

SUMMARY

A DECISION AID FOR AN INFORMED CHOICE WHEN PATIENT ASKS FOR PSA SCREENING





The Belgian Health Care Knowledge Centre

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■ FOREWORD

In our culture, it almost seems as if physicians and patients have come to a tacit agreement that taking a 'wait and see' approach is not an option. Of course there is no denying that, in a system where people have a choice of physicians, a disappointed patient may very well take his business elsewhere. At that, it only stands to reason that the average patient expects 'something to be done about his problem'. So it will take a fair amount of lucidity and courage to, as physician, suggest to a patient to 'leave well enough alone', not to mention an extraordinary amount of time to explain that option to him, without any guarantees of course that this message will come across as it was intended, let alone that it will be accepted.

Now, when it comes to dissuading someone from opting for screening, matters become even trickier. From their clinical point of view, even physicians often find it hard to reconcile themselves with the fact that preventive tests on a healthy population can do more harm than good.

The same goes for the routine screening for the *prostate-specific antigen* (PSA) amongst men over 55 years of age who do not present any complaints: useful or harmful? Even after having meticulously sifted through the available scientific studies we have no choice but to admit that we don't have a conclusive answer. Sure, we can presume that it has to have a positive impact on the risk of dying from prostate cancer but the quality of the studies is rather poor and there is no way that the results can be interpreted unambiguously. The risks we are more familiar with: more tests lead to more invasive treatments, including the well-known complications of impotence and incontinence, but they do not necessarily alter a patient's ultimate fate. Even with today's improved approach, the risk remains real.

Current practice guidelines do no longer recommend systematic PSA screening. But if the patient himself wonders whether it might not be a good idea he does not only deserve more than an "I don't know" but also better than the personal opinion of the physician sitting across from him. With this publication we offer physicians a scientifically validated visual tool. It is meant to be used during consultations, to underpin a (hopefully better) informed, considered choice. In parallel to this tool, the Flemish League against Cancer developed a patient decision aid. Their analysis resulted in slightly different figures but, given the tremendous uncertainty, those differences are only marginal.

In conclusion, we would like to thank the BSM-Management and Tempera teams for their much appreciated expert help with translating complex concepts into more comprehensible language. We also thank all the doctors and patients who gave their insights and time to test this tool in practice. In the healthcare sector, empowerment is a much talked about concept. We do hope that this publication will help concretise that concept a little further.

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Deputy General Manager

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General Manager



■ ABSTRACT

CONTEXT

This report is an update of KCE Report 31 which was published in 2006. In March 2009, the long awaited results of two randomized controlled studies were published: an American study, the “Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial”¹ and a European study, the “European Randomized Study of Screening for Prostate Cancer (ERSPC)”². As these studies shed fresh light on the issue, quite a number of bodies, European³ and American alike, reviewed their position on prostate cancer screening. Even though the recommendations of the two studies contradict one another on a number of points, both studies are at one about the importance of proper patient information. Any man who asks to be screened must be informed as comprehensively as possible about the advantages but also about the uncertainties and the possible disadvantages of screening as this is the only way he will be able to make an informed decision.

In Belgium, prostate cancer screening using the PSA test no longer features on the list of preventive measures recommended within the framework of the global medical record (GMD-DMG+) or in the health objectives of the communities. Since March 2013, PSA tests within the framework of individual prostate cancer screening for people who don't have any notable family antecedents are no longer refunded. The test is still performed at a patient's request however and subject to the patient paying a personal contribution of some ten euro. When a patient asks to be screened it is his physician's job however to fully inform him about the pros and cons, including the uncertainties, of screening so that the person in question can come to an informed decision.

OBJECTIVE

The aim of this project was to compile a neutral and accessible overview of the (positive and negative) consequences of the use of PSA for prostate cancer screening. The messages were subsequently incorporated into a patient decision aid that can be used during consultations.



METHODS

Our messages are based on data from scientific literature and on epidemiological data. To properly assess the consequences of screening, we conducted a literature review, followed by a critical analysis of the relevant studies. For pragmatic reasons, the results of the ERSPC were used as starting point. Our model applied the ERSPC results to the Belgian incidence and mortality figures. This does entail however that the figures listed must be interpreted as giving an order of magnitude and not by any means as absolute references.

We based ourselves partially on the 'content development' stage of the methodology used by the Informed Medical Decision Foundation and the IPDAS (International Patient Decision Aid Standards) criteria.^a The development of the tool itself encompassed the following five phases:

1. The first draft
2. Ex-ante evaluation
3. Acceptability and legibility by general practitioners test
4. The physician-user interaction test
5. Summary and finalisation

RESULTS

The tool consists of two sections: "Information aimed at physicians" and "Information to be discussed with patients". The first section, which physicians can use when preparing for a consultation, brings them up to speed on the (positive and negative) consequences of screening and offers them definitions which they can use in the *Shared Decision Making (SDM)* process.

The second section was designed to support the SDM process. Every message is supported by a visual on the right-hand page which physicians can show to their patients. The information on the left-hand pages on the other hand is aimed at physicians.

The visuals contain the following messages:

- What are the causes of death among men aged 55 to 69 years?
- What happens during the 15 years after initial screening?
- What are the mid and long-term consequences (situation two years after treatment originally started)?
- What are the short-term consequences of screening?

These messages meet the following criteria: the statistical data are expressed in absolute numbers and are presented using the same denominator (1000 men). The information lists the pros and cons and the possible positive and negative aspects with the same level of detail. The timeframe is specified and is identical for the different options. The visuals were all produced on the same scale and a narrative style was avoided.

The objective of this tool is to create greater transparency about the pros and cons of prostate cancer screening using PSA and about the prevailing scientific uncertainty. It ought to enable men to make a decision that best matches their life choices.

The scientific associations of practitioners will put this tool at the disposal of their members.

^a <http://ipdas.ohri.ca/IPDAS>



■ SYNTHESIS

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1. INTRODUCTION

1.1. Background: PSA for all or for certain men only?

Intuitively speaking, cancer screening makes sense. As Schwartz demonstrated at the start of the 21st century, the media, as a rule, wholeheartedly embrace screening⁴. A survey conducted in the United States showed that 87% of adults applaud the idea of cancer screening. Three-quarters of all respondents stated that an early diagnosis of cancer tends to save lives. Such was the enthusiasm of respondents that the majority went as far as to say that screening is not a decision but a moral obligation.⁵

That enthusiasm about screening used to be shared by most healthcare providers. At the end of the 20th century, the benefits of organised prostate cancer screening had become topic of debate among the scientific community.

Now, at the start of the 21st century, the situation has changed dramatically. KCE Report 31 ended with the following conclusion in 2006: "From the age of fifty, many men make it their business to regularly have their PSA levels checked. The Belgian Health Care Knowledge Centre (KCE), which thoroughly examined the issue, came to the conclusion that not all men necessarily need to have this test performed and that they should be properly informed before taking a decision to that effect".⁶

The publication in March 2009 of the long awaited results of two randomized controlled studies, an American study, the "Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial", on the one hand,¹ and a European study, the "European Randomized Study of Screening for Prostate Cancer (ERSPC)", on the other hand,² shed fresh light on the matter. On the basis of these new results quite a number of bodies, European³ and American alike, reviewed their position on screening.

The recommendations they issued vary however: some recommend that screening be dispensed with (USPSTF)⁷, while others (AUA)^b advocate screening in certain circumstances.

In spite of these contradictions, the various recommendations all agree on the importance of informing patients. If users ask to be screened, they must be informed as comprehensively as possible; not only about the advantages but also about the uncertainties and the possible disadvantages of screening as this is the only way they can make an informed decision. Also the professional associations of physicians-urologists who attended the "Prostate Cancer World Congress", which took place in Melbourne in August 2013, are of a similar mind.

In Belgium, prostate cancer screening using the PSA test no longer features on the list of preventive measures recommended in the centralised medical record (CMR+) nor by the communities. Since March 2013, PSA tests within the framework of individual prostate cancer screening in men without significant familial antecedents are no longer refunded. The test can still be performed at a patient's request however and provided the patient is prepared to cover the cost (some ten euro). To allow patients (applicants) make an informed decision, physicians are expected to inform them, not only of the advantages, but also of the uncertainties and the potential disadvantages of this type of screening.

Thus, the aim of this project was to bring all the fundamental concepts about the (positive and negative) consequences of prostate cancer screening using the PSA test together in a neutral and accessible format.

^b <http://www.AUAnet.org>



1.2. Fundamental concepts: prostate cancer and screening

1.2.1. A "cancer unlike any other"

Prostate cancer is not a cancer "unlike any other": even though it is the most frequently diagnosed form of cancer in men, it is not by any means the most common cause of death. Cancer registers teach us that prostate cancer features well down the list of leading causes of death from cancer, and certainly well below lung cancer and colorectal cancer. Yet, on the whole, less than 4% of men in Belgium actually die from prostate cancer (between 3.5 and 4% in over-70-year-olds). (cf. scientific)

This paradox can be explained by the fact that prostate cancer is a cancer that tends to evolve slowly over time and, in half of all cases, is only diagnosed in over-75-year-olds. In view of the length of time this cancer takes to develop to the metastatic stage, a certain number of men suffer from the disease until the end of their days without actually ever having been aware of or affected by it. By way of example: over the age of 80, more than 4 men in 10 suffer from prostate cancer without showing any symptoms whatsoever. This slow evolution and late manifestation explain why the number of life years lost (LYL) associated with lung cancer is four times higher than the LYL associated with prostate cancer.⁸

1.2.2. Pros and cons of screening

It is a commonly held belief that: "the early detection of cancer tends to save lives" (cf. above). This translates into the hope that: *positive test result = effective treatment = guaranteed cure* becomes reality. Even though that hope does indeed become reality for some, it applies to a minority of cases only and is not automatically a given. On the other hand, this line of reasoning does also relegate a number of possible disadvantages associated with screening to oblivion.

Prostate cancer screening is a complex process and its consequences (pros and cons) should be explained as clearly as possible. Screening consists of a PSA blood test and a digital rectal examination (during the same or a subsequent consultation). The decision to proceed to a biopsy will be based on the following elements: the patient's consent, PSA levels, the digital rectal examination and familial anamnesis. If the biopsy shows the presence of cancerous cells, treatment will be recommended. The generally accepted therapies for localised prostate cancer include: active follow-up, radical prostatectomy and/or (internal or external) radiotherapy. In this stage, the treatment has a therapeutic objective; the focus lies on "curing" the patient in other words so that he does not end up succumbing to this type of cancer.

The effectiveness of this type of screening is therefore measured by the drop in the number of deaths associated with prostate cancer among the population of screened men.

The short-term disadvantages of this form of screening are the discomforts associated with the taking of biopsies after a PSA test produced a positive or false-positive result. If the biopsy turns out to be positive and cancer is diagnosed, the disadvantages will be determined by the side effects of the treatment opted for. These side effects mainly include:

- Associated with the active follow-up: the discomfort caused by frequent biopsies and the fear of being diagnosed with cancer
- Associated with surgery: erectile problems (up to and including impotence) and incontinence
- Associated with radiotherapy: problems with the digestive system (a.o. radiation proctitis) and erectile problems (one to two years after treatment)

Early diagnosis and overdiagnosis (followed by treatment) have proven to be two important disadvantages of this form of screening. Yet, the wider public is completely unaware of these disadvantages with the result that the matter remains a highly complex one.



Early diagnosis is inherent to the objective of screening, for the objective of screening is to detect a tumour before it becomes large enough for symptoms to manifest themselves. Screening can show up "minor" prostate cancers several years earlier. This means that the individual in question becomes a "cancer patient" earlier on in life and, in general, it also marks the moment at which the person in question no longer enjoys "good health".

When screening for prostate cancer, the diagnosis is brought forward by 7 years on average (confidence interval: 4-8 years).⁹ Early diagnosis in the case of patients who were diagnosed as a result of screening means that they will live longer with the disadvantages and the consequences of the treatments than patients who were diagnosed on account of a symptom.

Fictieve illustratie van de vervroeging van de diagnose



The risk of overdiagnosis is associated with the detection of "latent" tumours. Latent tumours are cancers that develop extremely slowly. If a latent cancer is diagnosed years before any symptom manifests itself (as a result of early diagnosis), there is a fair chance that the patient in question will probably end up dying from an entirely different cause altogether. The consequence of this is that an unscreened patient would never have suffered from that cancer.

Voorbeeld van overdiagnose

ZONDER SCREENING



MET SCREENING

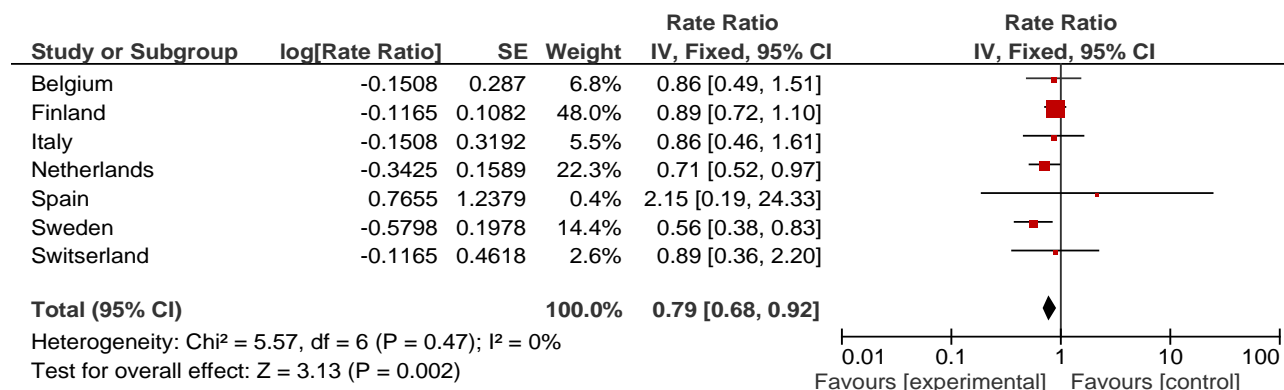


1.3. Available data on the effectiveness of PSA

So as to obtain a full picture of screening, a literature review, followed by a critical analysis of the relevant studies (cf. section 2 of the scientific report), was conducted. This review led us to the PLCO and ERSPC studies.^{1, 2} As these studies produced heterogeneous and conflicting results, pooling the results they produced (pooled analysis) was not an option.

Moreover, the results of the PLCO study were rejected by the European practice guidelines due to contamination of the control group (high screening frequency by means of PSA within the control group itself).³

The ERSPC study, on the other hand, should be regarded as a meta-analysis of various studies rather than a traditional multicentric randomised trial. This particular study, which was conducted in nine European countries, was characterised by differences in recruitment, randomization and screening procedures (PSA threshold and screening intervals). Yet, these differences do not adequately explain the considerable heterogeneity among the various participating countries (cf. figure below).

**Figure 1 – Meta-analysis of the individual countries that contributed to the ERSPC.**

The considerable drop in mortality is especially evident from the Swedish, and to a lesser extent, from the Dutch results. The particularly minor reduction in mortality noted in Finland, which has a 48% bearing on the overall result (in view of the large number of participants), is not statistically significant however. The results of these three large centres are very different in other words.

Haines et al.¹⁰ suggest that this heterogeneity could be caused by the fact that, in a number of participating countries, treatment of the control group was not as effective as that of the patients in the screening group.

In view of the uncertainties of the estimations, the lack of coherence between the studies and the conflicting results, within the ERSPC study itself and between both the ERSPC study and the PLCO study, it proved impossible to confirm or refute the favourable or unfavourable effect of screening using PSA on mortality with any great level of certainty.

However, the aim of this project requires that the pros and cons of screening are quantified and this calls for a pragmatic approach. Even though the team is aware of the uncertainties and the lack of coherence between the available results, a decision was taken to use the ERSPC results as point of departure to quantify the effects of screening. This decision was in particular driven by the facts that the study was a European one and that Belgium took part in it. So as to approximate reality on the ground in Belgium as closely as possible, our model applied the ERSPC results to the Belgian incidence and mortality data. That decision does imply however that the figures furnished must be interpreted as giving an order of magnitude and cannot be interpreted as absolute references. This explains why the data presented hereafter may differ from other data presented in a different context.



In view of the uncertainties, the lack of coherence and the conflicting results, firstly within the ERSPC study and secondly between the ERSPC study and the PLCO study, it seems impossible to confirm or refute the favourable or unfavourable effect of screening using PSA on mortality with any great level of certainty.

The pros and cons of screening can only be illustrated by means of figures. In view of the questionable nature of the data we were supplied with, a decision was taken to only quote them in the form of rate ratios.

2. DEVELOPMENT OF THE PATIENT DECISION AID

2.1. Theoretical approach

'Informed consent' or 'shared decision making (SDM)' presupposes a basis for discussion consisting of prior information that is intelligible and neutral from both a care provider's and a user's point of view. That discussion may facilitate a shared decision-making process where user and care provider exchange relevant information and share their preferences with one another within the framework of a consultation. To ensure that all the relevant information is transferred - a prerequisite to any informed decision -, "decision aids" have been developed. Decision aids are defined as tools that help patients make specific and conscious choices between the various treatment options. Patient decision aids complement the advice offered by physicians (but are not a substitute)."¹¹

To develop the messages that need to form part of these patient decision aids, we allowed ourselves to be led by the theoretical knowledge that was elaborated in greater detail in the KCE report.¹² This report more specifically studied the quality criteria that govern patient decision aids. The criteria themselves were derived from the standards published by the "International Patient Decision Aid Standards (IPDAS) Collaboration".^c

As a basis, IPDAS describes the essential information as follows:

- Causes of death among men within the age category
- The short and long-term positive and negative consequences of screening

^c <http://ipdas.ohri.ca/IPDAS>



In terms of format, IPDAS defines the criteria the messages must meet if they are to be as intelligible, credible and neutral as possible:

- Statistical data must be expressed in absolute numbers rather than in percentages or fractions
- Statistical data must all have the same denominator (1000 persons)
- The information must include both gains and losses
- The information must deal with both the negative and positive aspects in an equally elaborate manner
- The timeframe must be specified and be identical for the different options.
- All the visuals (illustrations) must be designed on the same scale
- The narrative style is to be avoided.

2.2. Practical approach

The patient decision aid was created on the basis of the theoretical approach criteria. The tool was duly tested and subsequently fine-tuned in line with the test results. The aid itself was developed in five phases:

1. The first draft
2. Ex-ante evaluation
3. Acceptability and legibility by general practitioners test
4. The physician-user interaction test
5. Summary and assignment of the exact objective

2.2.1. *The first draft*

The first draft was developed by KCE researchers internally. A preparatory internal brainstorming session brought to light that not all physicians are equally au fait with the basics of screening and the current methods of dealing with prostate cancer. As prior knowledge is essential if the messages are to be understood correctly, a special section to allow physicians bring their own knowledge up to speed was developed. The various practice guidelines (NICE, KCE) and reference documents (HAS 2004)^{6, 8, 13} were used to that effect.

The patient decision aid was developed in line with the format and content-related quality criteria defined by IPDAS (cf. point 2.1). As indicated under point 1.3, the figures and data were presented on the basis of the ERSPC study. As the ERSPC study focused on men aged 55-69 years, the data presented apply to men in this particular age category.

2.2.2. *Ex-ante evaluation*

The first draft was then submitted to representatives of the scientific associations of general practitioners (Domus Medica and SSMG). A few days after they had received the document, the representatives of these associations were interviewed (by KCE researchers). The three chairmen of the associations of urologists (Belgische Vereniging van de Urologen (BVU), Belgian Association of Urology (BAU), Belgian Society of Urology/Société belge d'Urologie (SBU)) also received a copy of the draft. In conclusion, the draft was also discussed at two meetings of stakeholders involved in this project (cf. the list of participants in the colophon).

Following a thorough revision of the draft, both versions (Dutch and French) were checked by a specialised graphic designer on the basis of the experience gained when the messages about breast cancer screening for women were developed.¹²



2.2.3. *Acceptability and legibility by general practitioners test*

Physicians were recruited on a voluntary basis via an advertisement disseminated by the two scientific associations of general practitioners (Domus Medica and SSMG) and then selected by BSM-Management/Tempera to ensure a balanced spread between male/female physicians, urban/suburban or rural surgeries, without claiming any representativeness. The 16 participants (8 French-speaking general practitioners and 8 Dutch-speaking general practitioners) received the document a few days before they were individually interviewed to establish whether the patient decision aid was sufficiently clear and acceptable to the general practitioner.

2.2.4. *The physician-user interaction test*

In the final phase, we tested the use of the document during physician-patient consultations. Physicians were asked to, on a voluntary basis, check with patients looking for information about the PSA test whether they were willing to test the shared decision making process during their consultation. The physicians in question had to complete an assessment form of these interactions and were given eight weeks to run the tests. After that eight-week period, the researchers visited the physicians again. During that visit, physicians were first given an opportunity to convey their impressions informally before reporting on the test result and on the basis of the forms in a more formal fashion.

2.2.5. *Summary and assignment of the exact objective*

The test results ensuing from steps 3 and 4 were presented to the KCE team and the stakeholders before the tool was fine-tuned further on the basis of the remarks and comments made.

3. RESULTS

3.1. *Description of the tool*

Once the test described under 3.2. had been completed, both the Dutch and the French tool consisted of two sections: "Information aimed at physicians" and "Information to be discussed with patients".

3.1.1. *Information aimed at physicians*

The objective of this section is two-fold: bringing physicians' knowledge about the (positive and negative) consequences of screening up to speed and furnishing them with definitions they can use in the *shared decision making (SDM)* process.

This section comprises:

- the objectives of the document
- scientific comments about the PLCO and ERSPC tests
- epidemiological data about prostate cancer in Belgium
- the characteristics of men at serious risk of contracting prostate cancer
- a chronological description of the consequences of screening: biopsies and treatments.

The active follow-up, a relatively innovative treatment method in Belgium, is dealt with in greater detail in this section. Also *early diagnosis* and *overdiagnosis*, two complex and little known concepts, are looked at more closely and illustrated here.

The table with the end results for a cohort of 1000 men aged between 55 and 69 years is presented from a public health point of view that does not take individual interests into account; the latter are elaborated on in the section that has been designed to use in conjunction with users.



3.1.2. Information to be discussed with patients

This section is the actual tool that can be used in the SDM process. The introduction, designed for physicians, contains the 'manual' of this tool and a number of useful definitions. At the physicians' request, an anatomical diagram of the prostate was added. The right-hand pages that follow all contain diagrams (or visuals) designed to show to users while the (mirrored) left-hand pages contain the explanation for physicians.

Hereafter we present the visuals, subdivided into the following sections:

- Causes of death among men aged between 55 and 69 years
- What happens the next 15 years after initial screening?
- Mid and long-term consequences (situation two years after treatment was originally started)
- Follow-up of the screening: short-term consequences

3.1.2.1. Causes of death among men aged between 55 and 69 years

This visual shows the number of deaths (without distinguishing between causes) among Belgian males aged 55-69 years and clarifies the main causes of death, among which the number of deaths caused by prostate cancer. Please note that, in the case of prostate cancer, the figure shown includes all the cases of prostate cancer contracted between the ages of 55 and 69 years, regardless of the fact whether an individual patient lived beyond the age of 70 or not.

The aim of this visual is to paint an objective picture of the number of people who actually end up dying from prostate cancer in relation to all the other causes of death. On the other hand, this visual can also shed light on the general health of an individual. In this age category, we do indeed note some 200 deaths in 1000 men but only 8 of these deaths can be explained by prostate cancer. This visual also gives GPs an opportunity to raise a number of effective preventive measures (quitting smoking for instance) with their patient.

3.1.2.2. What happens the next 15 years after initial screening?

This visual depicts the consequences of prostate cancer for 1000 men who did and for 1000 who did not take part in screening. It shows:

- The number of men who will not be diagnosed with prostate cancer
- The number of men who will be diagnosed with prostate cancer and who will die within a period of 15 years
- The number of men who will be diagnosed with prostate cancer and who will still be alive 15 years later
- The number of men with prostate cancer and metastases

In respect of the group of men who took part in the screening, the visual also shows:

- The number of lives that were saved thanks to screening
- The number of men who were overdiagnosed followed by overtreatment for prostate cancer, in other words, men who were treated for a cancer that was not going to progress during their lifetime and/or would never have posed a problem if they had not been screened.

3.1.2.3. Mid and long-term consequences (situation two years after treatment was originally started)

Just like the previous visual, this visual shows the long-term consequences of the treatment for prostate cancer for 1000 men who took part in the screening and for 1000 men who were not screened. It shows the number of men who were treated for prostate cancer and the number of them who did or did not suffer any adverse effects as a result. With regard to those who suffered disagreeable adverse effects, the visual shows:

- The number of men whose sexual experience changed dramatically^d. The number of men who developed incontinence problems.
- The number of men who specifically experience discomfort and worry about repeated biopsies.

^d The expression "whose sexual experience changed dramatically" refers to impotence or to men who no longer have any sexual relations.



- The number of men who mainly experience digestive problems (a. o. radiation proctitis).

In respect of the group of men who took part in the screening, the visual also shows that prostate cancer diagnosed as a result of screening rather than a specific complaint is, on average, treated 7 years earlier.

3.1.2.4. Follow-up of the screening: short-term consequences

In respect of the 1000 men who took part in the screening, the visual shows the number of men who had a biopsy during a one-off screening (and not in relation to the entire screening period). In respect of the men who underwent a biopsy, the visual shows the number of men who were either or not diagnosed with prostate cancer.

3.2. Tests

Both a readability test amongst practising physicians only (cf. point 2.2.3) and a physician-user interaction test were performed (cf. point 2.2.4.).

3.2.1. Readability test

Sixteen general practitioners who received the tool in advance took part in the acceptability and readability test. In relation to the first section ("Information aimed at physicians") no more structured questions were asked during the interview. The second section ("Information to be discussed with patients"), which can be used for the SDM itself, was tested in terms of readability (intelligibility test) and acceptability.

The intelligibility test comprised ten closed questions, the answers to which were contained in the document. The aim of these questions was to check whether physicians unambiguously understood the information and visuals concerned. After having perused the document, the overall majority of participants answered the questions correctly.

The first series of tests also offered participants an opportunity to give their opinion on the tool they had been presented with (acceptability). No one formulated any fundamentally negative comments about the content of the document. Most physicians agreed that both the wording and the presentation were neutral even though some of them did stress that the illustrated facts could possibly dissuade potential test participants. The "a priori" reservation with regard to using the aid tended to be motivated by practical and psychological considerations. Practising physicians feared that the information might be too complex to be useable across the board and without taking a patient's level of education into account, and, furthermore, that the presentation would take up a lot of time. They estimated that the presentation could take anything between 5 and more than 10 minutes. At that, since the document does not evade the eventuality of death, some physicians feared that the frequent references to the possibility of dying would prevent patients from taking in the overall message. In conclusion, a number of suggestions for improvement were formulated including the possibility of producing a patient information leaflet containing the most relevant information. In addition, a number of alternative ways to present the graphic information were suggested.

The physicians welcomed the effort that had been made to inform patients and to involve them in the decision-making process. The tool fills an actual need as, to date, no such document has been available. This tool furthermore ensures that practising physicians will not forget to impart anything important while they are talking to their patients.



3.2.2. *Physician-user interaction test*

In this phase, the tool was tested in the course of 43 GP surgery consultations. Save for one exception, the participants had all looked for a general "check-up" or a cancer screening test themselves. Most patients did already have their PSA levels checked in the past. The results that were collected during these debriefing sessions highlighted the following difficulties physicians have to deal with:

- Emotional difficulties: some physicians dread having to be the bearer of "bad news" and discussing death. They are also afraid of instilling fear into their patients.
- Practical difficulties: some physicians pointed out that it would take them a considerable amount of time to properly familiarise themselves with the diagrams and to explain the diagrams to their patients.
- Contextual difficulties: the content of the document is contradictory as far as the former attitude (regular PSA test without prior information) and the current enthusiasm about cancer screening are concerned (breast cancer screening is quoted as one example).
- Conceptual difficulties: the notion "overdiagnosis" which suggests not treating a "potential" cancer is contra-intuitive and complex.

Assessment by physicians

- Once all these issues had been dealt with, twelve GPs agreed to take part in the experiment. Much to their own surprise, they found that using the tool was actually less time-consuming than originally feared. Even though the consultation took longer on account of the extra ten minutes, this time was perceived as positive in terms of the quality of the consultation. Most physicians did not use all the visuals during their consultations. The first three visuals (causes of death among men aged between 55 and 69 years", "3.1.2.2. What happens the next 15 years after initial screening? "Mid and long-term consequences") seemed to be the most popular. The visual: "Follow-up of the screening: short-term consequences" was used the least as the information it contained was perceived to be complementary. The fear that the information is too complex to indiscriminately show it to every patient caused some practicing physicians to show it to a select group of patients only. This could explain why the majority of registered

patients seems to have enjoyed a moderate to high level of education (secondary or university education).

Assessment by patients

According to the physicians, the patients welcomed the initiative enthusiastically. Just about every patient showed an interest in the tool. Some patients were intrigued by the data they were presented with while others found them hard to comprehend; that having been said, everyone did try to, with the help of their physician's clarifications, understand them. At that, patients valued the fact that they had been involved in the decision-making process and were pleased to have been taken seriously. Also patients of whom their physician had feared that their poor level of education would prevent them from assessing the tool at its merit turned out to be appreciative.

A small minority of patients was not as interested. In the main, these were patients whose decision had been taken already, who had a friend or relative who had been diagnosed with cancer, or who wanted the physician to take the decision on their behalf. Patients who had not asked for any information were nevertheless given the opportunity to share their preference on screening.

At the end of the SDM process, almost every registered patient had taken a decision; slightly over half of them indicated that they had been influenced by the information they had been given.



4. CONCLUSIONS

The aim of this project was to bring together all the fundamental concepts about the (positive and negative) consequences of prostate cancer screening using PSA in a neutral and accessible fashion. The tool developed for that purpose summarises and clarifies the consequences. As the underlying data were questionable they had to be interpreted with caution, all the more in view of the scientific uncertainty that currently prevails. On that account, the figures will need to be updated once more reliable information becomes available.

In an attempt to give healthcare users greater autonomy, this tool was designed to enhance transparency as far as the pros and cons of using PSA for prostate cancer screening purposes and current scientific uncertainty are concerned. It should allow users to choose the attitude that best matches their personal life choices.

This tool also hopes to trigger a change in behaviour among practising physicians who can use this aid in first instance to discuss this complex theme in a more structured and pedagogically underpinned manner.



■ RECOMMENDATIONS^e

To the people involved in health promotion and patient organisations:

- Integrate the content of these messages into any communication tools that deal with prostate cancer screening.

To the universities and the scientific associations of general practitioners:

- Include specific training on how to use these tools as presented in this report in the general training curriculum and in the further training programmes for physicians.
- Elaborate a summary of the key messages, preferably in collaboration with DOMUS and SSMG. KCE recommends that the associations integrate this source material into their teaching materials.

To the National Council for Quality Promotion (NCQP) of the National Institute for Health and Disability Insurance (RIZIV):

- Ensure that this tool is put at the disposal of all doctors (all specialties) who prescribe the PSA test.

To the people in charge of the EBM-PracticeNet platform:

- Put these messages at the disposal of practitioners, notably by activating a direct link at Electronic Health Record level.

To the GPs

- Use this tool in case a patient asks for a screening test.

^e KCE bears sole responsibility for the recommendations issued.



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