Development and evaluation of a decision aid about fertility preservation for Dutch breast cancer patients : informing patients about fertility preservation

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Chapter 3

Development of a decision aid about fertility preservation for women with breast cancer in the Netherlands

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Abstract

Background To improve information provision about fertility preservation for breast cancer patients in the Netherlands, a web-based decision aid (DA) with additional values clarification exercise was developed according to the International Patient Decision Aid Standards criteria. This study reports on development of the DA.

Methods Development consisted of four stages: I) development of a draft DA, II) acceptability of the draft DA to patients, III) understanding (knowledge) in healthy populations, IV) acceptability of the revised DA among patients and physicians. The study population consisted of 185 participants: 20 patients, 17 physicians, 148 healthy volunteers.

Results The draft DA was considered to be relevant and understandable by patients, physicians and healthy volunteers. The values clarification exercise needed adaptation in explanation and navigation, which was done after stage II. Knowledge scores improved by 18% for lower educated women (from 4.1 (41%) to 5.9 (59%) correct answers), and by 34% for higher educated women after viewing the website (from 3.9(39%) to 7.3 (73%) correct answers). Design of the DA was evaluated to be clear, but not always very appealing.

Conclusions The DA was regarded as a relevant source of information that seemed coherent and understandable.

Introduction

For many cancer patients, fertility is an important aspect of quality of life [1-3]. As a result of better survival rates after cancer and the known side effects of cancer treatment on fertility, interest in fertility preservation (FP) has increased over the last decade. In the Netherlands, FP-options for women with breast cancer currently comprise cryopreservation of embryos, cryopreservation of ovarian tissue, and cryopreservation of oocytes[1]. Embryo cryopreservation has already been performed routinely for some years, and ovarian tissue and oocyte cryopreservation are experimental but regularly offered.

Information provision about FP is not always sufficient and is often (too) late [4-8]. Known reasons are lack of knowledge among clinicians [8-10], the difficult timing and complexity of the information [8;11], and the experimental character and ethical issues regarding the treatments [8-10;12].

In order to explore patients' experiences with the current information provision and decision making process about FP in the Netherlands, a needs assessment was conducted [13]. Interviews were held with 33 patients who had received a counseling consultation about FP and had made a decision regarding FP in the past. Results indicated that the information provision was overall deemed to be sufficient, timely and important. However, women recommended standardization of the information provision, improvement of communication among clinicians and medical centers, and availability of FP-specific patient information materials (before and after the consultation) [13].

Other studies have also found that patients wanted more information earlier in the trajectory [14] (preferably education materials to read before and after the counseling consultation with the gynecologist [15]), and wanted to have more time for decision making [15]. Therefore, internationally, initiatives have been taken to improve information provision by means of brochures, websites and Decision Aids (DAs) [16].

Decision aids are tools that provide at minimum some information about the (medical) problem, possible solutions including an option to wait and see, information about risks and uncertainties, and a balanced overview of the advantages and disadvantages of each option [17]. Over the last decade, DAs have been increasingly applied to inform patients and help them to decide about preference-sensitive decisions (i.e. where there is more than one option to choose from, with no specific best option for everyone [18]). It is thought that, with a DA, patients can make up their mind before the consultation, which facilitates decision making with the physician. Decision aids can, for example, be leaflets, booklets, CD-ROMs, or websites. Many (types of) DAs have proven to be effective in increasing knowledge, reducing decisional conflict, and increasing satisfaction with the decision [17].

Internationally, many English websites, brochures, and some DAs about FP have been developed (see overview Kelvin et al. [16]). Effectiveness has been studied for one of those, the DA-booklet of Peate et al (2012), which has been found to reduce decisional conflict, and increase knowledge about FP for breast cancer patients [19].

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[1] In some hospitals ovarian suppression with GnRH-antagonists is offered to patients, but only in research settings.

A disadvantage of this is that it is a linear booklet, and does not have the advantages of an interactive decision aid. To our knowledge, no other trials have been conducted after the effectiveness of DAs about FP.

Further, few Dutch patients have sufficient knowledge of the English language to consult existing (DA) websites, and countries differ in their medical guidelines with regard to cancer treatment and fertility preservation options. Therefore, a Dutch evidence-based web-based DA (website) about FP for women with breast cancer was developed (www.borstkankerenkinderwens.nl) in order to improve and standardize information provision in the Netherlands. The aim of the DA is to inform patients about FP, to prepare patients for a counseling consultation about FP with a physician who could then provide additional personalized information, and to enable decision making about FP. This article reports on all stages of the development of this DA.

Methods

Stage I: Initial development of the DA

Following the needs assessment (summarized in the introduction of this paper [13]), we aimed to develop a tool to improve patient information provision which would be able to contain large amounts of information, be easily accessible, and could be updated easily. Therefore, a web-based DA (www.borstkankerenkinderwens.nl) was systematically developed in accordance with the International Patient Decision Aid Standards (IPDAS) criteria for development and content of DAs [20], with additional use of international and national guidelines (respectively, a workbook on developing and evaluating patient decision aids [21], and a manual for the development of decision aids [22]). A website designer was responsible for the layout and design of the website and a website developer for building the website and programming functional requirements (such as the values clarification exercise (VCE), a print and enlarge text option, and a web statistics tracking system for research purposes).

Medical content

The website consists of 5 chapters, with a total of 26 informational pages (Box 1). This content was determined through literature review, Dutch guidelines [23], and in consultation with a multidisciplinary team consisting of medical oncologists, radiotherapists, gynecologists, fertility specialists, embryologists, psychologists, clinical geneticists, medical decision making experts, and researchers from our hospital. Patients were consulted prior to the development of the DA, and after a concept DA was developed (stage I-II). All texts were written in cooperation with a linguistic expert in writing medical texts aimed at less-educated patients, in order to increase understandability for a broad public. Probabilities are given in proportions (e.g. 3 out of 100)(13;14). Literature references are provided in a separate chapter, as well as a disclaimer with potential conflicts of interests.

Values clarification exercise (VCE)

In accordance with the IPDAS criteria and Dutch DA guidelines, our DA contains a VCE. Values clarification can be either implicit or explicit. In implicit values clarification patients value the treatments after reading or viewing the information in the DA (non-interactive). In explicit values clarification patients are asked to explicitly consider the importance of benefits and risks of the treatments or outcomes, in order to structure and provide insights in how values affect decision making (interactive; e.g. rating options) [21].

Few studies have evaluated the impact of VCEs [24]. Yet, there are indications that explicit VCEs are more effective in decision making than implicit VCEs. A systematic review comparing DAs with and without VCEs, found that DAs with explicit VCEs led to a higher percentage of patients who made an informed decision that was in agreement with their personal values [17], and to higher congruence between values and treatment [17;25]. More recent studies found that explicit VCEs lead to more satisfaction with preparation for decision making [26] and lower decisional conflict [27]. However, some studies did not find significant improvements in decision making when adding an explicit VCE to a DA [28].

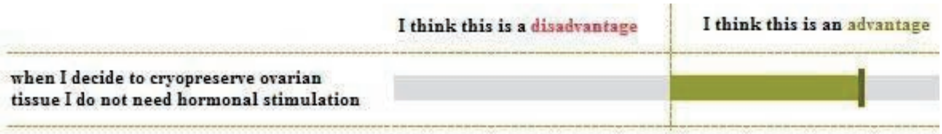
Based on the above mentioned effects of explicit VCEs we decided to add an explicit VCE to our DA [27]. In the literature, several types of explicit VCEs are mentioned, with different ways of assigning importance to the treatments or other decision outcomes, such as five-point Likert scales (not at all to very much), three-point Likert scales with the options advantage/disadvantage/no advantage nor disadvantage to choose from, and Visual Analogue Scales (VAS) [21;29]. On a VAS, respondents specify their level of agreement to a statement by indicating a position along a continuous line between two end-points. Based on considerations mentioned by Feldman-Stewart et al. (2006)[29], we chose a combination of the latter two, consisting of statements about the consequences of each FP option, for which patients were asked to indicate whether it was an advantage or disadvantage and the extent to which the (dis)advantange was considered to be important in decision making about FP (Figure 1,2). We used an additive exercise [29], as we wanted patients to choose only between pursuing (or not) the options for which they are eligible. Patients have the option to add arguments and rate these as well. After rating the importance of the separate statements, the website generates a summary that provides an overview of patients' answers in descending order from most important to least important (as indicated by the patient). This overview, rather than a summary bar indicating how much someone is in favor of one of the treatments [29], was chosen because we did not want to steer patients towards one of the treatments. Instead, patients were provided with a leaning scale on which they were asked to indicate on a 5-point scale their attitude towards a specific FP option ranging from very negative to very positive (adapted from Feldman-Stewart et al 2006 [29](Figure 3).

Question prompt sheet

To offer structured guidance in deliberation and communication, the website provides a list of questions to ask the physician (which can be supplemented with extra questions). These questions need a tailored answer, which could not have been provided on the website, like "what is my personal risk of becoming infertile after breast cancer treatment?", and "how long after my breast cancer treatment will I know whether I still am fertile or not?".

Visual content (illustrations, graphs)

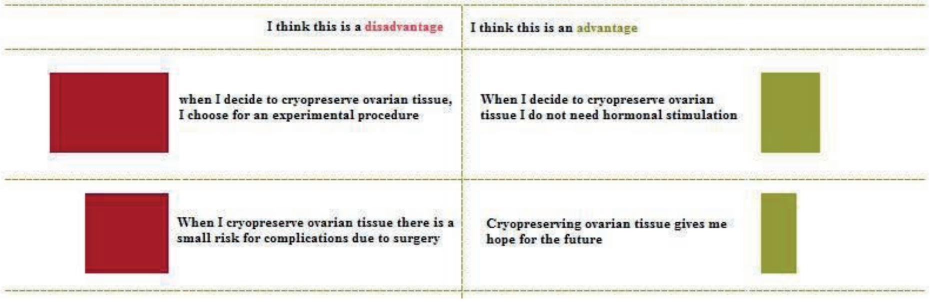
IPDAS criteria suggest visualizing information about outcomes, and to describe treatment procedures and outcomes [30]. Drawings of the cryopreservation procedure were therefore used to increase understanding of the FP processes. Furthermore, a flowchart indicates the possible FP options per age category, tables and graphs indicate the risks of several treatment regimens to become menopausal. No videos were used because this would require software that not all computers (in our hospital) have. No narratives or patient testimonials were used, because these may influence decision making [31-33].


I think this is a disadvantage

I think this is an advantage

when I decide to cryopreserve ovarian tissue I do not need hormonal stimulation

Figure 1. Example of a statement in the value clarification exercise (cryopreservation of ovarian tissue) For each statement in the value clarification exercise, patient rate whether it is an advantage (green; right side of the figure) or disadvantage (red; left side of the figure) and the extent to which the statement is considered important in decision making about FP.


I think this is a disadvantage

I think this is an advantage

when I decide to cryopreserve ovarian tissue, I choose for an experimental procedure

When I decide to cryopreserve ovarian tissue I do not need hormonal stimulation

When I cryopreserve ovarian tissue there is a small risk for complications due to surgery

Cryopreserving ovarian tissue gives me hope for the future

Figure 2. Example of the summary of given ratings (cryopreservation of ovarian tissue). The *red* boxes in the column with *disadvantages* (left side of the figure) represent the extent to which each rated disadvantage is important in the decision whether or not to opt for a certain FP option (in this case cryopreservation of ovarian tissue), as indicated by the patient herself in the previous step (figure 1). The *green* boxes in the column with *advantages* (right side of the figure) represent the extent to which each rated advantage is important in the decision whether or not to opt for a certain FP option (in this case cryopreservation of ovarian tissue), as indicated by the patient herself in the previous step (figure 1).

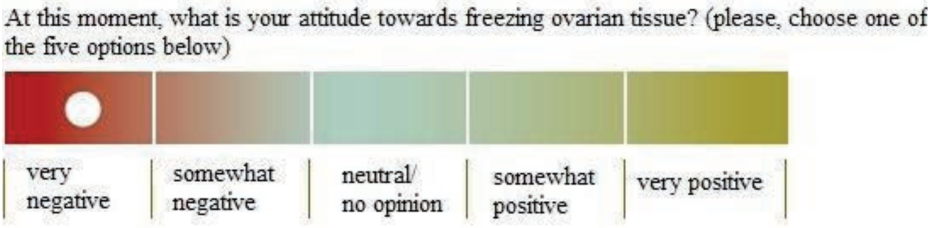

At this moment, what is your attitude towards freezing ovarian tissue? (please, choose one of the five options below)

Figure 3. Example of a leaning scale (cryopreservation of ovarian tissue)

Box 1. Content of the web-based decision aid "Breast Cancer and Wish for Children"

1. Can I still achieve a pregnancy (after my treatment for breast cancer)?
    a. Chemotherapy
    b. Hormonal therapy
    c. Other treatments
2. What can I do now to be able to have children later?
    a. Wait and see
    b. Cryopreservation of embryos
    c. Cryopreservation of ovarian tissue
    d. Cryopreservation of oocytes
3. What if I cannot achieve a pregnancy later?
    a. No children
    b. Oocyte donation
    c. Adoption
    d. Foster parenting
4. Background information
    a. Fertility
    b. Pregnancy and breast cancer
    c. Genetics and breast cancer
5. Deciding about fertility preservation
    a. What is important to me?
        i. Wait and see
        ii. Cryopreservation of embryos
        iii. Cryopreservation of oocytes
        iv. Cryopreservation of ovarian tissue
    b. Question prompt list

Studies conducted for developing and optimizing the DA (Stages II-IV)

After a draft of the DA had been developed, acceptability and understandability of the website were assessed with patients, physicians, and healthy volunteers in the following three stages (II-IV). All stages were approved by the Medical Ethics Committee of the Leiden University Medical Center.

Stage II Acceptability I: patients

To assess acceptability of the website, structured interviews were undertaken with 10 breast cancer patients between the ages of 18 and 45 who had made a decision about FP at least one year ago. We chose to include former patients since they already had experience with information provision about FP, and were therefore expected to be better able to oversee what this DA would add to the information provision as it was. In addition, it would be unethical to offer a DA that has not been (pilot) tested to patients who are actually facing the decision. Respondents were identified through a database for FP-counseling consultations in our hospital, and were invited by mail, after which they could return an opt-out form within two weeks. When they did not return an opt-out form they were called by the researcher; they were further informed about the study and asked if they wanted to participate after which an appointment was made. Informed consent was obtained before the interview started. During the interviews, respondents were asked to go through the web-based DA while thinking aloud. Additionally, women were asked some overall evaluation questions, and what improvements could be made to the DA. The topic list consisted of questions regarding difficulty in understanding the information, relevance, length, and the use of figures/illustrations for each chapter in the DA. During the interviews, answers were written down on a structured answer form. Additionally, all interviews were audiotaped to check for relevant comments, mumbling, or background information later on. However, the structured answers allowed for quantitative data analysis using Statistical Package for Social Sciences (SPSS, IBM version 20.0).

All interviews were conducted at the women's homes or in our hospital (depending on the women's preference) by a researcher not involved in the treatment or counselling of the women (MG, MF). Two interviews were held by both a researcher (MG or MF) and a clinician (LL). Women received a 15 euro incentive for their participation.

Based on the acceptability test for patients, the website was adapted and used in the next stages (stages III-IV).

Stage III Understandability of the information

Less-educated women

To assess whether women with lower levels of education understood the information on the website, we undertook a knowledge test with 8 less-educated women (lower vocational training; Mean=10.5 years (yrs) of education, range 10-14 yrs.), who were 18-40 years old. Respondents were invited through flyers distributed in local shops. Women were asked to imagine themselves in the situation of having breast cancer and having to decide about FP by reading a hypothetical script before viewing the website. The knowledge test consisted of 10 statements about FP (for example: "Cryopreservation of embryos is possible until the age of 40 (true)", or; "Surgery is necessary to be able to freeze ovarian tissue (true)"), with answering categories "true", "false", or "do not know", which had to be completed before and within one week after viewing the website. All answers could be found on the DA. Internal consistency of the knowledge scale was satisfactory at T0 (α=0.76). Differences in women's knowledge were calculated using the Wilcoxon Signed-Rank Test.

More-highly-educated women

To assess whether women with higher levels of education (higher vocational training or higher; Mean=14.1 yrs of education, range 12-15 yrs) understood the information on the website, we asked 140 healthy students to view the website and make a hypothetical decision regarding FP as part of a one hour psychological experiment in which the effectiveness of aspects of the DA was evaluated [paper in preparation]. Women were randomized to the DA with information only, or to the DA with information + VCE (the type used in all other studies). Before and after viewing the website and making a decision, we assessed knowledge with 10 statements about FP (see above). Internal consistency of the knowledge scale was satisfactory at T0 (α=0.69). Knowledge increase was assessed using a General Linear Model (GLM) for repeated measures.

Stage IV Acceptability II: patients and physicians

As part of a Delphi-study about implementation of the DA for FP [12], acceptability of the website was assessed among 17 clinicians (breast cancer nurses, oncologists (medical, surgical, and radiotherapy) and gynecologists specialized in fertility issues) and 10 breast cancer patients who had decided about FP in the past. Participants were asked to view the website and rate 13 statements about the layout and content (table 2). Agreement was assessed on a five-point Likert scale ranging from 1 (totally disagree) to 5 (totally agree), which were recoded to disagree (scores 1-2), do not know (score 3), and agree (scores 4-5). Percentages of (dis-)agreement are described. Differences between patients and clinicians were tested with χ^2-tests. Furthermore, respondents were asked to value the website with a school mark (grade) from 1-10 (1=poor, 10=excellent, a 6 or higher is judged sufficient in the Netherlands– comparable to a C, B, or A, in USA).

Results

Participants

One-hundred and eighty-five participants took part in the development studies, of whom 20 were patients (stages II n=10, and IV n=10), 17 physicians (stage IV), 8 healthy less-educated volunteers, and 140 healthy more-highly-educated volunteers (stage III). For characteristics of the participants see Table 1.

Stage II

Ten interviews were undertaken (mean duration=106 minutes, range 67-143 minutes). For socio-demographic characteristics and decisions regarding FP, see table 1. In general, respondents appreciated the fact that a DA for fertility preservation had been developed. Eight women thought that the length of the form was just right, one thought it was too short and one thought it was too long.

Table 1. Socio-demographic characteristics of the study participants

	Stage II Patients N=10	**Stage IIIa Healthy volunteers** N=8	**Stage IIIb Healthy volunteers** N=140	**Stage IV Patients** N=10	**Stage IV Physicians** N=17
Mean age, years (range)	33(26-38)	26(18-37)	20(18-36)	34(31-38)	46(35-58)
Partner yes, n(%)	6[a](60)	5(63)	76 (54)	8 (80)	n/a
Children yes, n(%)	6	3(38)	3 (2.1)	2 (20)	14 (82)
FP option chosen					
Cryopreservation of embryos, n(%)	8(80)	n/a	n/a	5(50)	n/a
Cryopreservation of ovarian tissue, n(%)	1(10)	n/a	n/a	3(30)	n/a
None, n(%)	1(10)	n/a	n/a	2(20)	n/a
Education					
Low-intermediate, n(%)	0	8 (100)	0	1 (10)	0
High, n(%)	5[b](50)	0	140(100)	9 (90)	17 (100)
Country of birth, the Netherlands, n(%)		7(88)	126 (90)	10 (100)	16 (94)

FP= fertility preservation, II=acceptability test, III= knowledge test, IV= pre-implementation study, n/a= not applicable, [a]=2 missing, [b]=5 missing.

Nine women thought that there was enough information on the website to decide about FP, and thought that the website would have helped them in decision-making if they had been able to use it. Furthermore, they thought that the presentation of the options was balanced. The design of the website and its division in chapters were highly valued, though the colors of the website were evaluated as somewhat sober.

Evaluation of the textual information (chapters 1-4)

All informative chapters were thought to be (very) relevant and most information was understandable to all respondents. However, some women thought that too much medical jargon was used (ductal/lobular cancer, laparoscopic surgery). Regarding the length of the text, suggestions were made as to divide texts in subheadings, and to provide more links to extra information on other external websites; these would provide more information, but also make the texts look more comprehensibly organized. Some respondents missed information about aspects of FP treatments (such as guidelines, side effects, success rates, replacement of cryopreserved material). The figures and illustrations were considered to be acceptable, though references between the text and figures could be improved. Figures that were illustrative of the FP procedures were thought to be nice and, especially in combination with the text, informative.

Evaluation of the chapter "decision making"

The VCE was thought to be relevant, but most women had trouble understanding what they had to do with the VCE, and how to navigate within it. Moreover, there were too many statements, and some were double negatives. The "continue" button which would lead to a summary of the statements was not prominent enough, so women did not click it (unless the researcher emphasized it). The question prompt sheet was valued highly by all respondents.

The final DA

Content of the DA was adapted based on the comments made in stage II with focus on increasing understandability, by simplifying medical jargon used in the informational chapters. Missed information that was relevant for this website was added. Links to external websites were added for missed information that was not directly relevant to this website, but related to fertility and cancer.

References to figures and illustrations were made clearer in the text. Additionally, one figure was deleted, because it was judged by the participants to be misleading and unclear. The decision making chapter with VCE was adapted with an explanation about how to use the VCE above each FP-option instead of centered on one introduction page, because it is important that women who miss the introduction page for the VCE, still know what to do with it. Furthermore, the introduction to the VCE was shortened, so that women did not have to click through multiple pages before they could start with the VCE. Statements that had been judged to be confusing were adapted. Screenshots (translated) of the final DA are provided in Figures 1-3.

Stage III

Less-educated women

Participants had spent on average 22 min on the website (range 2-51 min), and had viewed on average 16 pages (range 1-30; some pages were viewed more than once). At baseline, participants had correctly answered on average 4 out of 10 questions (41%), which increased to an average of 5.9 correct answers (59%) after viewing the website, an absolute increase in knowledge of 18% (Z=-2.263 p=0.024).

More-highly-educated women

There were no differences with regard to DA-use between participants in the DA+VCE group (*n*=70) and the information only group (*n*=70). Participants spent on average 8.3 minutes on the informational pages, 2.5 minutes on the VCE (only DA+VCE), and viewed on average 13 pages (range 2-38). There were no differences in knowledge scores between women in the information only and information+VCE groups at both measurement moments. At baseline, participants had correctly answered on average 3.9 out of 10 questions (39%), which increased to an average of 7.3 correct answers (73%) after viewing the website, an increase of 34% (*F*(1,138)=324.38, *p*<0.001; Cohen's *d*=1.79).

Table 2. Statements about layout and content of the decision aid addressed to patients and physicians (N=27) [12]

I think..	**Disagree n (%)**	**Do not know n (%)**	**Agree n (%)**
..the amount of information is too much (C)	**22 (81)**	5 (19)	-
..the website will do more harm than good (R)	**25 (93)**	2 (7)	-
..the website does not contain information that can help a patient decide about FP (R)	**24 (89)**	2 (7)	1 (4)
..the information is relevant (R)	-	1 (4)	**26 (96)**
..there is a clear red line through the website (A)	1 (4)	2 (7)	**24 (89)**
..the website is very easy to use (A)	4 (15)	1 (4)	**22 (81)**
..the division of chapters and paragraphs are presented in a clear manner (A)	2 (7)	-	**25 (93)**
..the chapter "deciding about FP" is a good supplement to the information (C)	2 (7)	5 (19)	**20 (74)**
..the information is understandable (U)	-	3 (11)	**24 (89)**
..the FP treatments are explained in a clear manner (U)	3 (11)	3 (11)	**21 (78)**
..the pros and cons of FP are presented in a clear manner (U)	3 (11)	6 (22)	**18 (67)**
..the website looks attractive (L)	8 (30)	4 (15)	**15 (55)**
..the font and font size are clear (L)	8 (30)	2 (7)	**17 (63)**

L=layout, A=accessibility, C=content/length, R=relevance, U=understandability,

Stage IV

The average school mark (grade) given to the website was 7.4 (B in USA; range 5-9). Both patients and physicians were positive about the website. An overwhelming consensus was reached on all statements, apart from the visual attractiveness of the website, while a minority disagreed. Because no significant differences were found between the opinions of physicians and patients with regard to all topics asked, results are presented for both groups together (Table 2).

Discussion

This article outlined the development of a DA about FP for premenopausal women (18-40 yrs) with breast cancer. Conclusions that can be drawn from this study are that after simplifying medical jargon and improving navigation and explanations in the VCE, the DA was seen as a relevant source of information, which seemed coherent and understandable, and was found to be acceptable to patients and physicians. Respondents appreciated the attention that is paid to improving information provision about FP and development of such tools.

Although this website was developed in accordance with the IPDAS criteria, some criteria (5/48 criteria) with regard to the content and development process of DAs could not be met. Three of these five criteria that were not met, were related to tailoring information; in our DA there is no option to enter personal health information and receive feedback regarding fertility status or any exact numeric outcomes, because we cannot give personalized risks and advice without feedback from a physician. We added a question prompt list for patients to make sure that those questions that need a personalized answer are asked in the counseling consultation. The other two unmet criteria were related to reporting of the quality of scientific evidence, and reporting of the stages in reviewing the literature. We reported a list of references, but not the steps in searching this, because we did not think this would be relevant for patients.

In the knowledge test, the increase in knowledge after viewing the website was 18% for less-educated, and 34% for more-highly-educated women. More-highly-educated and less-educated women both reported low knowledge scores at baseline (3-4 out of 10 correct answers). This may be explained by the fact that participants were healthy volunteers. Differences in knowledge scores between less-educated and more-highly-educated women after viewing the website, may be explained by differences in study design (eg. follow-up time). The absolute increase in knowledge scores of more-highly-educated healthy women was comparable to knowledge increase in other patient populations after viewing several kinds of DAs [17;34]. However, relative knowledge increase from baseline to follow-up in populations with patients or persons who are close to patients (relatives, carers) is often smaller than the 18% and 33% we found, ranging from 6%-9% in studies after decisions other than FP [17;34-37], possibly due to higher baseline knowledge in those studies. This might be explained by the fact that patients (or persons who are close to patients) often already know more about their disease or treatment options than healthy volunteers do. A study of Peate et al. (2012) which measured baseline knowledge in patients about FP and knowledge after viewing a DA booklet, found a significant increase (with a large effect size of Cohen's *d*=0.83) from baseline to follow-up, comparable to ours [19]. This might be a result of the relative paucity of available information about FP (thus resulting in lower baseline knowledge) compared to availability of information about other more common medical decisions for which DAs have been developed. Additionally, although some studies used knowledge measures that had been used in multiple studies [19;36], due to the specificity of studied decisions, most knowledge scales, including ours, had been developed by the authors, and were not validated [34;35;37]. Therefore, caution should be taken in interpreting scores of these knowledge scales.

Differences in DA-use between less-educated and more-highly-educated women (time taken to read materials, number and type of pages visited) may be explained by differences in study design as well. For the less-educated women the whole study consisted of a baseline knowledge test, one week time to view the DA, and a follow-up knowledge test after one week. For the more-highly-educated women the knowledge test was part of a one-hour experiment in which a larger set of measurements both before and after viewing the DA were measured [paper in preparation]. It is likely that the latter group spent less time on the DA because they wanted to make sure that they were ready in time. Both samples were not actually facing the decision of whether or not to preserve fertility, so the information should have been just as relevant for both samples.

Patients in acceptability study I (stage II) thought that the information on the website was relevant, necessary and comprehensible, but the VCE was less clear. The IPDAS advocate the addition of a values clarification exercise, but with our method of evaluating acceptability (interviews), we indicated that a VCE can also confuse patients. Previous studies have found varying effects of different kinds of VCEs [10;17;19-21], it is therefore currently not known which type of VCE is most effective in facilitating decision making (processes), if at all. Part of the confusion with our VCE may be because we have combined two types of VCEs; women both have to indicate whether a statement is an advantage or disadvantage for them, and rate their importance. To improve understanding of the VCE we have added instructions on how to use it above each VCE and adapted some statements after stage II. Other aspects of the original VCE were maintained. Caution should be adopted with conclusions about the VCE. Even though patients in the different developmental stages of this DA thought the VCE was relevant, this does not have to indicate that patients will use it, nor that the VCE has a beneficial effect. A study by Peate et al (2013) also found that women indicated that the VCE in the DA about FP was useful, but in practice, in a subsequent trial, the majority (77%) did not use it [19;38]. In our samples, the VCE was used by five of the eight less-educated women who logged into the website (63%), and by 33 of the 70 more-highly-educated women who were randomized to the information + VCE group and logged into the website (47%) [19]. Further research is necessary to investigate the additional value of a VCE in actual decision making about FP.

The design and colors of the website were not always highly-valued. We have used basic colors (green, blue, red) because they were considered to be appropriate regarding the topic of the website. The aim of the website is to be a reliable source for information about FP, and to offer assistance in decision making. The layout should not draw attention away from the content. However, in development of future DAs, more attention could be paid to design and color issues, because this topic seems to be relevant to patients.

The results of the current studies have to be interpreted with caution in view of the small sample sizes per stage (total n=160; stage II n=10; stage III n=8/n=115; stage IV n=27). Although these sample sizes should be sufficient for research related to developing and reviewing DAs [21], the knowledge test with less-educated women (stage III) would have benefitted from more participants. We chose only 8 participants, since we first thought of the study as an extension of the acceptability test with patients (stage II, *n*=10). Later on we decided to test knowledge in a large, more-highly-educated sample as well. Furthermore, patients that participated in this stage were not currently facing the decision to undergo FP. We thought they would be better able to evaluate newly-developed materials than recently diagnosed patients, because they could compare the situation with their own experiences with information provision about FP.

Since medicine continuously strives to improve options to preserve fertility, and information provision for patients is not always sufficient, this DA may be very important for young breast cancer patients in the Netherlands. It is important that before the DA will be widely available, its efficacy in decision making processes and outcomes is studied in a patient population. When the effectiveness of the DA in newly-diagnosed patients has been confirmed, the website should become nationally available in order to prepare patients for counseling about FP with a gynecologist or fertility specialist.

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