Improving shared-decision making and the use of patient-decision aids in general practices: a prospective quality-improvement study.

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Abstract

1. Nederlands

Achtergrond: Shared decision making (SDM) krijgt steeds meer aandacht in de medische literatuur en praktijk, desondanks blijft de implementatie ervan in de klinische praktijk moeilijk. Barrières beschreven door artsen zijn onder andere een tekort aan tijd en beperkte toepasbaarheid bij bepaalde situaties of patiënten. Een mogelijke interventie om SDM te faciliteren is het opleiden van artsen in het toepassen van SDM en het gebruik van een 'patient- decision aid' (PDA). Het three-talk model van Elwyn et al. biedt artsen een consultatie-model om SDM toe te passen.
Huidige literatuur toont dat PSA-screening een onderwerp is dat zich goed leent tot het toepassen van SDM. De British Medical Journal (BMJ) biedt in samenwerking met Making GRADE the Irresistible Choice (MAGIC) Evidence Ecosystem Foundation een Rapid Recommendation (RR) over PSA-screening. Deze bevat een patient decision aid (PDA) die kan worden geïmplementeerd om het SDM proces te vergemakkelijken.

Doelen: Het doel van deze studie is om huisartsen op te leiden in het toepassen van SDM en het gebruik van een PDA om de kwaliteit van hun praktijk te verbeteren.

Studie design: Prospectief kwaliteitsverbeterende studie.

Methode: Huisartsen en patiënten van twee groepspraktijken werden geïncludeerd in de studie. We hebben een consultatie-model gecreëerd op basis van het three talk model van Elwyn et al. De huisartsen werden getraind in het toepassen van dit model en het gebruik van de PDA. De deelnemende patiënten kregen een folder met daarin informatie over PSA-screening en advies om de consultatie voor te bereiden. Een aantal patiënten werden na de consultatie geïnterviewd over hun ervaringen. Artsen werden geïnterviewd na de inclusieperiode. De interviews werden kwalitatief geanalyseerd via de QUAGOL-methode. Kwantitatieve analyse gebeurde door afname van de CollaboRATE en SDM-Q-DOC vragenlijst bij respectievelijk patiënten en artsen. Op de resultaten werd een 'mean-score analysis' uitgevoerd.

Resultaten: In totaal werden 13 patiënten en 4 artsen geïncludeerd. 5 patiënten en de 4 deelnemende artsen werden geïnterviewd. Patiënten voelden zich goed geïnformeerd na het doorlopen van de consultatie met de arts en vonden hun beslissing om de PSA-waarde al dan niet te laten bepalen goed onderbouwd. Uit hun antwoorden bleek dat sommige patiënten de informatie niet goed begrepen hadden. De artsen stonden open voor SDM en gaven aan het reeds toe te passen in de praktijk. Ze vonden PSA-screening een moeilijk onderwerp voor SDM. Ze vonden het SDM model nuttig, vooral de voorbeeldvragen die aangeboden werden. De PDA werd te complex gevonden om in de dagelijkse praktijk toe te passen. Kwantitatieve analyse werd niet uitgevoerd gezien het beperkt aantal responsen.

Conclusie: Dit onderzoek was een belangrijke eerste stap in het verbeteren van de SDM-vaardigheden en het gebruik van een PDA bij de deelnemende artsen. Er blijven echter verschillende barrières bestaan. Het is dan ook niet duidelijk of onze interventies zullen leiden tot een beter en langdurig gebruik van ons SDM-model en de PDA.

2. English

Background: Shared decision making (SDM) is receiving increasing attention in the medical literature, yet its implementation in clinical practice remains difficult. Barriers described by physicians are: lack of time and limited applicability to certain situations or patients. A possible intervention to facilitate implementation is to train doctors in the application of SDM and use of a patient decision aid (PDA). The three-talk model by Elwyn et al. offers physicians a consultation model for applying SDM. Current literature shows that PSA screening is a topic that is well suited for the application of SDM. The British Medical Journal (BMJ), in collaboration with Making GRADE the Irresistible Choice (MAGIC) Evidence Ecosystem Foundation, offers a Rapid Recommendation (RR) on PSA screening. It includes a patient decision aid (PDA) that can be implemented to facilitate the SDM process.

Goals: The aim of this study is to train GPs in the application of SDM and the use of a PDA to improve the quality of their practice.

Study design: Prospective quality improvement study.

Method: GPs and patients from two group practices were included in the study. We created a consultation model based on the three-talk model of Elwyn et al. The GPs were trained in applying this model and using the PDA. The participating patients received a leaflet containing information on PSA screening and advice on how to prepare for the consultation. Some patients were interviewed after the consultation about their experiences. All the GPs were interviewed after the inclusion period. The interviews were analyzed qualitatively using the QUAGOL method. Quantitative analysis was done by performing a 'mean score analysis' on the CollaboRATE and SDM-Q-DOC questionnaires, filled by patients and GPs respectively.

Results: A total of 13 patients and 4 GPs were included. 5 patients and all 4 GPs were interviewed. Patients felt they were well informed after going through the consultation with the physician and felt that their decision whether or not to have the PSA value determined was well-founded. Responses from some patients showed that they had not understood the information well.
The GPs were open to SDM and indicated that they were already applying it in their practice. They found PSA screening a difficult topic for SDM. They found the SDM model useful, especially the sample questions that were provided. The PDA was found too complex to apply in daily practice. Quantitative analysis was not performed due to the limited number of inclusions.

Conclusion: This study was an important first step in improving SDM skills and the use of a PDA among the participating physicians. However, several barriers remain. It is therefore not clear whether our interventions will lead to a better and long-term use of our SDM model and the PDA.

Introduction

Shared decision making (SDM) has gained significant popularity as a research topic in medical literature. SDM has been described by Elwyn et al. as 'a decision-making process where physician and patient share the best available evidence, where patients are supported to consider options, and to achieve informed preferences'.[1] Several benefits have been attributed to implementation of SDM: better patient and physician satisfaction, improved communication and possibly reduced healthcare costs.[1,2,3,4,5] SDM can be particularly useful for decisions with no strong scientific evidence, clarifying the different alternatives to a particular medical approach.[2,3,4,5] Primary care in particular is a suitable environment for applying SDM, given its broad variety of different topics and accessibility.[6]

Nevertheless, SDM often doesn't appear to be a high priority in current clinical practice.[7,8,9] Several barriers have been described. Healthcare providers often fear that they will run out of time when applying SDM.[10] Some assess that SDM doesn't seem applicable in every situation. This depends on the degree of involvement, health literacy, or personality of the patient.[11] The three main facilitators in literature are: motivating caregivers to apply SDM, the caregiver's expectation that the patient will benefit and the expectation that the overall care will improve.[11]

There are many possible interventions to remove the current barriers for SDM, but only a few have been studied in clinical practice and the literature on this is limited.
One of these possible interventions is the training of healthcare providers in the application of SDM. Unfortunately, the observed results of implementing a SDM training program are limited. This is mainly due to the lack of uniformity in both the training and evaluation methods, leading to low quality of evidence.[12, 13]
Another intervention is aimed at educating the patient by offering knowledge and strategies to interact more with the healthcare provider.[12]
Several practical guides have already been written to implement SDM during the consultation. One of the existing SDM-models is the three-talk model by Elwyn et al.[14] This model provides a structure for clinical consults, by dividing the consult in three parts: (1) The 'Team talk': the doctor declares to the patient that a choice can be made for a particular decision. (2) The 'Option Talk': the doctor explains all the possible testing or treatment options. (3) The 'Decision Talk': during this step a decision is made among doctor and patient.

Patient decision aids (PDAs) can support the SDM process by making clinical information and statistical data clearer and more accessible. They can be used in the form of a folder, website or application, and help the caregiver and patient to make an informed decision by offering the most recent knowledge about the discussed subject.[10,15,16]

The BMJ Rapid Recommendations (RR) indicate that PSA-screening is an interesting subject for applying shared-decision making: current evidence for the usefulness and advisability of screening for prostate cancer is weak and inconsistent.[17] Moreover, opinions and ideas about this subject can differ between patients and physicians, making an elaborate discussion about this topic preferable.[18,19] The BMJ RR are a collaborative initiative developed by the British Journal of Medicine (BMJ) and MAGIC (Making GRADE the Irresistible Choice) Evidence Ecosystem foundation. The MAGIC Evidence Ecosystem foundation is a non-profit research and innovation organization, with an international team involving clinicians, researchers, methodologists and patient representatives.[20] The BMJ RR's aim is to quickly translate recent emerging research to user-friendly and trustworthy recommendations, evidence summaries, and PDAs.[21] The BMJ-RR guideline about PSA screening provides evidence summaries, recommendations and a PDA to facilitate making an informed decision about detection of prostate cancer at an early stage.[17] The evidence provided by this guideline was retrieved from 5 trials, in which 721.718 patients were included in total. According to the overall evidence, screening for PSA provides no significant evidence for general or prostate cancer mortality. Selected evidence at lower risk of bias (from European Randomized Study of Screening for Prostate Cancer only), shows that out of 1000 screened men, one prostate cancer related death could be

prevented.[17,22] There could be adverse effects to further examinations (imagery, biopsy, surgery) after finding an elevation of the PSA value.[23] The patient should therefore know well whether he wants to have the PSA value in his blood checked. The BMJ RR suggests discussing these options applying SDM to help the patient make an informed decision.[24]

The aim of this study is to train general practitioners in the use of SDM and the application of patient decision aids to improve their practice. To improve the SDM process and reduce the aforementioned barriers in the participating practices, physicians were teached how to apply SDM in their consultation and use a PDA.

Methods

1. Study design

A prospective quality improvement (QI) study has been used as a study design. This study model allows to bring immediate improvements in a health care setting using a systematic, data-driven approach and to test the effect of implementing a patient-decision aid and empowering general practitioners (GPs) and patients on the quality of daily care.[25] Specific improvement actions have been taken on the level of the GPs as well as the participating patients.

2. Intervention

2.1 Preparations

A SDM-consultation model (Appendix I), based on the ‘three-talk model’ by Elwyn et al.[14] was developed. To improve the degree of involvement of patients, the ‘expectation talk' was added: the patient must actively formulate his expectations before really starting the decision process. We found that in the model by Elwyn et al., the patients’ expectations were not gauged early in the consultation. This only comes up in the last stage of the model, during the ‘decision talk’. Adding the ‘expectation talk’ can also save time, because the physician can focus on what is important to their patient when going over the PDA with them. Additionally, sample questions were offered in the SDM model to make it easier for GPs to formulate their patients' wishes and expectations in a specific way.

A folder for the participating patients was made to improve their health literacy. It provided basic information to improve their knowledge about PSA screening before the consultation took place. This would also improve their involvement because the patient would understand the GP’s explanation more easily. Additionally, the folder contained recommendation questions that patients could ask themselves as a preparation before the consult, motivating the patient to specify his wishes and expectations.

2.2 Instruction of GPs

The overall duration of the training was approximately one hour.
To begin with, the student-researchers instructed the participating GPs on the main background and principles on prostate cancer screening and the use of the corresponding BMJ Infographic.[21] The aim was to clarify as much as possible the intent and content of the guideline. The training session was supported by a slideshow presentation, and interaction between student-researchers and participating GPs was encouraged. The GPs received the web link to the guideline, and a printed and PDF version of the infographic.

As a second part of the training session, the GPs became acquainted with the MAGIC-app PDA about PSA-screening. The PDA was presented, and application demonstrated and practiced by means of clinical consult simulations held between the GPs. The participating GPs were instructed to use the

PDA in their daily practice, during clinical encounters with included patients.
Additionally, the student-researchers presented the SDM-model to provide a framework for the consults. The model was available on PDF and a schematic summary on a one-sided A4 paper.

2.3 Patient empowerment

The participating patients were given an information leaflet by email, post or in person by the GP or one of the student-researchers at the moment of inclusion. Patients were encouraged to write down their ideas and concerns as a supporting tool during the consults. The leaflet was available in a digital and paper version.

3. Participants

3.1 Inclusion criteria

General Practitioners
Inclusion criteria were: currently practicing general practitioners in Belgium, speaking and understanding Dutch.

Patients
Inclusion criteria for patients were: men between 45-69 years old, speaking and understanding Dutch and able to consent. They were included by the participating GPs.

3.2 Exclusion criteria

General Practitioners
Not willing to fill in the informed consent.

Patients
Not willing to fill in the informed consent, not able to speak or understand Dutch, history of prostate cancer.

4. Recruitment

General Practitioners
GPs from two general group-practices were invited to participate in the study. The GPs received an information letter with the main substantive and practical aspects of the study.

Patients
A poster inviting patients to participate in the study was hung up in the waiting room.
Patients were not actively recruited by mail, e-mail, or phone.
Additionally, patients consulting the participating GPs or student-researchers with a question about PSA-screening or on the occasion of a general blood draw for medical screening were introduced to the study and given an information leaflet and informed consent form. They were invited by the GP or student-researcher to come back for a consultation with one of the participating GPs (not the student-researchers) within one week for the shared-decision-making consult.

5. Data collection

The previously described interventions were evaluated by a mixed-method methodology: they were evaluated quantitatively as well as qualitatively.

General practitioners

Quantitative assessment
GPs were asked to complete the SDM-Q-Doc questionnaire (Appendix II) right after the consultation. The SDM-Q-Doc is an instrument for assessing the physician's perspective on the SDM process during a clinical encounter.[26] The questionnaire consists of 9 statements, to which the GP has to answer by checking one of six responses (completely disagree, strongly disagree, somewhat disagree, somewhat agree, strongly agree or completely agree).

Qualitative assessment
The participating GPs were also interviewed by means of a semi-structured interview, following a topic guide. The overall goal of these interviews was to know if and in which way they thought applying the SDM-model and using the PDA improved the SDM-process.

Patients

Quantitative assessment
After every SDM-contact, participating patients filled the CollaboRATE scale questionnaire (Appendix III). The scale explores the patients' experience of the SDM process using three statements. The patient can assess these statements by choosing one of six responses (From 'no effort was made' to 'every effort was made').

Qualitative assessment
Patients who were willing, were interviewed by means of a semi-structured interview after a clinical encounter. They were asked to give feedback about the SDM-process using a topic guide with open questions. These open questions gauged the personal opinions and feelings of the participants; the privacy and the confidentiality of this personal information was handled with care.

6. Data analysis

Quantitative analysis
To analyze the results of the CollaboRATE scale, we decided to conduct a 'mean score analysis'.[27] Questionnaires in which one or more responses to the questions are missing, were excluded. Comparisons of mean score distributions were made between the three questions, individual patients and patient populations linked to a GP.
The SDM-Q-Doc-scale-results were analyzed by the same technique, this allowed us to compare trends in appreciation of the SDM-process between GPs and patients.

Qualitative analysis
All the semi-structured interviews were audio-recorded and transcribed. Afterwards, the interviews were analyzed by using the Qualitative Analysis Guide of Leuven (QUAGOL) methodology.[28] The analysis consists of two parts: (1) the preparation and (2) the actual coding process. They both contain 5 stages. The preparation starts with analyzing the interview by reading it thoroughly and making a narrative interview report. A conceptual overview scheme is made from this. This scheme undergoes a fitting test by going back to the interview data and checking whether the content corresponds to the main concepts in accordance with the research question. Constant comparison is necessary. The actual coding process starts with a list of concepts that are tested against the interviews. After this, an across-analysis of all concepts takes place, after which they are poured into a conceptual framework. Finally, these results are described, ideally in relation to the research question.

7. Ethical considerations

This study was validated by the research ethics committee of KU Leuven University (MP017089) (Appendix IV). The participating GPs and patients received an information letter explaining the objective and methods of this study. Before starting the SDM consultations, they were asked to sign an informed consent form. They received no compensation for participating and were told that they could step out of the study at any given moment.

Results

The 8 general practitioners from the participating practices were instructed by means of a slideshow presentation in May 2021. Afterwards, the patient inclusion period started, which ran from 01/06/2021 and ended on 28/02/2022. During this period, 13 patients were included, of which 5 were interviewed. These interviews lasted on average 15.8 minutes. At the end, 4 GPs took part in the study, the other 4 were not included: 1 doctor had insufficient knowledge of the Dutch language, the other doctors didn't participate due to practical issues. The 4 participating physicians (1 man, 3 women) were interviewed after the inclusion period and the interviews lasted on average 25.6 minutes. The average age of the patients was years old, that of the doctors 50 years old. Both practices are in a city environment: the Linkeroever district in Antwerp and the center of Leuven.

GP no	Gender	Age	Practice
1	Male	43	Antwerp
2	Female	54	Leuven
3	Female	52	Leuven
4	Female	50	Leuven

Table 1: characteristics of participating GPs

Patiënt No.	Age	Practice	GP No.	Interview	PSA determined
1	69	Antwerp	1	Yes	Yes
2	63	Antwerp	1	No	Yes
3	68	Antwerp	1	No	Yes
4	62	Antwerp	1	Yes	No
5	48	Antwerp	1	Yes	No
6	58	Antwerp	1	Yes	Yes
7	54	Antwerp	1	Yes	Yes
8	56	Leuven	3	No	No
9	50	Leuven	2	No	Yes
10	57	Leuven	2	No	No
11	50	Leuven	2	No	No
12	61	Leuven	2	No	No
13	55	Leuven	4	No	Yes

Table 2: characteristic of participating patients

1. Qualitative analysis

1.1 Patient interviews

In the patient interviews we tried to formulate an answer to the following question: 'which elements are important in PSA screening and the decision-making process around PSA screening for patients?' Of the 5 patients interviewed, 3 had their PSA determined, the other 2 decided not to.
An underlying worry seemed to play a role in all cases. They came up with questions about prostate cancer or the desire to get a PSA test to allay their concerns.

> *"But I do want to know it, to be able to estimate in advance. Whether or not it is possible. (...) Then you ask yourself the question, and you want to know the test result, have the PSA measured. To see if it evolves in that direction."*

Prostate cancer in their environment seemed to be an important reason for several participants to ask about their risk for prostate cancer and the possibility for PSA screening.

> *"It was just a question because it was diagnosed with my father."*

> *"Because of course I know a lot of colleagues, friends, acquaintances and so on. Contemporaries, fellow students who have already been confronted with it. So then you also want to know that for yourself."*

Three patients mentioned during the interview that their increasing age plays a role in their concern and decision to take action.

> *"But given that you're 48, you start to think about that. It suddenly came close, with my father, and then you start to think, should I have had an examination done myself?"*

One participant mentioned that he was confronted with conflicting information.

> *"In the past they always said: people older than 50 years should have a PSA screening because it is important to detect prostate cancer. So yes, I also had on my mind, that when I take a blood test, I ask for a PSA value. But yeah, apparently the numbers aren't so convincing to do that after all."*

The consultation has provided clarification for a number of patients.

> *"Koen (GP) explained to me to what extent the PSA value is reliable. Because apparently you can, I think he used your figures for that, have an increased value but have no problems,*
> *and vice versa. So I concluded, why should I have a PSA test? (...) If we actually don't have a clear picture with those results. (...) He gave me that clear explanation, for me it was very clear. Also with those numbers. And then the decision turned out to be, "Well, we're not going to do that."*

> *"It has given me a better understanding. Absolutely."*

Evidence and clear figures seem to have played a decisive role in the two patients who did not have their PSA determined. They were able to support their decision by listing all the facts.

> *"Yes, it was well supported. He then gave all the explanations with all the numbers. And I assumed that those figures are reliable, so then it was clear to me."*

It was clear to all participants that the accuracy of the test is not 100%.

> *"They also said that it is always inconclusive, if it is tested in the blood, isn't it?"*

During the patient interviews, we noticed that some patients didn't understand all the information provided by the GP. We concluded this because some patients stated incorrect information and didn't appear to be engaged. It is not clear if this lack of engagement was also due to disinterest.
One participant reported hearing about the risk of unnecessary surgery with false positive tests. He was also concerned about unnecessary worries with falsely elevated PSA levels.
The importance of being able to make autonomous decisions came up with some patients. They thought it was important for them to make the final decision. In addition, confidence in the doctor's judgment was regularly mentioned. In those cases, the GPs preference seemed to have at least partially influenced their final decision. The trusting relationship with the GP was mentioned several times by patients.
Some of the patients were routinely tested for PSA every other year. It is unclear whether this is at the request of the patient or at the recommendation of the doctor.

1.2 GP interviews

SDM in general

The 4 general practitioners that participated in the study, were all interviewed. The underlying question we tried to answer in these interviews is: how did the GPs experience the application of the SDM model and the PDA during the consultations?

All the doctors that were interviewed said they already applied SDM to some extent in their daily practice. They said they applied it according to the problem, the number of options and the patient sitting in front of them. Two doctors mentioned applying SDM more when confronted with ambiguous issues, where there are several possible approaches.
For the majority of doctors, the patient's level of education is an important factor in the SDM process: people with a higher education are more interested in SDM and find it easier to understand the doctor's explanations. For the doctors, however, it remains important to involve the patient in some way.

> *"I still think [it's] for people with a higher degree. And don't forget, the whole shared decision making thing, who thinks about that, those are people with a higher degree. And those who want to be involved. But the others... they're not concerned with that. They just come to the doctor to buy health. But that's just too difficult for them."*

> *"I think in Alvinnenberg [residence for people with mental disabilities], I'm not going to have to try that because, well, most of it won't be possible there, but erm, it's still important, even with simple things, to involve them, right."*

The statement that SDM promotes patient involvement and empowerment is repeated several times in the interviews.

> *"I think that if patients know what you think is going on and knows how you came to that thought, and understands why you are proposing a policy, they are much more motivated to do what you say and also, how should I put it (...) be empowered to take action to provide feedback if something doesn't happen what you think is expected."*

Two GPs see it as a challenge that patients are confronted with information outside the doctor's practice, that may not always be correct. They see it as the GPs task to inform the patient correctly.

"You have the internet, I think you already have a lot of shared decision making going on there. A lot of people are therefore already well informed, or sometimes not well informed. I think that's also a major issue. Of how to get the right information, therefore not necessarily enough, but the correct information to the people."

Doctors feel that PSA is a difficult topic to discuss with patients. PSA screening is a complicated, ambiguous and difficult subject to understand.

"...the fact that you come up against the issue that we don't know very well either, that you have to grasp the matter very well, and if you take the time to do so, you actually end up with the fact that it's not that clear at all in the end. That you have to guide someone in that decision, while it is not so... straightforward."

"Yes, the PSA, it's not like an iFOBT test or a PAP smear, where you clearly know that yes, within that window of your population, it clearly has advantages."

The SDM model

One GP did not use the SDM model, despite instructions before starting the study.
For the GPs, the sample questions offered in the SDM model were useful to implement. One GP mentioned that they served as an inspiration in the lack of ideas for starting the conversation. One GP says that she did not use the model literally, but rather as a guideline.

"Yes, it does provide a manual, it's not that I really put it next to me and then go it through one by one or something like that, but I rather use it as a manual like, okay, which questions can you ask, that's more how I used it."

"I think it's also something that we already did, or tried to do. Perhaps not as extensively and not as concretely (...) or with these concrete questions. But it does make it clear if you don't know how to approach it, then it's clear with the examples that are there, how I could formulate it, or I could get to this man's expectation, or... Yes, I found that useful."

Some GPs stated that the model was useful for questioning the patient's expectations in a more conscious way, instead of immediately directing the patient towards their own opinion.
One GP said she needed some preparation/time and effort to understand exactly what needed to be done.

"You still need to pay close attention for a while like: ah yes, what should I do exactly in concrete terms? And then, when you read through it carefully, go through it thoroughly, you see: oh yes, okay, but that's actually how I do it, or ... yes, I try to make the possibilities clear and I try to gauge what he wants, what the options are."

The GPs did not have enough time to go through all the steps of the SDM model in depth with the patients.

"So I think, I was able to finish, but if you want to go even wider, what is a prostate, what does a prostate do, what can go wrong there, I mean if you really want to go even wider, you won't get it done in that amount of time. So you can actually only pick out a bit of his topic and go into it a bit more, but it takes a lot of time."

"And given the time frame that it takes, (...) you might not always take enough time to go into it in sufficient depth."

PDA

All the GP's used the PDA during the SDM consults. Most of the GPs found that the PDA provided clarification to the participating patients about the PSA screening and its nuances.

> *"He was pleased to have had such a conversation. There were also very basic questions, like what is PSA and why is it determined? What is it? Where does it come from? And then, erm, yes, we first talked about that and then about what it means when you start determining PSA and the whole course of it and what the advantages and disadvantages are. And, um… Yes, that did give him a better, or a more complete picture."*

> *"But it did have its value, because I think some people changed their minds. (…) I've had some, I think two, who said 'OK, I want to do it' at the start and then changed their minds and said 'I'm not doing it'. Because, hey, what's the point?"*

Some GPs found the PDA too complex and elaborate to use. They found the content of the PDA too difficult for most patients. Additionally several patients were not interested in the figures. The limited understanding by some patients seems consistent with our findings from the patient interviews.

> *"That much mortality: okay, no difference, but more biopsy complications if you do screen (thinks),… Well, it's too complex to explain at that moment, just like that, like 'let's discuss it a bit, take a look at it now'. You wouldn't understand it as a patient."*

It also requires preparation on the part of the GP, which makes spontaneous use difficult.

> *"I found it actually much too extensive. I had to look at it myself beforehand, all those numbers."*

> *"Too complex, too much information. So I think that if you want to use that, as a doctor, you actually have to extract what it comes down to. Well, the summary of those numbers has to be either listed or, erm… (…) But you really have to draw your attention to it for too long in order to be able to draw any conclusions from it yourself in the moment."*

> *"First, you have to put it into a system beforehand because otherwise, if you don't know at the moment what numbers stand for what, well, that's annoying.''*

They also mention that the patient needs a certain level of education to understand the figures of the PDA. Two GPs said that before the study they already used their own default explanation for patients with questions about PSA screening. One GP finds his explanation more practical than using the figures in the PDA.

> *"No, I do explain. But in a reasonably shorter, and more manageable chunk, and less with real numbers because you see (…) it doesn't usually reach them."*

The other GP will extract things from the PDA for her own explanation, but she will not use the PDA herself.

> *"I would rather have looked at it in advance and said 'those are important points that are in there.'"*

> *"So what I did until now was: okay to try in five minutes to create awareness like: look, it's not just a little test, like: yes or no."*

The GPs sense a difference between their policy and that of the specialists, and they do not feel supported in this.

> *"The difficulty is that urologists also do something else, that you don't feel backed up by specialists, and that then, despite the fact that it is recommended, they still sometimes do other things or make other recommendations."*

> *"And what also plays a part is that the specialists, the urologists, always have to measure it. And then you have to row against the tide."*

In the end, one GP said she will use the PDA again in the future. Two GPs will only use it when patients have specific questions about PSA screening or with higher educated patients. One GP clearly stated that she will not use it again.

Folder

Two GPs suggested a practical approach to the use of the folder. It could be used in the context of a preventive consultation, by giving it to the patient so that they can read up on PSA screening.

> *"The question is how to get the folder to the patient at the right time. People come to us expecting, 'Today I will know if I have prostate cancer'. Erm, when do you give them the brochure? So I think it's certainly useful, but people are only open to it if they have that question. And you don't know, who has that question when? So either you say at the moment: 'look, it's important before I take this test that you go through it and come back, and we'll take more time', if they want to and if that's OK with them. Or you do a brief explanation and decide at that moment."*

> *"Maybe if someone comes for a preventive consultation, (…) maybe that leaflet should be included and you should give it to them and then say "look at it, if you want to know more about it, come back and we'll see if we take it further or not." Just informative. But maybe it stops there?"*

The question 'what is important to me?' was considered by one GP to be too general.

> *"What is important to me? That is a very big open question. I think that in this context, people may not immediately know what to answer. I think it's not a very obvious question, I think they would rather move on to the next questions."*

For another GP, a leaflet was too limited to provide sufficient information. However, she found it useful to encourage the patient to talk about PSA screening.

2. Quantitative analysis

2.1 Patients (CollaboRATE scale)

12 patients completed the collaboRATE scale. The number of participants was not sufficient to make a mean score analysis prescribed by Elwyn et al. The answers are listed in table 3.

	Question 1	Question 2	Question 3	Mean score
Patient 1	8	8	8	8
Patient 2	9	9	9	9
Patient 3	9	9	9	9
Patient 4	9	9	9	9
Patient 5	/	/	/	/
Patient 6	/	/	/	/
Patient 7	7	7	7	7
Patient 8	8	8	8	8
Patient 9	9	9	9	9
Patient 10	9	9	9	9
Patient 11	9	9	9	9
Patient 12	9	9	9	9
Patient 13	/	/	/	/

TABLE 3: results of the CollaboRate scale (Appendix III), filled in by the included patients after the SDM-encounter. '/' means the questionnaire was not filled in. The three questions were rated from 0 (no effort was made) to 9 (every effort was made).

2.2 GPs (SDM-Q-Doc)

3 GPs completed the SDM-Q-Doc scale. One GP (encounter 8-13) didn't fill the questionnaire. Since statistical analysis of the results is not sufficiently relevant to this study, moreover not feasible with limited and missing data, we decided to only show the results, listed in table 4.

	Question 1	Question 2	Question 3	Question 4	Question 5	Question 6	Question 7	Question 8	Question 9	Mean score
Encounter 1	5	5	5	5	4	6	4	5	3	4,3
Encounter 2	5	5	5	5	6	6	6	6	6	5,6
Encounter 3	6	6	6	6	6	6	6	6	6	6
Encounter 4	6	5	6	6	6	6	6	6	1	5,3
Encounter 5	5	5	5	5	5	5	5	5	5	5
Encounter 6	6	6	5	5	5	5	5	6	6	5,4
Encounter 7	4	6	6	6	6	6	6	6	4	5.6
Encounter 8	/	/	/	/	/	/	/	/	/	/
Encounter 9	/	/	/	/	/	/	/	/	/	/
Encounter 10	/	/	/	/	/	/	/	/	/	/
Encounter 11	/	/	/	/	/	/	/	/	/	/
Encounter 12	/	/	/	/	/	/	/	/	/	/
Encounter 13	/	/	/	/	/	/	/	/	/	/

Table 4: results of the SDM-Q-Doc scale (Appendix II) , filled in by the participating GP's after each SDM-encounter. The nine questions were rated from 1 (completely disagree) to 6 (completely agree).

DISCUSSION

1. Summary of results

Of the 13 participating patients, 5 have been interviewed. In these interviews, we tried to gain a better understanding of the concerns and needs of patients in the decision-making process. Worries about prostate cancer motivated patients to come to their GP. These worries were often provoked by a case of prostate cancer in their surroundings, in combination with their own increasing age.
An important request to the general practitioner was to provide reliable information. Most of the patients were therefore interested in the figures presented in the PDA and found that they provided clarity. Although, some patients didn't seem to be interested in the figures, and only requested a PSA test. All patients stressed that it was important for them to be able to make their decision autonomously. On the other hand, they all valued the judgment and advice of their general practitioner.

The 4 general practitioners that participated in the study, were all interviewed. The main question was how they experienced the use of the SDM model and the PDA.
The GPs were favorable towards shared decision making, and already applied it to a certain extent in their daily practice. They felt it was their duty to provide patients with correct information and to address their concerns. They considered that SDM is easier to apply in highly educated patients.
PSA screening was found to be a suitable but also a difficult theme for shared decision making.
3 of the 4 GPs used the SDM model. They believed the most useful elements of the SDM model were the sample questions that were practical to apply and provided inspiration and structure for the conversation. Besides, it made them consciously soliciting the patient's ideas and expectations. One GP wouldn't go over the 'talks' in detail, but rather apply the general idea behind it. From the interviews it is unclear to say if the GPs would use the model again in the future. They stated that it takes a lot of time to go over the whole process in full detail.

All the GPs used the PDA during the SDM consults. Most of them felt the PDA helped them provide useful information to their patients, so that they could make an informed decision. One GP would therefore use it again in the future, one would not, and two would only use it again in certain situations. Reasons to not use the PDA systematically are: too complex and difficult to use with most patients (especially with a lower education level), and not all the patients were interested in the figures. Nevertheless, they said they would implement the contents of the PDA in their routine explanation on PSA screening. The use of the PDA required an additional time investment for all GPs.

During the SDM consultations, all GPs gave a folder to their patients, but none of them has actively discussed the content of the folder. GPs seemed to see a useful role for the leaflet in the SDM process, but had questions about its use in practice. It was not clear how and when they should hand it over to the patient in their daily practice. The three questions, offered to the patients to ask themselves before the consult, seemed useful for the GPs. The question '*What is important to me?' was* considered to be too vague.

2. Interpretation

We learned that adding the expectation talk and sample questions was valuable for the participating GPs. We think that gauging the patient's expectations to help them make a deliberate decision is an essential principle in SDM. It seems crucial to us to do this as soon as possible in the SDM process, in order to make optimal use of the precious consultation time. We therefore think that adding this step to

the original three talk model could be useful. If the expectations are clear early on in the process, the use of the PDA will also be facilitated.

In this study, the PDA helped some patients to be better informed, thereby supporting them in making a well-founded decision. This result of PDAs has been widely described in literature.[2,29]
For others, the PDA seemed too difficult. This was observed during the patient interviews and confirmed by GPs. A possible solution is an adjusted PDA tailored to the patients' health literacy or as suggested by Alden et al, to culture.[30]
However, having to choose between multiple PDAs for each different patient could create an additional barrier: assessing the health literacy of patients is difficult, and may take additional time. As previously described, time constraints are already an important barrier.[11]

We can imagine that some patients would be put off by numbers if they were to study a PDA in depth with their doctor. Therefore, we propose to strive for a PDA that provides clarity by using clear colors, images and an intuitive structure. Helpful design features have already been described in the literature.[31] Additionally, we suggest designing a universal layout on (inter)national level.
Another proposal in literature is to have patients go through an interactive PDA, and use the results during the next consultation.[31,32] A possible danger of interactive PDAs is the loss of an important role of using a PDA: facilitating discussion between doctors and patients. Therefore, it could be preferable to use a PDA during the consultation rather than outside it, as stated by Joseph William et al.[33]

The impression of GPs that applying the PDA takes a lot of time has been widely reported in literature.[10,33] However, this has not been unanimously confirmed by current evidence.[2] Further investigation is necessary to assess if using a PDA effectively takes more time in the long term.

Our main intervention was training doctors in the use of SDM and a PDA. As indicated by Légaré et al, there is currently a lack of uniformity in training methods.[8] We did not try to use a standardized training method, but we would like to underline the importance of the proposal by Légaré et al. to seek consensus for training programmes and their assessment at an international level. [8]

3. Strengths and limitations

This study has been conducted by two researchers, which made it possible to discuss the results and their implications among each other. The QUAGOL-method, used for the qualitative analysis, allowed systematic and thorough analysis. The study has been conducted in two different practices, situated in different environments.

Implementation of the folder couldn’t be evaluated properly because GPs were not sufficiently acquainted with it. Patients that have been interviewed were all patients of the same GP. Unfortunately, this GP didn’t implement the SDM model. It is therefore not possible to make a conclusion about the SDM model from the patients' interviews.
The sample size was too limited to make general conclusions. Since this was a quality improvement project, this was not the main purpose of the study.
PSA is an exemplary subject to apply SDM to, but given the complexity of PSA screening for both physicians and patients, it is quite a challenge to introduce physicians to a SDM model and PDA for the first time using this subject. We think it would be easier to use a less complex topic for training GPs in SDM. Quotes from the interviews were translated from Dutch to English, we have tried to preserve nuances as much as possible.
There was no analysis of physicians' opinions and ideas around SDM prior to the introduction of our intervention.

4.Implications for future practice and research

Further investigation to assess whether our adapted SDM model provides added value compared to the three-talk model.[14]
Since we noticed that some patients were misinformed about PSA screening, we think that tackling disinformation about PSA screening can be useful. This could be done by means of campaigns by health organizations or governments, and ensure that patients, when they visit their doctor, are better informed in advance.
Lastly, a big question for us is whether and how the SDM model and the PDA will be used in the participating practices in the future. It is clear that there are barriers such as time investment, patient interest and physician willingness to study the models. These can be reduced but not eliminated. Further research is needed to determine how many GPs continue to use these tools in the long term after training.
There are still some unanswered questions regarding the practical implications of a folder: when should it be handed to the patient? Who is the target group? Is this a task for the GP or can a nurse do it as part of a preventive consultation in primary care? Further investigation is needed.

5. Conclusion

In conclusion, we can state that in this study an important first step was taken in improving the SDM skills and the use of a PDA in the participating GPs. However, several barriers remain. It is therefore not clear whether our interventions will lead to a better and long-term use of our SDM model and the PDA.

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Appendices

Appendix I: modified three-talk model

1. TEAM TALK

GOAL: make clear that there are different options

a) Summarize the purpose of the SDM process:
eg. "I've invited you to see how we can answer your question about PSA screening"

b) Offer choice:
eg. "There are several options that I want with you discuss."

c) Emphasize the importance of the selection process:
* Personal Preferences: "Options have different consequences, which have different interests for each person"
* Uncertainty: "In medicine there is not always certainty of tests and treatments."

d) Request feedback from patient
eg. "Is it okay if we go over the options?"

1. EXPECTATION TALK

GOAL: explore the patient's initial preferences

"What is most important to you?"

- I want to know clearly if I have prostate cancer
- I don't want to worry unnecessarily by testing tests

- I want to reduce the chance of dying from prostate cancer
- I want to avoid possible side effects of tests/treatments (incontinence, blood in urine/semen, impotence)

- I know people in my environment with prostate cancer
- I have seen/heard information about prostate cancer (screening)

1. OPTION TALK (with PDA)

GOAL: discuss options with the patient

a) Assessing the patient's knowledge
Eg "What do you already know about prostate cancer and PSA screening?"

b) List options
E.g. "I'll start by listing all possible options:

c) Describe options
=> using PDA
'

d) Review the pros and cons of the options with PDA

e) Summarize
eg. via teach-back: "Can you explain to me what you understood have any of these?"

1. DECISION TALK
GOAL: making decisions with the patient **a) Gauge patient preferences** *Feedback to expectation tal E.g. "Which decision best meets your needs/expectations?" **b) Guide patient in his considerations** *or provide more time to think if necessary

Appendix II: SDM-Q-Doc

SDM-Q
versie voor artsen

Vragenlijst Over Gezamenlijke Besluitvorming (SDM-Q-Doc)

Vanwege welke reden heeft uw patiënt u bezocht (bijvoorbeeld met welke klachten, voor welke diagnose)?

Welke beslissing is er genomen (bijvoorbeeld welke behandeling)?

De volgende uitspraken hebben betrekking op uw ervaringen bij het bovengenoemde consult. Kruist u a.u.b. aan in hoeverre elke uitspraak van toepassing is.

1. Ik heb de patiënt duidelijk gemaakt dat er een beslissing genomen moet worden.

helemaal niet van toepassing	grotendeels niet van toepassing	eerder niet van toepassing	eerder wel van toepassing	grotendeels van toepassing	helemaal van toepassing
☐	☐	☐	☐	☐	☐

2. Ik wilde precies van de patiënt weten hoe hij/zij betrokken zou willen worden bij het nemen van de beslissing.

helemaal niet van toepassing	grotendeels niet van toepassing	eerder niet van toepassing	eerder wel van toepassing	grotendeels van toepassing	helemaal van toepassing
☐	☐	☐	☐	☐	☐

3. Ik heb de patiënt verteld dat er voor zijn/haar klachten verschillende behandelings-mogelijkheden zijn.

helemaal niet van toepassing	grotendeels niet van toepassing	eerder niet van toepassing	eerder wel van toepassing	grotendeels van toepassing	helemaal van toepassing
☐	☐	☐	☐	☐	☐

4. Ik heb de patiënt de voor- en nadelen van de behandelingsmogelijkheden precies uitgelegd.

helemaal niet van toepassing	grotendeels niet van toepassing	eerder niet van toepassing	eerder wel van toepassing	grotendeels van toepassing	helemaal van toepassing
☐	☐	☐	☐	☐	☐

zie achterzijde ➔

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February 2012, translated by M. Koelewijn-van Loon &AM Stiggelbout.
Translation of the original "9-Item Shared Decision Making Questionnaire (SDM-Q-9)".
Authorised by Martin Härter & Isabelle Scholl (University Medical Center Hamburg-Eppendorf, Germany).

SDM-Q versie voor artsen

5. Ik heb de patiënt geholpen alle informatie te begrijpen.

helemaal niet van toepassing	grotendeels niet van toepassing	eerder niet van toepassing	eerder wel van toepassing	grotendeels van toepassing	helemaal van toepassing
☐	☐	☐	☐	☐	☐

6. Ik heb de patiënt gevraagd welke behandelingsmogelijkheid zijn/haar voorkeur heeft.

helemaal niet van toepassing	grotendeels niet van toepassing	eerder niet van toepassing	eerder wel van toepassing	grotendeels van toepassing	helemaal van toepassing
☐	☐	☐	☐	☐	☐

7. De patiënt en ik hebben de verschillende behandelingsmogelijkheden grondig afgewogen.

helemaal niet van toepassing	grotendeels niet van toepassing	eerder niet van toepassing	eerder wel van toepassing	grotendeels van toepassing	helemaal van toepassing
☐	☐	☐	☐	☐	☐

8. De patiënt en ik hebben samen een behandelingsmogelijkheid uitgekozen.

helemaal niet van toepassing	grotendeels niet van toepassing	eerder niet van toepassing	eerder wel van toepassing	grotendeels van toepassing	helemaal van toepassing
☐	☐	☐	☐	☐	☐

9. De patiënt en ik hebben een afspraak gemaakt over het verdere vervolg.

helemaal niet van toepassing	grotendeels niet van toepassing	eerder niet van toepassing	eerder wel van toepassing	grotendeels van toepassing	helemaal van toepassing
☐	☐	☐	☐	☐	☐

Appendix III: CollaboRATE scale

CollaboRATE **vragenlijst Nederlandse versie**

Als u terugdenkt aan het bezoek aan uw zorgverlener vandaag …

1. Hoeveel moeite is er gedaan om u te helpen uw gezondheidssituatie te begrijpen?

0	1	2	3	4	5	6	7	8	9
Helemaal geen moeite gedaan									Alle mogelijke moeite gedaan

2. Hoeveel moeite is er gedaan om te luisteren naar de dingen die voor u belangrijk zijn als het gaat om uw gezondheidssituatie?

0	1	2	3	4	5	6	7	8	9
Helemaal geen moeite gedaan									Alle mogelijke moeite gedaan

3. Hoeveel moeite is gedaan om de dingen die voor u belangrijk zijn mee te nemen bij het kiezen van een volgende stap?

0	1	2	3	4	5	6	7	8	9
Helemaal geen Moeite gedaan									Alle mogelijke moeite gedaan

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Appendix IV: OCB: definitive favorable advice

Dutch

Ons kenmerk: MP017089
Uw kenmerk: Masterproef studie: Improving the usage of patient decision aids in the daily practice of general practitioners: a quality improvement study.
Leuven, 25-01-2021

DEFINITIEF GUNSTIG ADVIES

Geachte Mieke Vermandere
Geachte Frederik Dekock, Jalil Haddioui

De Ethische Commissie Onderzoek UZ/KU Leuven verleent hierbij een gunstig advies aan de voorgestelde studie, zoals ze werd beschreven in het protocol. De Commissie is van oordeel dat er vanuit ethisch standpunt geen bezwaren zijn bij de voorgestelde studie. De studie werd goedgekeurd op 25-01-2021

(Goedkeuring) Het betreft een prospectieve studie waarbij men semi-gestructureerde interviews met huisartsen zal afnemen. Het doel van dit onderzoek is om de kennis, attitudes en vaardigheden van huisartsen over het gebruik van keuzehulpen voor pati&eu

Aangezien het om een Masterproefproject binnen de Groep Biomedische Wetenschappen van de KU Leuven gaat, werd de aanvraag tot de Ethische Commissie Onderzoek UZ/KU Leuven ingediend via de Onderwijs-Begeleidings-Commissie.

De Commissie heeft geen bezwaar tegen het project mits vertrouwelijke behandeling van de gegevens en naleving van de Belgische wetgeving omtrent privacy. De Ethische Commissie Onderzoek UZ KU Leuven wenst de hoofdonderzoeker/promotor van de studie te wijzen op zijn/haar verantwoordelijkheid betreft de privacy van de persoons-/patiënt-gegevens bij contact met levende personen, patiënten en/of inzage in het elektronisch medisch dossier, inclusief de correcte implementatie hiervan door medewerkers en studenten.

Dit gunstig advies betreft de indiening van 12-01-2021 en wordt gegeven voor de duur van de Masterproef van de betrokken student(en). Elke wijziging aan het protocol doet dit gunstig advies vervallen. U dient in dat geval tijdig een amendement voor advies voor te leggen aan de commissie die eerder uw dossier goedkeurde.

De Commissie bevestigt dat ze werkt in overeenstemming met de ICH-GCP principes (International Conference on Harmonization Guidelines on Good Clinical Practice), met de meest recente versie van de Verklaring van Helsinki en met de van toepassing zijnde wetten en regelgeving.

De Commissie bevestigt dat in geval van belangenconflict, de betrokken leden niet deelnemen aan de besluitvorming omtrent de studie.

Met vriendelijke groet,

Prof. dr. Minne Casteels
Voorzitter
Ethische Commissie Onderzoek UZ/KU Leuven

Prof. dr. Pascal Borry
Voorzitter
Onderwijs-BegeleidingsCommissie voor Medische Ethiek KU Leuven

Aandachtspunten (indien van toepassing)

De Ethische Commissie UZ KU Leuven wenst de hoofdonderzoeker/promotor van de studie te wijzen op zijn/haar verantwoordelijkheid betreft de privacy van de persoons-/patiëntgegevens bij contact met de patiënt en/of inzage in het elektronisch medisch dossier, inclusief de correcte implementatie hiervan door medewerkers en studenten. Het EC verwijst naar de richtlijnen van ICH/GCP hierover op de website, en benadrukt dat een GCP-opleiding van elke hoofdonderzoeker verwacht wordt voor studies die vallen onder de Wet op Medische Experimenten. Het EC verwijst tevens naar de Belgische wetgeving (Wet van 8/12/1992 ter bescherming van de persoonlijke levenssfeer en Wet van 22/8/2002 betreffende de rechten van de patiënt), en de Algemene Verordening Gegevensbescherming (van toepassing op 25 mei 2018).

Bij gebruik van elektronisch medische gegevens is een formeel akkoord van de dienstraad vereist. De opdrachtgever is verantwoordelijk voor de conformiteit van de anderstalige documenten met de Nederlandstalige documenten.

Onderzoek op embryo's in vitro valt onder de wet van 11 mei 2003. Voor dergelijk onderzoek is er naast een positief advies van het EC Onderzoek UZ/KU Leuven ook een goedkeuring van de Federale Commissie voor medisch en wetenschappelijk onderzoek op embryo's in vitro noodzakelijk vooraleer dit onderzoeksproject kan doorgaan.

Vooraleer u dierexperimenten mag opstarten is een goedkeuring vereist van de Ethische Commissie Dierproeven (ECD). U dient zich bijgevolg aan te melden bij deze commissie voor het onderdeel met dierproeven en hun adviezen te volgen. Gelieve te noteren dat u het onderzoek pas mag starten nadat u een definitief gunstig advies van deze commissie heeft verkregen.

Onderzoek op humane kadavers vereist een goedkeuring van het Ethisch Comité voor Zorg en Begeleiding. U dient zich bijgevolg aan te melden bij deze commissie en hun adviezen te volgen. Gelieve te noteren dat u het onderzoek pas mag starten nadat u een definitief gunstig advies van deze commissie heeft verkregen

Dit gunstig advies van de Commissie houdt niet in dat zij de verantwoordelijkheid voor de geplande studie op zich neemt. U blijft hiervoor dus zelf verantwoordelijk.
Bovendien dient u, als betrokken hoofdonderzoeker, erover te waken dat de resultaten van dit onderzoek, correct worden weergegeven in publicaties, rapporten voor de overheid enz.

U wordt eraan herinnerd dat bij klinische studies iedere door u waargenomen ernstige verwikkeling onmiddellijk zowel aan de opdrachtgever (desgevallend de producent) als aan het EC Onderzoek UZ/KU Leuven moet worden gemeld, ook al is het oorzakelijke verband met de studie onduidelijk.

English

Our reference: MP017089
Your reference: Master's thesis study: Improving the usage of patient decision aids in the daily practice of general practitioners: a quality improvement study.
Leuven, 25-01-2021

DEFINITIVE FAVOURABLE ADVICE

Dear Mieke Vermandere
Dear Frederik Dekock, Jalil Haddioui

The Research Ethics Committee UZ/KU Leuven hereby grants favourable advice to the proposed study, as it was described in the protocol. The Commission is of the opinion that from an ethical standpoint there are no objections to the proposed study. The study was approved on 25-01-2021

(Goedkeuring) Het betreft een prospectieve studie waarbij men semi-gestructureerde interviews met huisartsen zal afnemen. Het doel van dit onderzoek is om de kennis, attitudes en vaardigheden van huisartsen over het gebruik van keuzehulpen voor pati&eu

Given that the study takes the form of a master's thesis within the Group Biomedical Science, the application to the Research Ethics Committee UZ/KU Leuven was submitted to the Educational Support Committee.

The Committee has no objection to the project on the basis of confidential treatment of the data and compliance with the Belgian legislation concerning privacy. The Research Ethics Committee UZ/KU Leuven wishes for the head researcher / promoter of the study to be aware of their responsibilities with regard to the privacy of personal / patient details, when in contact with living persons, patients, and / or contained within electronic medical records, including the correct implementation by employees and students.

This favorable advice concerns the submission of 12-01-2021 and is given for the duration of the Master's thesis of the student(s) concerned. Any amendment to the protocol will invalidate this favorable advice. In that case, you must submit an amendment for advice to the committee that previously approved your file.

The Committee confirms that they work in accordance with the ICH-GCP principles (International Conference on Harmonization Guidelines on Good Clinical Practice), with the most recent version of the Helsinki Declaration, and with applicable laws and regulations.

The Committee confirms that in case of a conflict of interest, the members concerned have not participated in decision regarding the study.

Kind regards,

Prof. dr. Minne Casteels
President / Chairperson
Research Ethics Committee UZ/KU Leuven

Prof. dr. Pascal Borry
President / Chairperson
Education-Support Committee for Medical Ethics KU Leuven

Points of Interests (if applicable)

The Research Ethics Committee UZ/KU Leuven wishes for the head researcher / promoter of the study to be aware of their responsibilities with regard to the privacy of personal / patient details, when in contact with living persons, patients, and / or contained within electronic medical records, including the correct implementation by employees and

students. The Ethics Committee refers to the guidelines of the ICH/GCP here on the website, and emphasizes that GCP-training is expected from every head-researcher for studies that come under the Law on Medical Experimentation. The Ethics Committee refers at the same time to the Belgian legislation (Law from 8/12/1992 for the protection of personal privacy and Law from 22/8/2002 regarding the rights of the patient), and the General Data Protection Regulation (which comes into effect on May 25th 2018).

For use of electronic medical data, a formal agreement from the clinical board is required. The study promotor is responsible for the conformity of foreign language documents with the Dutch language version.

In vitro research on embryos comes under the Law of 11 May 2003. For such research, besides positive approval from the Ethics Committee, approval by the Federal Committee for Medical and Scientific Research on Embryos In Vitro is also necessary before a project can commence.

Before you may commence animal experimentation, approval is required from the Animal Ethics Committee. You must register with this committee for the animal testing component and follow their advice. Please note that you may start the investigation only after you have obtained a definitive favorable opinion from this committee.

Research on human cadavers requires approval of the Care and Support Ethics Committee. You must therefore register with this committee and follow their advice. Please note that you may start the investigation only after you have obtained a definitive favorable opinion from this committee.

This favorable opinion from the Commission does not mean that it takes responsibility for the planned study. You remain responsible for this yourself. In addition, as the principal investigator, you must ensure that the results of this research are correctly displayed in publications, reports for the government, etc.

You are reminded that any serious complication you observe must be reported immediately to both the study promotor (if applicable, the producer) and the Ethics Committee, even if the causal link with the study is unclear.

Reflectieverslag

Frederik Dekock

Samenwerking met Jalil

Algemeen liep de samenwerking erg goed. Op veel vlakken versterken we elkaar, en andere vakken zijn we eerder complementair wat zorgde voor een vlotte progressie van het proces.
We waren allebei gemotiveerd om een goede thesis af te leggen, wat zorgde voor een positieve sfeer met weinig frustratie. Normaal gezien was er nog een derde HAIO die zou mee zou doen met ons project, echter van hem ervaarden we sinds het begin een gebrek aan motivatie. We waren dan ook gerustgesteld dat we met twee verder konden nadat deze HAIO uit de opleiding stapte: een frustratie bespaard.

Samenwerking met onze promotor

In de beginperiode hadden we regelmatig contact met de promotor want er was nood aan sturing van het project. Ook bij het schrijven van het protocol hadden we nood aan sturing. Toen het project eenmaal liepen was alles redelijk duidelijk, en hebben we in feite weinig contact gehad met onze promotor. Hier hadden wij niet zo veel nood aan gezien ons protocol wel omschreven was. Ook bij gebruik van de QUAGOL methode hadden we geen sturing nodig gezien dit ook duidelijk omschreven staat. De Introductie en methodes hebben we regelmatig laten nalezen. Maar aangezien we nipt op tijd klaar waren, hebben we geen feedback kunnen vragen op resultaten en discussie. Dit had eventueel wel beter gekund.
We hadden nog een meeting de laatste week voor de deadline om vragen te beantwoorden. Deze heeft ons erg geholpen het eindresultaat te verbeteren, met name de discussie.

Persoonlijke aandeel

De taken waren goed verdeeld volgens mij. Ik heb me persoonlijk meer geconcentreerd op het uitpluizen van de literatuur en het schrijven van de inleiding voor het onderdeel van introductie en methodes. Had hierbij het gevoel dat mijn sterktes eerder lagen in het efficiënt uitvoeren van taakjes die minder analytisch zijn, zoals ik ook bijvoorbeeld de transcriptie van interviews vooral heb uitgevoerd. De resultatensectie deden we vooral samen, gezien dit gedeelte met het gebruik van de QUAGOL methode in groep dient te gebeuren.

Verloop van de studie

Algemeen vind ik dat we efficiënt hebben gewerkt om een degelijk eindproduct af te leveren.
We hadden in het begin wat moeilijkheden met het protocol op tijd af te werken, we hadden namelijk onderschat hoe volledig het moest zijn. Uiteindelijk heeft het afgeleverde protocol er wel voor gezorgd dat de rest van de studie erg vlot verliep. Wat eventueel beter kon was de inclusieperiode. Ten eerste lag het aantal inclusies iets te laag. Het was moeilijker dan gedacht om patiënten te vinden. Toegegeven, we hadden zelf ook wat meer pro actief kunnen zijn in het includeren van patiënten door ze actief op te bellen. Ten tweede was de studie op sommige vlakken te complex waardoor artsen inclusie van patiënten een drempel ervaarde. Mijn praktijkopleider had voor zichzelf een systeem gevonden dat makkelijker was, het betrof een gesimplificeerde versie van de studie die uiteindelijk onvolledig bleek. Ik had dit sneller moeten opsporen en corrigeren. Het was ook jammer dat we één arts uit de praktijk in Antwerpen moesten schrappen, gezien haar gebrekkig Nederlands leek ze het opzet van de studie niet goed te begrijpen.

Implicaties studie

Praktijkniveau

Ik denk dat we met deze studie de deelnemende artsen hebben gestimuleerd na te denken over shared decision making en vooral het belang ervan. We hebben ze een SDM mode en een PDA aangereikt die ze hopelijk in de toekomst nog gaan gebruiken. 'Hopelijk' want de kans lijkt ons eerder gering. Er blijven voor hen namelijk belangrijke barrières bestaan om het te implementeren in de dagelijkse praktijk. De voornaamste barrière is tijd. Zoals aangegeven in de studie moet het inderdaad nog verder onderzocht worden of het gebruik van een PDA of SDM al dan niet meer tijd in beslag neemt. Een andere barrière is de complexiteit van het onderwerp dat we hebben gebruikt: PSA-screening. In retrospect hadden we misschien beter gekozen voor een meer 'clear cut' onderwerp, waar het effect van SDM beter te meten valt. PSA-screening en SDM is echter wel een héél interessant onderwerp, en zou een goed idee zijn voor een toekomstige thesis.
Samengevat: de artsen zijn geprikkeld om SDM toe te passen, maar of ze het op langere termijn nog zullen doen is te betwijfelen. Indien er in de toekomst meer zou gebeuren in de vorm van campagnes of opleidingen zullen zij alvast een streepje voor hebben.

Werkveld Niveau

In onze studie worden bestaande barrières beschreven in de literatuur bevestigd. Een unieke interventie is het toevoegen van een stap aan het three talk SDM model van Elwyn et al: het bevragen van de expectation in het begin van het SDM proces. Dit werd reeds warm onthaald door de deelnemende artsen maar moet uiteraard nog verder getoetst worden op grotere schaal. Wat ook we ook zagen was dat SDM voor sommige patiënten te complex was. De vraag naar meer toegankelijke PDA's is dus groot.

Jalil Haddioui

Ik heb het thema van de manama paper gekozen uit een aangeboden lijst. De beschrijving (het toepassen van een BMJ patient decision aid in de huisartsenpraktijk door middel van een kwaliteitsverbeterende studie) interesseerde me: het is concreet, praktijkverbeterend en laat toe om zelf praktisch toepasbare dingen bij te leren.

Samenwerking

We zijn initieel met 3 personen aan het project begonnen, maar de derde HAIO bleek van in het begin minder betrokken te zijn dan de twee anderen. We hebben dit met hem kunnen bespreken, en hij heeft redelijk snel aangegeven dat hij twijfelde om te stoppen met geneeskunde. Uiteindelijk is hij afgehaakt, waardoor we met twee overbleven. Achteraf gezien ben ik blij dat we met twee hebben gewerkt aan deze paper, want het is niet altijd makkelijk om een overlegmoment af te spreken en ideeën met elkaar af te stemmen als je met verschillende personen bent. De samenwerking met Frederik verliep erg goed, we hadden over de meeste zaken ongeveer dezelfde ideeën en konden bij meningsverschillen vlot een compromis vinden. Het was een meerwaarde om samen te kunnen discussiëren over het bepalen van het studie-opzet, de studiemethodes en de interpretatie van de resultaten. Vooral tijdens de analyse van de kwalitatieve interviews vond ik het zinvol om onze interpretatie van de interviews met elkaar te vergelijken.
Ik heb het gevoel dat we het werk evenredig hebben verdeeld, er waren ook nooit problemen over wie wat of hoeveel deed. Wanneer de ene een drukkere periode had werkte de andere eraan verder, en vice versa.

In het begin hebben we wat moeten zoeken naar een goede onderzoeksvraag. We wilden niet louter het gebruik van de BMJ richtlijn en digitale beslishulp implementeren in de praktijk, daarom hebben we besloten een tweede luik aan toe te voegen dat focust op het shared-decision-making proces zelf. Prof Vermandere heeft ons geholpen om ons te oriënteren, we hebben tijdens het zoeken naar een goede onderzoeksvraag op regelmatige basis contact gehad met haar. In het begin met 2

videogesprekken, nadien via mail. Zij heeft ons kort de huidige stand van zaken en interessante pistes die nog moeten onderzocht worden, uitgelegd. De communicatie verliep vlot en duidelijk, we waren blij om altijd relatief snel een antwoord van haar te ontvangen. Het opstellen van het protocol verliep bij momenten moeizamer, vooral het concreet maken van de methode en evaluatie. Ik vind dat we uiteindelijk een goed studiedesign hebben kunnen uitwerken. Achteraf gezien denk ik dat we het wel eenvoudiger hadden mogen aanpakken: drie verschillende interventies zowel kwalitatief als kwantitatief evalueren was te veel. We hadden het kwantitatieve luik kunnen laten vallen, aangezien de studie sowieso te kleinschalig was om hier goede conclusies uit te trekken.

Werkverdeling en persoonlijke aandeel
De werkverdeling was correct en evenredig, we hebben een verdeling gemaakt naargelang onze interesses en vaardigheden. Frederik heeft meer dan ik de literatuur bestudeerd en aangegeven welke bevindingen er al gemaakt zijn en wat er nog onderzocht moet worden, en de introductie geschreven. Ik heb de methodes meer in detail uitgewerkt. We hebben op regelmatige basis overlegd, en uiteindelijk hebben we allebei onze visie en mening kunnen inbrengen in alle delen van de paper. Tijdens de kwalitatieve analyse hebben we heel veel overlegd, na elke stap van de QUAGOL methode hebben we onze bevindingen met elkaar vergeleken.
We hebben de discussie samen geschreven.

Implicaties studie
De studie bevestigt verschillende zaken die we reeds vastgesteld hadden bij het bestuderen van de literatuur rond shared decision making. Ik heb het gevoel dat we ons einddoel (het verbeteren van shared decision making in onze huisartsenpraktijk) op zekere hoogte bereikt hebben. Ik voel dat met de collega's bij die meegedaan hebben aan de studies, we het sneller hebben over shared decision making bij situaties of problemen waar geen duidelijk of eenzijdig wetenschappelijk antwoord is. Ik vind vooral onze aanpassing van het three talk model succesvol, we hebben veel positieve reactie gekregen van de deelnemende huisartsen over de toegevoegde 'expectation talk' en voorbeeldvragen. Het zou dan ook interessant zijn om te kijken of dit zich resultaat zich door zou zetten in grotere studies. Dat is volgens mij de essentie van dit soort interventies: de huisarts het gevoel geven dat zijn dagelijkse praktijk niet alleen verbeterd maar ook vergemakkelijkt kan worden door een interventie, want het is erg moeilijk voor artsen om tijd en mentale ruimte te maken om een nieuwe manier van werken toe te passen in hun dagelijkse praktijk. Het was dan ook fijn bepaalde huisartsen te horen zeggen dat prostaat kanker screening een heel moeilijk onderwerp is om te bespreken met de patiënt, maar dat onze interventie hun manier van consult voeren rond dit thema makkelijker gemaakt heeft. Het opstellen en uitvoeren van de studie heeft mij geholpen om bepaalde persoonlijke vaardigheden te verbeteren. Ik heb het gevoel dat ik in de toekomst makkelijker praktijkverbeterende interventies zou kunnen doorvoeren zoals implementeren van een nieuwe guideline, patiënten informeren en empoweren,…

GROEP BIOMEDISCHE WETENSCHAPPEN
HERESTRAAT 49, O&N II – BUS 700
BE-3000 LEUVEN

Template 2020.10

MASTERPAPER PROTOCOL: PROSPECTIVE STUDY USING A (SEMI-)STRUCTURED INTERVIEW

1. APPLICANTS

Protocol - full title	Improving the usage of shared-decision-making aids in general practices: a prospective quality-improvement study.
Version 1: Date submission	Date:3/12/2020
Version 2: Date resubmission	(to add in case of resubmission) Date:Click here to enter a date.
Version 3: Date third submission	(to add in case of third submission) Date:Click here to enter a date.
Principal Investigator – Promotor	**Name: Mieke Vermandere**
	Telephone:
	E-mail: mieke.vermandere@kuleuven.be
Following both questions should be answered:	
The principal investigator is a health professional according to the Law of 10 May 2015. YES	
The supervisor has read and approved the submission for ethics approval. YES	
Co-Investigator – Co-Promoter	**Name:**
	Telephone:
	E-mail:
The co- investigator is a health professional according to the Law of 10 May 2015. YES □	
Sub-investigator – Student(s)	**Name: Frederik Dekock**
	Student number: r0462548
	Telephone: +32 476248771
	E-mail: dekockfrederik@gmail.com
	Name: Jalil Haddioui
	Student number: r0369001
	Telephone: +32485560979

	E-mail: jalil.haddioui@student.kuleuven.be

2. BACKGROUND AND RATIONALE

In recent years, shared decision making (SDM) has gained significant popularity as a research topic in medical literature. Shared decision making is defined by the American Medical Association as: '*a formal process or tool that helps physicians and patients work together to choose the treatment option that best reflects both medical evidence and the individual patient's priorities and goals for his or her care'* (American Medical Association, 2012).

The idea of SDM started with ethicists in the 1970s and has evolved into current models, which use dialogue to help patients discover their values and preferences (1,2). The ethical argument thus emphasizes the importance for the patient to make a decision in dialogue with the doctor about his or her treatment in the light of their autonomy. In addition, choices and practices often differ between physicians and institutions, although these individual preferences are not always clear to the patient (1). In this light, SDM can clarify that alternatives are possible for a particular treatment. Its importance is even bigger for decisions with no strong scientific evidence for one approach or the other. These benefits have led to SDM being associated with better patient and physician satisfaction, improved communication and possibly reduced costs. (3-8).

Nevertheless, SDM often doesn't appear to be a high priority in current clinical practice (9-11). When implementing new evidence or interventions in clinical practice, it is important to know why it is not picked up (barriers) and what promotes incorporation in practice (facilitators) (12). Possible barriers are: 1) Healthcare providers fear that they will run out of time when applying SDM. This is a barrier that can be applied to practically any new implementation. Current evidence shows that the duration of consultations after implementation of SDM-techniques is very variable (13). 2) Some health care providers assess that SDM does not seem appropriate in case of certain patient characteristics, depending on education, degree of involvement or personality. 3) The caregiver estimates that SDM does not lend itself well to certain clinical situations. The main facilitators are: 1) Motivating caregivers to apply SDM, 2) The caregiver expects that the patient will benefit and 3) The expectation that the overall care will improve (14).

There are many possible interventions to remove the existing barriers, but only a few have been studied in clinical practice and the literature on this is limited.
An already proven effective intervention is the training of healthcare providers in the application of SDM. Currently, the results of implementation for an SDM training program are limited due to the lack of uniformity in the evaluation method.
Another intervention used is aimed at educating the patient by offering knowledge and strategies to interact more with healthcare and more specifically with the healthcare provider (10). An example of this intervention is 3goedevragen.nl, a Dutch initiative that encourages patients to ask the doctor 'three good questions' in order to talk to the doctor about what is best for the patient's specific situation (3goedevragen.nl).

Several practical guides have already been written to implement SDM during the consultation. One of the existing SDM-models is the Three-Talk-Model by Elwyn (4). This model provides a structure for clinical consults, by dividing the consult in three parts. 1. The 'Choice Talk': the doctor submits to the patient that a choice can be made for a particular decision. 2. The 'Option Talk': the doctor explains all the possible testing- or treatment options. 3.The 'Decision Talk': during this step a decision is made between doctor

and patient (4).
Using patient decision aids (PDA) can support the SDM process by making clinical information and statistical data clearer and more accessible. These can be used in the form of a leaflet, website or application, and help the caregiver and patient to make an informed decision by better understanding the most recent knowledge (13,15,16). In the Elwyn model PDA's are implemented in step 2.

As noted above, SDM is mainly useful in decisions where there is no strong evidence for or against a particular approach, for example prostate specific antigen screening (PSA-screening). Screening consists of determining the PSA value in the blood to detect prostate cancer at an early stage. However, the ultimate gain on prostate cancer death is only one person out of a thousand men tested over a 10-year period but none in overall mortality (17), and the PSA value is not only increased in cancer but also, for example, in infection, after a bike ride or recent ejaculation. This leads to further diagnostics and therapy, such as biopsies and operations, which can lead to possible complications.
The British Medical journal Rapid Recommendation guideline for PSA argues with weak evidence against systematic prostate screening in men (17,18). It is therefore important that the patient is aware of the implications of PSA screening. The BMJ-RR is the result of a collaboration between the BMJ and Making Grade Their Irresistible Choice (MAGIC), a Norwegian non-profit organization that aims to improve the creation, distribution and updating of clinical guidelines. There are also PDA's linked to these Rapid Recommendation, that can be found in the MAGICapp.

The aim of our study is to train general practitioners in the application of patient decision aids and the use of SDM to improve their practice. First, we teach physicians how to apply SDM in the consultation and use a PDA. For this we use the Elwyn model and the PDA of the BMJ RR on PSA screening in the MAGICapp, respectively. Second, we evaluate the effect of patient empowerment by using 3goeievragen.nl.

3. STUDY OBJECTIVES

The aim of this study is to improve the knowledge, attitudes and skills of general practitioners concerning the usage of patient decision aids in their daily practice.

4. RESEARCH METHOD

4.1 Study design: prospective quality-improvement study

As the main goal of our study is to improve and investigate the process of shared-decision-making in general practices, we will set up a prospective quality improvement (QI) study. The aim of this study design is to try to bring immediate improvements in a health care setting using a systematic, data-driven approach (19). Specific improvement actions will be taken on the level of the general practitioners (GP's) as well as the participating patients. This study model will allow us to test the effect of implementing a SDM-aid and empowering GP's and patients on the quality of daily care. We will use the Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) checklist as a guide for structuring the study (20).

4.2 Intervention

4.2.1 Instruction of GP's:

To begin with, the student-researchers will instruct the participating GP's on the main background and principles on prostate cancer screening and the use of the corresponding BMJ **Infographic**. The aim is to clarify as much as possible the intent and content of the guideline. The training session will be supported by a slideshow presentation, and interaction between study team members and participating GP's will be encouraged. The GP's will receive the web link to the guideline and PDA, and a printed/PDF version of the infographic.

As a second part of the training session, the GP's will become acquainted with the MAGIC-app decision-aid about PSA-screening.
The **PDA** will be presented and application will be demonstrated and practiced by means of clinical consult simulations.
Additionally, the student-researchers will present a **SDM-model** to provide a framework for the consults. This model will be based on the Three-Talk-Model by Elwyn (4), and will be available as a digital presentation and a schematic summary on a one-sided A4 paper (also on PDF).

The participating GP's will be instructed to use the infographics and PDA in their daily practice, during clinical encounters with included patients.

4.2.2 Patient empowerment:

The participating patients will be empowered to actively participate in the SDM-process. They will be given a patient **information leaflet** as soon as possible after recruitment (by e-mail, post or during a first clinical encounter), containing recommendations and questions they can ask themselves as a preparation for the consult. These recommendations will be based on the Dutch initiative '3 goede vragen'(www.3goedevragen.nl), described in the introduction. The leaflet will also contain basic information about prostate cancer and PSA-screening. The participating GP's (or student-researchers whenever possible) will shortly illustrate and explain the content of the information leaflet. Patients will be encouraged to write down their ideas and concerns as a supporting tool during the consults. The leaflet will be available in a digital and paper version.The student-researchers will try to share these informations from an objective point of view as much as possible, without a priori favouring one or another screening-approach.

4.3 Data collection

We will assess the previously described interventions by a mixed-method methodology: they will be evaluated quantitatively as well as qualitatively.

4.3.1 Quantitative assessment:

We will ask the participating GP's to complete the SDM-Q-Doc questionnaire after every SDM-contact with participating patients. The SDM-Q-Doc is an instrument for assessing the physician's perspective on the SDM process during a clinical encounter (21). The questionnaire consists of 9 statements, to which the GP has to answer by checking one of six responses (completely disagree, strongly disagree, somewhat disagree, somewhat agree, strongly agree or completely agree).

Participating patients will fill in the CollaboRATE scale after the consult. The scale explores the patients' experience of the SDM process using three statements. The patient can assess these statements by choosing one of six responses (From 'no effort was made' to 'every effort was made').

4.3.2 Qualitative assessment:

The GP's and a limited number of patients (10 to 20 in total) will be interviewed by means of a semi-structured interview after a clinical encounter. They will be asked to give feedback about the SDM-process using a topic guide with open questions. The overall goal of these interviews is to know which aspects of the SDM-process have improved according to the GP's and if patients feel sufficiently involved and empowered during the whole process. Defining facilitating factors and remaining barriers will be useful for further studies. These open questions will gauge the personal opinions and feelings of the participants; the student-researchers will handle their privacy and the confidentiality of their personal information with care.

5. SELECTION AND WITHDRAWAL OF PARTICIPANTS

5.1 Inclusion and exclusion criteria

5.1.1 Inclusion criteria:

General Practitioners:

The student-researchers will invite their GP-trainers from two general practices (two group practices and one solo-practice) to participate in the study. The participating GP's will receive an **information letter** with the main substantive and practical aspects of the study.

Patients:

Inclusion criteria for patients are: men between 45-69 years old, speaking and understanding Dutch and able to consent. They will be included by the participating GP's.
The age group was chosen at 45-69. Men aged >50 are at increased risk of getting Pca and aged >45 if there is a family history or are from African descent (22,23). Because we won't study PSA screening itself but implementation of the PSA guideline, we took the cut-off at 45.

5.1.2 Exclusion criteria

General Practitioners:

Not willing to fill in the informed consent.

Patients

Not willing to fill in the informed consent, not able to speak or understand Dutch, history of prostate cancer or benign prostate enlargement (BPE).

5.2 Sample size and population

5.2.1 Patients

All patients who qualify for inclusion, will be asked to participate to the study and fill in the CollaboRATE scale. It is difficult to predict how much patients will qualify and accept to participate to the study, but we aim to include in total 20 to 50 patients.
Additionally each student-researcher will conduct a semi-structured interview in 5 to 10 subjects.

5.2.2 General Practitioners

We aim to include 2-6 general practitioners.

5.3 Recruitment

Patients who qualify for inclusion, will be approached by the student researchers and GP's in participating practices through targeted recruitment (eg. patients who are getting an appointment for medical screening or follow-up consultation) or when a patient asks for a prostate cancer screening during a clinical encounter. Recruitment will take place in two general practices: 1) Huisartsen-Blancefloer, 2050 Antwerpen en 2) Groepspraktijk De Flint, 3000 Leuven. Patients who qualify for participation, will be invited for a clinical encounter in person to discuss PSA-screening through a SDM-process. Depending on the circumstances, the patient will be approached in person, by e-mail or by phone. **They will receive a folder (in person or by e-mail) with an information leaflet and an informed consent form (ICF, appendix). The leaflet will contain basic information about prostate cancer screening, the aim and course of our study, and specific recommendations to prepare and participate to the following consultation. Patients who consent to participate, will be asked to read and sign the ICF before the clinical encounter. They will give the signed ICF physically to the general practitioner or can submit it in the mail box of the general practice.** The physician will stress that participating is not obligated and that the patient can decide to stop the participation at any moment in the study. Participants will not receive a compensation for participating to the study. The foreseen interventions won't bring any additional cost or health risks for participants except the use of their time, which will be limited as much as possible by the student-researchers. **These will also transmitted clearly to the patients, verbally and in the ICF. The SDM-consult and interviews will only be conducted after participants have signed the consent form.**

The GP's of 'Huisartsen Blancefloer' and 'Groepspraktijk De Flint' have already consented to participate to the study. They will receive an information letter and an ICF (both in Appendix), and will be asked to sign the ICF after approval by the ethical committee and before starting the study.

5.4 Expected duration

04/2021: instruction of GP's and start patient recruitment

01/05/2021- 01/02/2022: patient/GP interviews and data gathering

01/02/2022-01/06/2022: data analysis and interpretation

Length of semi-structured interviews:
Since the interview will be conducted after the clinical consult and filling in the CollaboRATE scale, the patient interview will be limited to 30 minutes, Physicians' interviews will last up to 60 minutes, and will be conducted preferentially the same day as the concerning consult.

6. ANALYSIS

To analyze the results of the CollaboRATE scale, we decided to conduct a 'mean score analysis' (24). Questionnaires in which one or more responses to the questions is missing, will be excluded. Comparisons of mean score distributions will be made between the three questions, individual patients and patient populations linked to a GP.

The SDM-Q-Doc-scale-results will be analyzed by the same technique, this will allow the student-researchers to compare trends in appreciation of the SDM-process between GP's and patients.

All the semi-structured interviews will be audio-recorded and transcribed. Afterwards, the interviews will be analyzed by using the The Qualitative Analysis Guide of Leuven (QUAGOL) methodology (25).

7. DATA HANDLING AND MANAGEMENT

7.1 Data storage and management

(Dutch version - no English version available)

Alle data zullen tijdens het project vertrouwelijk en met de nodige zorgvuldigheid behandeld worden. In functie van onze onderzoeksvraag zal aan de hand van een interview informatie, namelijk de antwoorden op de SDM-Q doc door artsen en de Collaborate schaal ingevuld door patiënten, de analyse van de semi-gestructureerde interviews met de huisartsen en met de patiënten, worden verzameld. Alles wat de participanten tijdens het interview vertellen, zal via geluidsopnames worden opgenomen. Er zullen geen beelden worden gemaakt. De opgenomen interviews zullen enkel worden beluisterd en uitgetypt door de onderzoekers. De interviewopnames en persoonlijke notities van de interviewer zullen meteen na transcriptie worden vernietigd.

Transcripties van de interviews zullen geen namen bevatten en evenmin andere gegevens die identificatie mogelijk maken. In de eigenlijke masterproef zullen enkele fragmenten van de interviews worden geciteerd op een anonieme wijze en op zo'n manier dat het op basis van een citaat niet mogelijk is om de uitspraak terug te leiden naar een bepaalde participant. De transcripties zullen bewaard worden in een beveiligd computerdocument dat enkel in het bezit is van de promotor en de betrokken studenten. Indien mogelijk zal dit bestand bewaard worden in een project- of teamgebonden opslaglocatie op een server van KU Leuven of UZ Leuven, in OneDrive for Business, aangeboden door KU Leuven, of in REDCap. Zo niet, wordt een persoonlijke computer gebruikt die beveiligd is met een wachtwoord, tweestapsverificatie of gespecialiseerd programma zoals 7-Zip of AEScrypt.

Bij het versturen van een kopie van vertrouwelijke informatie of documenten zullen deze steeds versleuteld zijn met een wachtwoord of unieke code. Voor het verzenden van grote bestanden wordt gebruik gemaakt van Belnet Filesender. Toepassingen zoals Google Drive, een persoonlijke OneDrive (met uitzondering van OneDrive for Business, aangeboden door KU Leuven) of WeTransfer worden te allen tijde vermeden. Na afloop van het project zullen de bestanden met de transcripties aan de promotor worden bezorgd die verder zal instaan voor een veilige bewaring ervan. Conform het beleid van de KU Leuven zullen deze bestanden 10 jaar bewaard blijven, nadien wordt opnieuw geëvalueerd of het als zinvol wordt beschouwd om de data nog langer te bewaren.

Voor de verzameling en opslag van mijn data maak ik gebruik van:

- □ Persoonlijke computer, beveiligd met een sterk wachtwoord, tweestapsverificatie of gespecialiseerd programma (7-Zip, AEScrypt, …)

7.2 Declaration of Confidentiality and Careful Management of Information and Personal Data

In the framework of their Master's thesis, the students will have access to all kinds of data, information, results and documents. In order to ensure the confidentiality of this Information and the privacy of those involved, within the framework of their Master's thesis the students should always deal with the Information with the greatest care and discretion. In particular research related to patients and including the collection and analysis of

personal data requires the utmost of care and discretion. Therefore, at all times the students must observe complete confidentiality with respect to the Information they have collected during the course of their Master's thesis.

In performing this research, the students commit their self to the following confidentiality obligations:

- *They accept, during and after the completion of the Master's thesis,* ***the obligation to strictly observe the confidentiality of the Information they have collected*** *and the activities to which they have participated, and regarding the patients, healthy volunteers and the staff members with whom they come into contact;*
- *They will only process and collect data that is* ***relevant*** *and* ***necessary*** *for their Master's thesis;*
- *They will* ***not share information*** *with persons not directly involved within the framework of their research; only the* ***investigator, possible group members*** *and their* ***supervisor*** *will have access to the data;*
- *They will take* ***all necessary steps*** *to protect the confidentiality of Information and the privacy of those involved;*
- *They will handle with* ***care and responsibility*** *the Information and the access granted to them to information systems and digital media.*
- *They will discuss the* ***confidentiality****,* ***storage*** *and* ***sharing*** *of files with their supervisor. They will use* ***anonymisation*** *or* ***pseudonymisation*** *in order to limit the risks of data leaks and data loss.*
- *If pseudonymisation is used, they will treat the pseudonymisation* ***key*** *or the* ***encryption table*** *containing the pseudonyms and the identifiable information fields with the* ***same confidentiality*** *as the original data. They will* ***never store the key or encryption table at the same device*** *(e.g. laptop or desktop) as the work file or database containing the pseudonymised data.*
- *Wherever possible, they will use a* ***project based or team based storage location*** *for storing and exchanging data. They will contact their supervisor to discuss the possibility of using an internal or external service of KU Leuven or UZ Leuven to save data. If not possible, they will use OneDrive for Business, provided by KU Leuven, REDCap,provided by KU Leuven and UZ Leuven, or a password protected device for storing collected data. Applications such as* ***Google Drive, a personal OneDrive*** *(except OneDrive for Business, provided by KU Leuven)* ***or WeTransfer will be avoided at all times****.*
- *They will always encrypt confidential information and files with a* ***password****,* ***two-step verification*** *or* ***specialized program*** *such as 7-Zip or AEScrypt.*
- *When sharing a copy of strictly confidential data, they will always* ***encrypt*** *the data with a secure password or unique code. For sharing large files, a* ***secure application*** *such as Belnet Filesender will be used.*
- *In the event of a* ***data breach*** *they will immediately contact their supervisor*

As this research is conducted in the context of a Master's Thesis, the legal basis for the processing of personal data is the public interest. This research will generate knowledge and new insights that (directly or indirectly) will benefit society.

All investigators shall treat all information and data relating to the study as confidential and shall not disclose such information to third parties or use such information for any purpose other than the performance of the study. The collection, processing and disclosure of personal data, such as participants' contact information, health information and medical information, is subject to compliance with the General Data Protection Regulation (GDPR).

When approval is given by the Ethics Committee, it is confirmed that the proposed processing of personal data meets the requirements of the GDPR. Consequently, from a GDPR perspective, there is no objection to start the processing operations. When approval is given, this application will, In accordance with the GDPR, become included in KU Leuven's register of processing activities in the context of research and public service. ***No separate privacy application should be submitted for this type of studies.***

8. ASSESSMENT OF RISKS AND SAFETY

We confirm that the name of the Principal Investigator (PI) has been integrated in the ICF for the participants.

PI: Prof. Dr. Mieke Vermandere
+32 16 37 72 81
mieke.vermandere@kuleuven.be

9. APPROVAL

Hereby we confirm that data collection is performed with approval of the head of the respective unit(s) or department(s) where data collecting is taking place.

General practices:
1) Huisartsen Blancefloer:
Dr Koen Thomeer
koen@huisarts-thomeer.be
03/219.43.93

2) Groepspraktijk De Flint (approval still pending)
Dr. Johan Van Acoleyen
Dr. Sandra Pollers
info@deflint.be
spollers@deflint.be
016/23.36.20

10. PUBLICATION POLICY

Publications will be coordinated by the Principal Investigator. Authorship to publications will be determined in accordance with the KU Leuven policy on authorship.

11. DIRECT ACCESS TO SOURCE DATA AND DOCUMENTS

The investigator(s) and the institution(s) will permit study-related monitoring, audits, ethical review and regulatory inspections (where appropriate) by providing direct access to source data.

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13. ANNEXES

13.1 Interview guideline

Patiënten

Patiëntencode:
Datum:
Onderzoeker:
Locatie:

Stappenplan

- Stap 1: Patiënt ontvangen voor het interview op het afgesproken tijdstip.
- Stap 2: Patiënt nogmaals een korte uitleg geven over de studie aan de hand van de informatie die in de Informed Consent Form staat. Zaken die de patiënt niet begrijpt dienen verder uitgeklaard te worden.
- Stap 3: Het interview gaat van start, de audio opname wordt ook gestart.
  Volgende vragen zullen worden gesteld aan de patiënt:
  - In welke mate had u een goed idee van wat uw eigen wensen waren in verband met PSA-screening?
  - In welke mate hebt u het gevoel dat de gemaakte beslissing gezamenlijk genomen werd?
  - In welke mate hebt u het gevoel dat de genomen beslissing goed onderbouwd is?
  - Wat heeft u geholpen om te praten over uw voorkeuren?
  - Wat maakt het moeilijk voor u om te praten over uw voorkeuren?
  - Wat waren de doorslaggevende factoren die geleid hebben tot de eindbeslissing?
  - Was er iemand uit uw omgeving betrokken in het beslissingsproces?
  - Hoe voelt u zich over uw beslissing op dit moment?
- Stap 4: Het interview wordt afgesloten en de opname gestopt. De patiënt wordt hartelijk bedankt voor zijn tijd.

Huisartsen

Huisarts:
Datum:
Onderzoeker:
Locatie:

Stappenplan

- Stap 1: Op het afgesproken tijdstip wordt met de arts samengezeten om het interview af te nemen.
- Stap 2: Arts nogmaals een korte uitleg geven over de studie aan de hand van de informatie die in de Informed Consent Form staat. Zaken die de arts niet begrijpt dienen verder uitgelegd te worden.
- Stap 3: Het interview gaat van start, dus wordt de opname ook gestart.
  Volgende vragen zullen worden gesteld aan de arts:
  - Wat vond u van het gebruik van een PDA?
  - In welke mate zou u het in de toekomst nog gebruiken?
  - In welke mate had u het gevoel dat het gebruik van een PDA meer tijd in beslag nam?

- In welke mate vindt u dat elke consultatie zich leent tot het toepassen van SDM?
- In welke mate vindt u dat het toepassen van SDM geschikt is bij elke patiënt of in elke situatie?
- Wat vindt u van uw eigen vaardigheden rond het toepassen van SDM?
- Tijdens de consultaties, hoe ervaarde u de reactie van de patiënt op het gebruik van de PDA?

- Stap 4: Het interview wordt afgesloten en de opname gestopt. De arts wordt hartelijk bedankt voor zijn tijd.

13.2 Recruitment mail participants

Geachte heer,

Hierbij willen wij u uitnodigen om deel te nemen aan een studie over gedeelde besluitvorming en het gebruik van digitale beslishulpen in de huisartsenpraktijk. Deze studie kadert in onze masterthesis huisartsgeneeskunde. *Deze studie is goedgekeurd door de Ethische Commissie Onderzoek UZ/KU Leuven. (Masterpaper nummer: MP017089)*

Het doel van de studie is:
1) De vaardigheden van huisartsen te verbeteren in het toepassen van gedeelde besluitvorming en het gebruik van digitale beslishulpen.
2) Deelname van patiënten aan het gemeenschappelijke beslissingsproces te versterken door ze actief vragen te laten stellen.

Wij nodigen u uit om aan deze studie deel te nemen ofwel omdat u behoort tot de inclusiecriteria en vroeg naar een PSA-screening, ofwel omdat u op consultatie komt voor een bloedonderzoek.

Tijdens uw consultatie bij de huisarts zal deze gedeelde besluitvorming en digitale beslishulpen toepassen. Het onderwerp waarrond uw huisarts dit zal doen is de PSA-screening. Dit is een onderzoek om vroegtijdige prostaatkanker op te sporen in het bloed.

U zal na de consultatie gevraagd worden een korte vragenlijst in te vullen. U kan ook gevraagd worden deel te nemen aan een interview waar dieper op de genomen beslissing zal ingegaan worden.

Bent u geïnteresseerd om deel te nemen aan deze studie?
U kan antwoorden op deze mail of ons op onderstaande contactgegevens bereiken.
Dan bezorgen wij u met plezier verdere informatie.

Met vriendelijke groet,
Jalil Haddioui
Huisarts in opleiding
jalili.haddioui@student.kuleuven.be

Frederik Dekock
Huisarts in opleiding
frederik.dekock@student.kuleuven.be

- Will it be possible to respect the federal and institutional rules, e.g. social distancing, protective measures...? Yes
- Is additional protective material needed in order to execute the study? Please specify. No, except standard protection during consultations (already available in the practices)
- How many additional persons (researchers/observers) are envisaged in the interaction with the participants? Total of interactions per patient: 1 student-researcher and/or 1 GP.
- In which room/building will the study take place? In a consultation room in GP practice.
- If the study takes place in another institution, has this institution approved the re-start in writing? NA
- Is there a need for modifying the ICF, and if so, please provide a changed version with track changes? No

- Is there a need for modifying the protocol, and if so, please provide a changed version with track changes? No