



# BMJ Open Translation and cultural adaptation of a prostate cancer screening decision aid: a qualitative study in Portugal

Sofia Baptista <sup>1,2,3</sup>, Bruno Heleno,<sup>4,5</sup> Marta Pinto,<sup>3,6</sup> Bruna Guimarães,<sup>2</sup> Diogo China,<sup>2</sup> João Pedro Ramos,<sup>6</sup> Andreia Teixeira,<sup>1,3</sup> Kathryn L Taylor,<sup>7</sup> Carlos Martins <sup>1,3</sup>

**To cite:** Baptista S, Heleno B, Pinto M, *et al*. Translation and cultural adaptation of a prostate cancer screening decision aid: a qualitative study in Portugal. *BMJ Open* 2020;**10**:e034384. doi:10.1136/bmjopen-2019-034384

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2019-034384>).

89th European General Practice Research Network meeting (EGPRN) - prize for best poster.

Received 19 September 2019  
Revised 17 December 2019  
Accepted 07 January 2020



© Author(s) (or their employer(s)) 2020. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

## Correspondence to

Dr. Sofia Baptista;  
baptistas@med.up.pt

## ABSTRACT

**Objectives** To translate and culturally adapt an English language patient decision aid addressing prostate cancer screening, so it can be used by Portuguese men.

**Design** Qualitative study. We followed the European Centre for Disease Prevention and Control's (ECDC) five-step, stakeholder-based approach to adapting health communication materials: (1) selection of materials and process coordinators, (2) early review, (3) translation and back translation, (4) comprehension testing with cognitive semi-structured interviews and (5) proofreading. Content analysis was performed using Ligre software.

**Setting and participants** Cognitive interviews with 15 men to refine a decision aid after its translation. Eligible participants were Portuguese native-speaking men aged 55–69 years old recruited from the local community (urban and suburban) of Oporto district through advertisements in social media and senior universities between January and March 2019. A previous diagnosis of prostate cancer was the single exclusion criterion.

**Results** Five main themes are presented: informational content, information comprehension, sociocultural appropriateness, feelings and main message and personal perspective concerning prostate cancer screening. Most men found the translated version of the decision aid to be clear, comprehensive and appropriate for its target population, although some suggested that medical terms could be a barrier. The data collected from men's interviews afforded the researchers the opportunity to clarify concepts and expand existing content.

**Conclusions** A decision aid was successfully translated and adapted to the Portuguese cultural setting. Our ECDC based approach can be replicated by other workgroups to translate and culturally adapt decision aids.

## INTRODUCTION

Prostate cancer is the most common cancer among men worldwide (1.6 million cases) and the seventh leading cause of male cancer death, with a total of 366 000 deaths.<sup>1</sup> In Portugal, there are 90.5 new prostate cancer cases yearly per 100 000 inhabitants, making it the leading male cancer in terms of incidence. The adjusted mortality rate in 2014 was 20.3/100,000 with an absolute number of

## Strengths and limitations of this study

- This study led to the development of the first Portuguese language decision aid to support Portuguese men's decision concerning prostate cancer screening.
- With this qualitative design we aimed not solely at translating a previously tested English language decision aid, but also at culturally adapting it.
- Cognitive interviews allowed for usability and comprehensibility testing by engaging end-users and incorporating their preferences in an iterative process.
- Our sample of interviewed men proved to be diverse in terms of educational level and income, which is another strength.
- The idea of behaving in a social desirable way could have biased cognitive interviews; to address this the investigators informed participants they were interested in all kind of feedback (including criticisms) and mainly used open-ended questions and probes.

1787 deaths from prostate cancer. In 2016 prostate cancer accounted for 1.7% of all deaths.<sup>2</sup>

Screening for prostate cancer using prostate specific antigen (PSA) test remains controversial, implying a trade-off between benefits (low mortality reduction, possibility of an early diagnosis) and harms (high overdiagnosis and overtreatment with the consequent side effects, as well as false positive and false negative test results).<sup>3–6</sup> Digital rectal examination (DRE) has not been established as a screening test for early detection of prostate cancer and no survival benefit was found with combined PSA and DRE screening.<sup>7,8</sup> Many guidelines issued by medical organisations support a shared decision making process, in which decision aids may play an important role.<sup>9–13</sup> In spite of the scientific debate, PSA early detection is popular in Portugal. A 2013 population-based cross-sectional study showed that 67.3% of the Portuguese adult men consider that PSA test

should be performed. Men answered PSA test should be done, on average, every 14.7 months and 33.9% reported to undergo PSA test.<sup>14</sup> On the other hand, 65% of Portuguese primary care physicians reported they usually do PSA test for prostate cancer screening, 93% of these in median every 12 months.<sup>15</sup>

Decision aids are evidence-based tools which showed to improve the quality of the decision, increasing patient knowledge, making people feel clearer about their values, reducing decisional conflict and promoting an active patient role in decision making.<sup>16-17</sup> Language can be a barrier to accessing relevant and high-quality health information and delivering appropriate healthcare.<sup>18</sup> Developing new decision aids in a different language can be time-consuming and costly.<sup>19</sup> Consequently, adapting existing decision aids rather than developing new ones allows to benefit from previous fieldwork while avoiding duplication of developmental efforts and producing many similar material.<sup>20</sup>

Portuguese is the world's sixth most spoken language and the fifth most used in the web.<sup>21</sup> However, to date, there is no decision aid in European Portuguese to support men's decision regarding prostate cancer screening.

Translation alone is not enough and a decision aid depends on the accurate assessment and understanding of the target population's cultural background.<sup>22-23</sup> Thus, we aimed to translate and culturally adapt an English language patient decision aid addressing prostate cancer screening to be used by Portuguese men.

## METHOD

### Conceptual framework for adaptation

We followed the European Centre for Disease Prevention and Control's (ECDC) five-step, stakeholder-based approach to adapting health communication materials.<sup>22-24</sup>

The protocol for this study was previously published.<sup>25</sup>

### Step 1: selection of materials and process coordinator

We searched for prostate cancer screening decision aids in the A to Z inventory from the Ottawa Hospital Research Institute (<https://decisionaid.ohri.ca/>, accessed 9 September 2018). The A to Z inventory of decision aids is a part of a website belonging to the patient decision aids research group and affiliated with the University of Ottawa (Canada). The inventory contains up-to-date and available decision aids that meet a minimal set of criteria in accordance with the International Patient Decision Aids Standards (IPDAS) collaboration. The first author critically appraised the decision aids using IPDAS criteria. Thereafter, we identified those which fulfilled most of the quality criteria. Of those, we selected the 'Making the Best Choice' decision aid because it was presented in two different formats (paper and web, link: <https://decisionaid.ohri.ca/Azsumm.php?ID=1776> - accessed 9 September 2018). 'Making the best choice' is an English language prostate cancer screening decision aid

which has been rigorously developed<sup>26</sup> and extensively tested<sup>27-31</sup> by a workgroup from Georgetown University (USA). We sought permission to translate and adapt the decision aid to the Portuguese population. KLT, who was the principal investigator of the original decision aid, is a co-investigator in this project.

For this study we used the print version of the decision aid. Briefly, the informational sections include introductory material about the prostate gland; a description of screening tests and possible results; information about treatment options, risks and adverse effects; a review of prostate cancer risk factors and encouragement to discuss screening with a physician (but without instructions to make an immediate appointment); a 10-item values clarification tool; and resources for more information (references and a glossary). The decision aid has been found to improve prostate cancer knowledge and to reduce decisional conflict, with these changes remaining significant at the 13 months follow-up. Satisfaction was also higher for both formats in comparison with usual care; screening rates did not differ significantly among groups.<sup>28</sup>

We have reviewed the original version of the decision aid and associated published data in close cooperation with its developers to identify the core elements of the decision aid, namely, those concerning format and design features, structure, rationale and contents. SB was the process coordinator.

### Step 2: early review

Before starting the translation, the decision aid was reviewed by the process coordinator and by a linguistic expert. This early review aimed to ensure that culturally and technically inappropriate recommendations were removed. Relevant Portuguese data and materials were also incorporated in the decision aid. In addition, the linguistic expert reviewed the document in close contact with one of the authors of the original document and created a list of difficult concepts and alternative ways to convey the information.

The major changes after this early review included: (1) replacing the photos in the original decision aid with photos of Portuguese men; (2) replacing references to the American Societies/Associations' recommendations (with exception to United States Preventive Services Task Force (USPSTF)) by the recommendations of the Portuguese Directorate-General for Health; (3) replacing American epidemiological data by Portuguese epidemiological data; (4) in one of the testimonies there was this sentence: 'That's why I signed up for a free prostate screening programme'; this needed adaptation since it does not apply in the Portuguese healthcare service reality; (5) a new infographic was added, adapted from USPSTF.<sup>32</sup>

In addition, several years have lapsed since the original decision aid was developed. Therefore, a rapid review of clinical practice guidelines and systematic reviews of randomised controlled trials was performed to ensure the data provided were up-to-date.

### Step 3: translation and back translation

According to ECDC's approach step 3 should include translation, quality check and an independent review, with the major aim of obtaining a conceptual equivalent and not a literal translation.<sup>22</sup> Most studies describing the cultural adaptation of patient decision aids used forward and back translation by experienced, bilingual translators working independently and with a translation committee.<sup>20</sup> In our study, two forward translations from English to Portuguese were done: by SB (native in Portuguese and fluent in English) and by a professional translator (native of Portuguese). A consensus translated version was obtained after resolving divergences within the translation committee composed by the process coordinator, a linguistic expert and a team of professional translators. This was followed by a back translation by a professional translator, native speaker of English, fluent in Portuguese and then reviewed by KLT who was the coordinator of the original English decision aid. No major differences emerged either between the two translated versions or between the consensus translated version and the reverse translation; therefore no major changes were done. Afterwards, an independent expert (also familiar with the source language) reviewed the decision aid.

### Step 4: comprehension testing

This step is designed to ensure the adapted and translated decision aid is clear and understandable for its target end-users. Concerning this step, ECDC mentions a variety of approaches, including focus groups and interviews.<sup>22</sup> Similarly, to several authors aiming to culturally adapt decision aids, we opted for individual interviews in which participants are asked to share their impressions aloud while they are going through the decision aid.<sup>20</sup>

### Participants

Eligible participants were Portuguese native-speaking men aged 55–69 years old recruited from the local community (urban and suburban) of Oporto district through advertisements in social media and senior universities between January and March 2019. A previous diagnosis of prostate cancer was the single exclusion criterion.

### Individual semi-structured interviews

The interviews were conducted by SB, BG and DC who were general practice registrars, without any role in the participants' healthcare. They received training and supervision by an expert in qualitative research (MP). The interviews took place at different locations in Oporto district, indicated by participants at their convenience, providing confidentiality was assured.

Participants were presented a general description of the decision aid and the study aims. After giving their written consent to participate and to have the interview audiorecorded, they were asked to complete a questionnaire with basic demographic data.

During the individual interviews, researchers applied cognitive interview methods, using think aloud, probing

**Table 1** Barriers identified by men and respective changes to the decision aid.

Barriers or problems identified by men	Changes made (after the first 10 interviews)
"[The title in the cover page] should be different in order to indicate it is a manual to help people" [D3].	We added 'decision aid' in the cover page.
Difficult term: 'carcinoma'	Replaced with 'cancer'
Difficult expression: 'anomalous results'	Replaced with 'elevated PSA results'
Difficult concept: 'overdiagnosis'	A headline balloon was added with the definition of overdiagnosis at its first appearance
Asterisks at the bottom of the infograph—not very clear what they referred to	'To be continued in the next page' was added below the asterisks

and paraphrasing techniques.<sup>33</sup> Men were asked to share their impressions aloud while they were going through the decision aid with the purpose of identifying potential issues in the format and content.<sup>20</sup>

We conducted 10 interviews and updated the decision aid according to the interviewees' feedback, followed by a round of five interviews to further refine it. The barriers identified by men during interviews and changes made accordingly are presented in table 1.

### Data analysis

Participants' demographic data were analysed using Microsoft Excel 2016. Data obtained during the individual semi-structured interviews were analysed in the personal computers of two authors (SB, JPR), ensuring these had not a network connection. Each interview was given an alphanumeric code to omit the participant's identity. After verbatim transcription of the audiofiles (SB, BG, DC), transcripts were read until they became familiar.

Guided by the theoretical framework, we conducted a thematic analysis approach to the qualitative data.<sup>34</sup> A deductive approach was initially used to develop a categorisation matrix,<sup>35</sup> in accordance with similar studies testing decision aids for other health-related decisions.<sup>36–39</sup> Afterwards, data were analysed following the principles of inductive content analysis.<sup>35</sup> The units of analysis were expressions with the same core meaning. The first five interviews were read several times until they became familiar to both coders. Expressions with similar meaning or addressing the same issues were grouped into subcategories which were then put together to form the main categories.<sup>40</sup> The categories (open coding) were then grouped into themes (axial coding). The final codebook was established by consensus among the two coders (SB, JPR) and the supervising qualitative expert (MP). We performed thematic content analysis<sup>39 41</sup> using Ligre software. Two authors (SB, JPR) independently coded

**Table 2** Characteristics of participants and interviews

Variables	n=15
Age (years), $\bar{x} \pm sd$ , med, min, max	61±4.90, 61, 55, 68
Duration of interviews (minutes), $\bar{x} \pm s$ , med, min, max	67.93±15.01, 66, 45, 101
<b>Education level, n (%)</b>	
Cannot read/write	0 (0)
Till fourth grade	1 (6.7)
Between fifth and ninth grade	4 (26.7)
Between 10th and 12th grade	7 (46.7)
College degree	3 (20.0)
<b>Monthly income, n (%)</b>	
Below average	5 (33.3)
On average	3 (20.0)
Above average	7 (46.7)

\* $\bar{x}$  : mean, med: median, min: minimum, max: maximum, n: absolute frequency. Monthly income reports to a Portuguese employee's gross average monthly income of 924.90 in 2016. Source: PORDATA.

all the interviews. Divergences were solved by consensus. Throughout the analyses, data, codes and categories were discussed and regular meetings of the two coders and a qualitative expert took place. By including independent coding, peer review, confirmability checkpoints and the supervision by a qualitative expert throughout the process we aimed at improving our analysis' reliability.<sup>42</sup>

The audiofiles were destroyed 3 months after data analysis.

### Step 5: proofreading

After the comprehension testing, proofreading was conducted by two native Portuguese speakers selected by the process coordinator, who had not read the decision aid before. No changes were made to the decision aid translation at this stage.

## RESULTS

### Participants

A total of 15 men agreed to be interviewed. A brief description of the participants is provided in [table 2](#). Participants ranged in age from 55 to 68, with a mean age of 61 years. Interviews took on average 68 min to complete (range 45–101 min).

### Themes

Five main themes are presented: informational content, information comprehension, sociocultural appropriateness, feelings and main message, personal perspective concerning prostate cancer screening and related

subjects. We indicate the alphanumeric code to identify the interview fragment cited, to ensure accurate representation of all interviews (B1–B5, D1–D5, S1–S5). We have used qualitative terms to indicate the number of men who raised each issue: some or few (1–3), many (4–10) and most (>10). We reached thematic saturation by the tenth interview, when the same themes and similar comments and recommendations appeared in each interview. Nevertheless, we continued in a second round of five interviews with the refined version of the decision aid, ie, after addressing the major barriers identified by men ([table 1](#)).

### Informational content

This theme describes participants' opinions on the way content is presented as well as the perceived relevance and interest.

### Opinion on sections

Throughout their review of the decision aid most men stated that the decision aid was easy to read and insightful, but some changes were suggested. In particular, many men reported that the introduction, facts about prostate and prostate cancer and the symptoms sections were well written and made them more confident about participating in informed decision making with their providers. For instance, referring to the section on facts about the prostate and prostate cancer, one man said that 'the information you provide here gives people the possibility of putting at stake what has been established till now' [S4], which may suggest the information in the decision aid is presented in a balanced manner so men can make the choice which is more congruent with their own preferences and values. Alluding to the section describing the symptoms of prostate cancer, one participant stated 'It gives me peace of mind to know these symptoms can be associated with cancer or not' [B2]. For many men the information in the treatment section was previously unknown, so they considered it important to be included in the decision aid. In addition, most men thought that 'Beyond the basics' and 'Glossary' sections could be useful, for example, one man said 'It's never too much [information]...I would like to go forward and keep learning...I like this, I like to be up-to-date, to know a little more so I can have a conversation' [S3]. Few changes were suggested in the aforementioned sections.

Particularly concerning the cover page, most men thought it was well designed, 'transmitting ideas and thoughts (...) a stimulus to read [the decision aid]' [S3]. One man thought the cover page design and content were in accordance with the subject, since 'it shows the importance of men speaking to their doctors' [D1]. Some added that it should be more colourful and does not indicate adequately what the decision aid is about. 'Making the best choice'...then here says 'Prostate cancer screening', it should be different in order to indicate it is a manual to help people [D3]. Following this suggestion

we added ‘decision aid’ in the cover page for the last five interviews and no more comments arose concerning this.

### Missing contents

One man showed interest in knowing the number of false negatives from the PSA test, since the numbers are presented for false positives [S4] and another wanted to know more about the role of MRI [S1]. Radiotherapy impact on fertility [S5], prostate artery embolisation and robotic surgery, incontinence treatment, cancer recurrence and new screening tests under investigation [D3] were other missing themes identified by participants.

One man suggested addressing a ‘myth’ which according to him was spread among the male population: ‘The absence of sexual activity causes prostate problems (...) it’s a myth but most talked about’ [S5].

### Testimonials and values clarification method (VCM) grid

All men commented on the testimonials and values clarification method grid. Many men reported their own experiences after reading the two testimonials, indicating that they identified, at least in part, with one of the portrayed stories. Representative quotes are as follows.

‘Anyone reading this can see these Mr. A or Mr. B – and they have photos and everything – and these are two concrete cases (...) I’d say I think alike this 65 year old man [first testimonial] because, and citing ‘I’ve always believed it’s better to know more rather than less about my health’ [S3].

‘In fact, like this man [second testimonial] ... sometimes if we get an abnormal result we go home and start to overthink...it may be serious, we could die’ [B5].

Concerning the grid, most participants found it helpful and indicated their willingness to share the way they would answer the items in the grid, although this was not asked by the interviewers. Twelve men revealed an intention to undergo PSA screening from their answers to the values clarification grid, 2 answered against screening and 1 did not reveal the answers out loud but had said to be undecided before. Some illustrative quotes are presented below.

‘Really useful. Because there’s a summary of most of the things we’ve seen here, isn’t it?’ [D4].

‘This box in the end, after all the information has been presented, allows people to make a more informed choice’ [D2].

‘They’re reducing this to “yes” or “no” to these five questions, but, at their heart, people probably consider more things (...) but it’s a grid that can help’ [D3].

### Information comprehension

This theme explores how men perceive the information and how they are capable of translating it into their own words as well as the new concepts they learned from the decision aid.

### Clarity and completeness

Most men said the decision aid was globally written in a clear way, easy to read and understand, concluding, for

instance, that ‘everything here is easy to read and of easy comprehension’ [D2] or ‘Whoever reads this gets enlightened’ [S1].

In addition, many men indirectly showed reading comprehension by translating the information into their own words. One man stopped reading the decision aid to comment: ‘So the prostate can grow, be inflamed or be associated with cancer’ [B5]. As an example, another participant shared his comprehension explaining ‘So, what they’re saying here is that the PSA test can be unreliable...an abnormal result may not be cancer’ [B4].

Most of the interviewees also indicated the decision aid was comprehensive, containing the adequate amount of information concerning prostate cancer screening. One participant said ‘I think the decision aid is very complete’ [B1] and another explained further that he thought it was ‘very elucidative. It is not boring. It goes straight to the point, head-on. It goes directly to themes with accuracy and insight’ [S5].

### Figures and graphs

Figures and graphs were easily and correctly interpreted and turned out to help convey the information for most of the interviewees.

About a figure portraying the anatomy of the male reproductive system, participants commented: ‘By the way, I did not know the prostate was here’ [B5], ‘I got a much clearer image of the human body’ [S3] or ‘So the digital rectal examination is because the prostate is close to the intestines...now I understood’ [B2].

The infographic adapted from USPSTF and placed in the final decision aid (before the values clarification method) was a new feature of our version, not present in the original decision aid and most men thought it was useful in summing up the main information on benefits and harms of screening to support and informed choice. About the infographic one man commented it was ‘really interesting because it gives a percentage view’ [B1] and another pointed out ‘Here, 50 get erectile dysfunction, it’s much, I mean, surviving with these effects is serious... one has to judge wisely in fact...’ [B4]. Most men also shared their surprise with the numbers presented in the infographic. For instance, one man summed up that ‘Looking at this infographic we understand the results are not very encouraging to do the screening’ [B1] and another added ‘Avoiding one cancer death is not much... the problem is that as I understood we cannot know for sure the cancer stage, which cancers will be lethal and which not...but in fact looking at these number I didn’t know it was like this’ [B2].

### New information acquired

Most men mentioned that much of the information in the decision aid was new to them. This included the risk factors for prostate cancer (many did not know men of African descent had higher risk), the distinction between prostate cancer and benign prostatic hyperplasia, the existence of the PSA test and its false negative and false

positive results, the uncertainty surrounding prostate cancer screening and the side effects of treatment.

#### *Difficult concepts/expressions*

'Anomalous results', 'carcinoma' and 'overdiagnosis' were each mentioned by one man as difficult to understand.

After the first round of ten interviews, we changed the term 'carcinoma' for 'cancer' as well as 'anomalous results' for 'elevated PSA results'.

Although overdiagnosis was later defined in the glossary, we decided to add the definition of both overdiagnosis and overtreatment in a headline balloon at their first appearance. In the last round of five interviews, no more difficult terms or expressions were mentioned.

#### *Sociocultural appropriateness*

Many men commented on the appropriateness of the decision aid to the target group of men it was developed for; most found it adequate and easy to understand, although some indicated it was too long and language was technical at some points. One of the interviewees considered 'This was good, this information should be available to 90% of the population. (...) Society still hides a lot (...) that's one of the reasons why it's important to educate men to open themselves to talk about this with their doctor. (...) Some parts I found the language a little bit technical' [B3]. Another one pointed out some difficulties which could arise from differences in educational background 'I think our population educational level is not that high...if you go to a rural area I'm pretty sure the majority of people won't understand what's written here or will only with help from a doctor' [B1]. Considering the decision aid 'rather approachable' one of the participants suggested it would be good to make the decision aid widely available '(...)the ideal would be a website... and the possibility to download this' [S3].

#### *Feelings and main message*

This section summarises the closing comments of men after reading the decision aid, referring both to their feelings and impressions as well as what they found the main message to be. Some acknowledged the decision aid could be helpful to prepare for a doctor's appointment, as an example, one man said 'It's a way for people to clarify their doubts (...) and when going to a medical appointment to prepare the questions for the doctor to get the most information possible' [S2].

Most men were satisfied with the decision aid and thought it was helpful. One man explained this way: 'I liked it because there are many things in it I didn't know about (...) I learned a lot' [B2]. Another man added that reading the decision aid gave him 'peace of mind... because I thought there were more men dying of this cancer...' [B1].

Few participants mentioned that they felt anxious after learning about the uncertainties surrounding prostate cancer screening. Some men mentioned that the decision aid's main message was that screening was

beneficial, although the decision aid provides information on risks and benefits and does not encourage any particular decision. One man shared that to him the main message 'is that people should think by themselves and decide what to do. Doing the best choice is doing a conscious choice, balancing well what to do and not' [S3].

#### *Personal perspective concerning prostate cancer screening and related subjects*

Most men wanted to share their views, beliefs, values and preferences concerning prostate cancer screening and related subjects during the interviews. In many cases, participants told how their personal life experiences shaped their opinions.

#### *Personal perspective on prostate cancer*

Men often mentioned to associate the ideas of fear and death with the concept of cancer. For example, one man mentioned he did not know about the indolent course of some prostate cancers because 'whenever I hear about cancer I think of death if left untreated (...) cancer means fear of death' [B4]. Similarly another one said alluding to his personal experience 'for me cancer is fear, because I was with my wife who developed cancer' [B2].

#### *Personal perspective on prostate cancer screening*

Words like regret, prevention and anxiety appeared in many interviews in relation to screening. Most showed to be inclined to undergo prostate cancer screening. One man mentioned 'I think I would do the screening because otherwise I couldn't be calm...despite the side effects of treatment, I would be calmer if I did everything to prevent the worst' [B2]. With an opposite view, other man said 'I'm one of those who doesn't agree with it [prostate cancer screening]. (...) And since I only knew about digital rectal examination, for me it was not an option. I'd rather trust a blood analysis (...) if PSA didn't have all this uncertainty (...) I think I will stay the same' [S4].

Most men commented on false negative and false positive results of PSA test reflecting on this as a negative misleading aspect. 'Painful' was the most cited word in relation to DRE.

One man commented on overdiagnosis showing his own perspective: 'What is at stake here is overdiagnosis, right? And overdiagnosis perhaps is not that negative for me that would make me not to consider it [prostate cancer screening]' [D3].

Many men recognised a practitioner control role in decision rather a shared decision making process concerning prostate cancer screening and treatment decisions. For example, one man explained 'I never asked [PSA test], he [the doctor] used to order it for me' [D4] and another one stated 'When some test is ordered by a healthcare professional no one rejects it, do they? I don't. This usually is not up to us to decide, we don't have enough knowledge' [S1].

### *Personal perspective on prostate cancer treatment*

Despite some division was evident among men concerning the options of active treatment and active surveillance, although more were in favour of the first, most men commented on side effects of treatment and agreed in connoting these negatively. Interestingly, two men used the expression ‘double-edged sword’ to convey the uncertainty surrounding prostate cancer screening and treatment. One of them said: ‘A person is playing with a double-edged sword here...if treating causes problems... but if don’t treat, you may have problems and die’ [B3].

## DISCUSSION

### Summary of the main findings

The data collected from men’s interviews afforded the researchers the opportunity to clarify concepts and expand existing content of the translated decision aid. Most men found the decision aid to be clear, comprehensive and appropriate for its target population, although some suggested that medical terms could be a barrier. No major changes were proposed by men during the cognitive interviews to apply to the decision aid after the early review and translation steps, but instead punctual yet valuable amends were suggested. Most participants revealed interest in both the figure and the infographic and interpreted them correctly. In addition, the majority of interviewees indicated that they acquired new information from reading the decision aid and some were interested that additional information was added. All men commented on the testimonials and values clarification section. Participants identified either with the stories or statements and shared their personal experiences and preferences. Furthermore, most men revealed their personal preference to undergo prostate cancer screening.

### Comparison with existing literature

This is to our knowledge the first study to conduct cognitive interviews with men to adapt a prostate cancer screening decision aid after its translation. In terms of themes, our results are in line with similar studies conducted with cognitive interviews to evaluate decision aids for other preference-sensitive health decisions.<sup>36–38 43</sup> Previous studies have shown that messages that do not clearly support cancer screening are seen as counterintuitive and that the benefits of screening are overestimated.<sup>44–46</sup> Although participants evidenced surprise and interest in information on the risks of screening, for most these did not seem to change their intention to undergo screening. In fact, perception about harms is probably underestimated by the general population, since the media and even clinical trials report benefit more often than harms.<sup>47</sup>

Most studies with decision aids focus on measuring decision quality outcomes, but our study adds to the body of evidence concerning how the decision process develops throughout the reading of a decision aid. We noted three

main moments which caused men to weight the harms and benefits: the testimonials section, the USPSTF’s adapted infographic and the values clarification grid. In that sense, we hypothesise that the infographic itself may have worked as an implicit values clarification method, since it contains the most relevant characteristics for the screening decision and thus men are able to consider the potential value on their own.<sup>48</sup>

The most recent systematic review and meta-analysis assessing the impact of decision aids for screening decisions concluded that decision aids promote an active patient role in decision making.<sup>17</sup> A qualitative content analysis study to evaluate women’s views on a decision aid for breast cancer screening using focus groups showed that women preferred shared decision making.<sup>49</sup> Our findings differ in that most men reported a practitioner control role in decision making, although few have expressed their preference in this subject but rather shared their experience regarding decision making with their doctors and many evidenced surprise on the possibility of a patient role in decision making. This may in part be explained by a paternalist model of consultation still prevailing in many situations.

### Strengths and limitations of this study

The researchers strongly believe that decision aids are helpful, and that may have influenced how we analysed the data. We tried to address this by discussing methodological decisions and themes among authors. Furthermore, social desirability bias cannot be excluded, as participants were aware that the interviewers were clinicians. To minimise this, we informed participants that we were interested in all kind of feedback (including criticisms) and we mainly used open-ended questions and probes. The diversity of men’s background in terms of educational level and income was a strength of our convenience sample. In addition, the use of cognitive interviews proved to be instrumental in refining the decision aid based on men’s feedback. This was a strength of our study, since the cognitive interviews allowed for alpha testing (usability and comprehensibility) engaging end-users and incorporating their preferences in an iterative process and thus meeting IPDAS criteria for decision aid development.<sup>18</sup> Our sequential methodology with a second moment of data validation with participants after the first round of cognitive interviews is another strength.

### Implications for clinical practice and research

Our findings reinforce that decision aids may play an important role in supporting preference-sensitive health decisions and this should be taken into account by patients, physicians and policymakers. Portuguese men will have access to the first decision aid about prostate cancer screening written in Portuguese. In addition, we intend to make it publicly available also in a web-based version. So far, there has been little research related to translation and cultural adaptation of decision aids. We have found that a systematic approach to translate and

culturally adapt a decision aid was feasible under limited resources. Our experience may be refined and replicated by other workgroups, thus adding to the body of existing decision aids in a cost-effective manner. Delivery methods and implementation strategies of the decision aid need to be further studied.

#### Author affiliations

<sup>1</sup>Department of Community Medicine, Information and Health Decision Sciences (MEDCIDS), Faculty of Medicine, University of Porto, Porto, Portugal

<sup>2</sup>Serpa Pinto Family Medicine Unit, Agrupamento de Centros de Saúde Porto Ocidental, Porto, Portugal

<sup>3</sup>Centre for Health Technology and Services Research (CINTESIS), University of Porto, Porto, Portugal

<sup>4</sup>NOVA Medical School/Faculdade de Ciências Médicas, Universidade NOVA de Lisboa, Lisboa, Portugal

<sup>5</sup>Comprehensive Health Research Center (CHRC), Universidade NOVA de Lisboa, Lisboa, Portugal

<sup>6</sup>Department of Psychology of deviance and justice, Faculty of Psychology and Education Sciences, University of Porto, Porto, Portugal

<sup>7</sup>Department of Oncology, Lombardi Comprehensive Cancer Center, Georgetown University, Washington, DC, USA

**Twitter** Bruno Heleno @bruno\_m\_helena and Carlos Martins @mgfamiliarnet

**Acknowledgements** The authors would like to express their deepest gratitude to Professor Elena Galvão and master students Helena Santos, Alexandra Palmeiro, Carina Rodrigues and Fu Yujia from Faculty of Arts and Humanities of the University of Porto for their contribution to the translation of the decision aid. The authors are in debt to Professor Armando Brito de Sá for having conducted the expert revision of the translated decision aid. The authors would also like to thank to all interviewed who gave their time and considerations to improve the decision aid.

**Contributors** SB, BH, CM, MP and KLT designed the study. SB coordinated the translation process. SB, BG and DC conducted the interviews and their transcription, supervised by MP. SB and JPR coded the interviews. SB, JPR and AT undertook the data analysis. SB made the final manuscript. All authors approved the final manuscript after revising it critically.

**Funding** The authors have received financial support of €3808.20 from the #H4A Primary Healthcare Research Network scholars programme for support of research. This article was supported by National Funds through FCT - Fundação para a Ciência e a Tecnologia, I.P., within CINTESIS, R&D Unit (reference UIDB/4255/2020).

**Competing interests** None declared.

**Patient and public involvement statement** As target end-users of the prostate cancer screening decision aid, men are at the core of our methodology.

They were first involved during the usability and comprehensibility testing by participating in cognitive interviews. Men's opinions and preferences were used to refine the decision aid and complete its cultural adaptation. We also intend to make the decision aid publicly available to all Portuguese men.

**Patient consent for publication** Not required.

**Ethics approval** The study was approved by the Health Ethics Committee from Centro Hospitalar Universitário de São João/Faculdade de Medicina da Universidade do Porto (reference 339-18).

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** All data relevant to the study are included in the article or uploaded as supplementary information.

**Open access** This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

#### ORCID iDs

Sofia Baptista <http://orcid.org/0000-0002-2604-9369>

Carlos Martins <http://orcid.org/0000-0001-8561-5167>

## REFERENCES

- Fitzmaurice C, Allen C, *et al*, Global Burden of Disease Cancer Collaboration. Global, regional, and National cancer incidence, mortality, years of life lost, years lived with disability, and Disability-Adjusted life-years for 32 cancer groups, 1990 to 2015: a systematic analysis for the global burden of disease study. *JAMA Oncol* 2017;3:524.
- Saúde DGde. *Programa Nacional para as Doenças Oncológicas. Portugal – Doenças Oncológicas em Números*, 2015.
- Andriole GL, Crawford ED, Grubb RL, *et al*. Prostate cancer screening in the randomized prostate, lung, colorectal, and ovarian cancer screening trial: mortality results after 13 years of follow-up. *J Natl Cancer Inst* 2012;104:125–32.
- Hugosson J, Roobol MJ, Månsson M, *et al*. A 16-yr follow-up of the European randomized study of screening for prostate cancer. *Eur Urol* 2019;76:43–51.
- Heijnsdijk EAM, Wever EM, Auvinen A, *et al*. Quality-Of-Life effects of prostate-specific antigen screening. *N Engl J Med* 2012;367:595–605.
- Martin RM, Donovan JL, Turner EL, *et al*. Effect of a low-intensity PSA-Based screening intervention on prostate cancer mortality: the cap randomized clinical trial. *JAMA* 2018;319:883–95.
- Schroder FH, Kruger AB, Rietbergen J, *et al*. Evaluation of the digital rectal examination as a screening test for prostate cancer. *JNCI Journal of the National Cancer Institute* 1998;90:1817–23.
- Andriole GL, Crawford ED, Grubb RL, Buys SS, *et al*. Prostate cancer screening in the randomized prostate, lung, colorectal, and ovarian cancer screening trial: mortality results after 13 years of follow-up. *J Natl Cancer Inst* 2012;104:125–32.
- Mottet N, van den Bergh RCN, Briers E, *et al*. EAU guidelines on prostate cancer, 2018. Available: <http://uroweb.org/guideline/prostate-cancer/> [Accessed Dec 2018].
- American Cancer Society guidelines for the early detection of prostate cancer. Update 2010. *Ca Cancer J Clin* 2010;60:70–98.
- Final Recommendation Statement: Screening for Prostate Cancer and Final Evidence Review: Screening for Prostate Cancer. *U.S. preventive services Task force*, 2018.
- Qaseem A, Barry MJ, Denberg TD, *et al*. Screening for prostate cancer: a guidance statement from the clinical guidelines Committee of the American College of physicians. *Ann Intern Med* 2013;158:761.
- Saúde DGde. *Prescrição E Determinação do Antígeno Específico da Próstata – PSA. Norma de Orientação Clínica 060/2011*, 2017.
- Martins C, Azevedo LF, Ribeiro O, *et al*. A population-based nationwide cross-sectional study on preventive health services utilization in Portugal—what services (and frequencies) are deemed necessary by patients? *PLoS One* 2013;8:e81256.
- Martins C, Azevedo LF, Santos C, *et al*. Preventive health services implemented by family physicians in Portugal—a cross-sectional study based on two clinical scenarios. *BMJ Open* 2014;4:e005162.
- Volk R, H L-T. The 2012 IPDAS Background Document: An Introduction. In: Volk R, H L-T, eds. *Update of the International Patient Decision Aids Standards (IPDAS) Collaboration's Background Document*, 2012. <http://ipdas.ohri.ca/IPDAS-Introduction.pdf>
- Stacey D, Légaré F, Lewis K, *et al*. Decision AIDS for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2017;19.
- Adams P, Fleck F. Bridging the language divide in health. *Bull World Health Organ* 2015;93:365–6.
- Coulter A, Stilwell D, Kryworuchko J, *et al*. A systematic development process for patient decision AIDS. *BMC Med Inform Decis Mak* 2013;13 Suppl 2:S2.
- Chenel V, Mortenson WB, Guay M, *et al*. Cultural adaptation and validation of patient decision AIDS: a scoping review. *Patient Prefer Adherence* 2018;12:321–32.
- Miniwatts Marketing Group. Internet World Stats [internet] cited 2019 Jan] Available from. Available: <https://www.internetworldstats.com/stats7.htm> [Accessed Dec 2018].
- European Centre for Disease Prevention and Control. *Translation is not enough – cultural adaptation of health communication materials*. Stockholm: ECDC, 2016.
- Sousa VD, Rojjanasirrat W, Translation RW. Translation, adaptation and validation of instruments or scales for use in cross-cultural health care research: a clear and user-friendly guideline. *J Eval Clin Pract* 2011;17:268–74.
- European Centre for Disease Prevention and Control. *Let's talk about protection*. 26. Stockholm: ECDC, 2012.
- Baptista S, Heleno B, Pinto M, *et al*. Translation and cultural adaptation of the web and printed versions of a decision aid to support men's prostate cancer screening choice: a protocol. *BMJ Open* 2019;9:e028938.



- 26 Dorfman CS, Williams RM, Kassan EC, *et al.* The development of a web- and a print-based decision aid for prostate cancer screening. *BMC Med Inform Decis Mak* 2010;10:12.
- 27 Kassan EC, Williams RM, Kelly SP, *et al.* Men's use of an Internet-based decision aid for prostate cancer screening. *J Health Commun* 2012;17:677–97.
- 28 Taylor KL, Williams RM, Davis K, *et al.* Decision making in prostate cancer screening using decision AIDS vs usual care: a randomized clinical trial. *JAMA Intern Med* 2013;173:1704–12.
- 29 Tomko C, Davis KM, Luta G, *et al.* A comparison of web-based versus print-based decision AIDS for prostate cancer screening: participants' evaluation and utilization. *J Gen Intern Med* 2015;30:33–42.
- 30 Tomko C, Davis K, Ludin S, *et al.* Decisional outcomes following use of an interactive web-based decision aid for prostate cancer screening. *Transl Behav Med* 2015;5:189–97.
- 31 Starosta AJ, Luta G, Tomko CA, *et al.* Baseline attitudes about prostate cancer screening moderate the impact of decision AIDS on screening rates. *Ann Behav Med* 2015;49:762–8.
- 32 Final Update Summary: Prostate Cancer: Screening. *U.S. preventive services Task force. October, 2018.*
- 33 Collins D. Pretesting survey instruments: an overview of cognitive methods. *Qual Life Res* 2003;12:229–38.
- 34 Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3:77–101.
- 35 Elo S, Kyngäs H. The qualitative content analysis process. *J Adv Nurs* 2008;62:107–15.
- 36 Kelly-Blake K, Clark S, Dontje K, *et al.* Refining a brief decision aid in stable CAD: cognitive interviews. *BMC Med Inform Decis Mak* 2014;14:10.
- 37 Berry DL, Halpenny B, Bosco JLF, *et al.* Usability evaluation and adaptation of the e-health personal patient Profile-Prostate decision aid for Spanish-speaking Latino men. *BMC Med Inform Decis Mak* 2015;15:56.
- 38 Gillies K, Skea ZC, Campbell MK. Decision AIDS for randomised controlled trials: a qualitative exploration of stakeholders' views. *BMJ Open* 2014;4:e005734.
- 39 The Joanna Briggs Institute. *Joanna Briggs Institute Reviewers' Manual*, 2014.
- 40 Elo S, Kääriäinen M, Kanste O, *et al.* Qualitative content analysis: a focus on trustworthiness. *SAGE Open* 2014;1–10.
- 41 The Joanna Briggs Institute. Critical appraisal tools [internet]. [cited 2019 Jan]. Available: [https://joannabriggs.org/critical\\_appraisal\\_tools](https://joannabriggs.org/critical_appraisal_tools)
- 42 Krefting L. Rigor in qualitative research: the assessment of trustworthiness. *Am J Occup Ther* 1991;45:214–22.
- 43 Hahlweg P, Witzel I, Müller V, *et al.* Adaptation and qualitative evaluation of encounter decision AIDS in breast cancer care. *Arch Gynecol Obstet* 2019;299:1141–9.
- 44 Soloe C, McCormack L, Treiman K, *et al.* *Informed decision making about prostate-specific antigen (PSA) testing: findings and implications from formative testing of a multimodal intervention.* RTI Press publication No. RR-0006-0902. Research Triangle Park: RTI International, 2009.
- 45 Gigerenzer G, Mata J, Frank R. Public knowledge of benefits of breast and prostate cancer screening in Europe. *J Natl Cancer Inst* 2009;101:1216–20.
- 46 Hoffmann TC, Del Mar C, Mar CD. Patients' expectations of the benefits and harms of treatments, screening, and tests: a systematic review. *JAMA Intern Med* 2015;175:274–86.
- 47 Heleno B, Thomsen MF, Rodrigues DS, *et al.* Quantification of harms in cancer screening trials: literature review. *BMJ* 2013;347:f5334.
- 48 Brenner A, Howard K, Lewis C, *et al.* Comparing 3 values clarification methods for colorectal cancer screening decision-making: a randomized trial in the US and Australia. *J Gen Intern Med* 2014;29:507–13.
- 49 Toledo-Chávarri A, Rué M, Codern-Bové N, *et al.* A qualitative study on a decision aid for breast cancer screening: views from women and health professionals. *Eur J Cancer Care* 2017;26:e12660.