hoe controleerde de huisarts het begrip bij de patiënt?

Wanneer vulde de huisarts de fiche in (tijdens of na de consultatie)?

#### 3. De afzonderlijke fiches

3.1. Het aantal uitgevoerde tests is ........................................

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

Duiding van de huisarts bij het uitgevoerde aantal tests: ........................

Waren er patiënten die voldeden aan de voorwaarden, maar toch niet getest werden? Waarom?

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
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</tr>
</tbody>
</table>

3.2. Elke fiche overlopen met de huisarts. Vraag de huisarts om de test te becommentariëren
4. Evaluatie van het instrument

Blader door het deel voor de patiënt en/of huisarts

4.1. Welke verbeteringen of veranderingen moet het instrument ondergaan met het oog op toekomstig gebruik?

Inhoudelijk:
- Versie patiënt
- Versie huisarts

Vormtechnisch:
- Versie patiënt
- Versie huisarts

4.2. Overweegt de arts om het instrument te blijven gebruiken?
- Ja
- Nee

Waarom

Met welke aanpassingen wil de huisarts het gebruik alsnog overwegen?
5. Afronding  

*Herkijk de ingevulde fiches*

5.1. Wilt u nog iets toevoegen aan dit gesprek?

........................................................................................................................................
........................................................................................................................................
........................................................................................................................................

5.2. Beschrijf eventueel het vervolg van het project:
- Het schrijven van een rapport door het KCE
- Verspreiding van het uiteindelijke instrument door huisartsenvereniging

*Bedanken voor het gesprek en de deelname aan de test (ook namens het KCE)*
### Appendix 5.3  Analysis of patients forms

<table>
<thead>
<tr>
<th>SP</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
<td>11</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td>Socio-educational background</td>
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29. Legare F, Ratte S, Gravel K, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: update


37. NICE. Prostate cancer. 2008;Clinical guideline 58.


