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Development and evaluation of a decision aid for women eligible for organized breast cancer screening according to international standards: A multi-method study

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ABSTRACT

Background: and purpose:
In France, women lack information to make a shared decision to start breast cancer screening. Decision aids are useful to facilitate this discussion, yet few meet international standards. The objective of this project was to build, validate and measure the quality of a decision aid for organized breast screening in France, in line with international standards, intended for both women and healthcare professionals.
Materials and methods: This mixed-methods study was conducted between January 2017 and June 2022. The prototype was developed from a qualitative study, systematic review and targeted literature review and alpha tested during two Delphi rounds. Readability was evaluated with the Flesch score and content with International Patient Decision Aid Standards Instrument (IPSASi).
Results: An online decision aid, accessible at www.Discutons-mammo.fr, written in French was developed. The content included eligibility, information about breast screening the advantages and disadvantages of screening, patient preferences and a patient-based discussion guide using text, infographics, and videos. The Flesch readability test score was 65.4 and the IPDASi construct quality score was 176 out of 188.
Conclusions: This decision aid complies with IPDASi standards and could help women eligible for breast screening in France make a shared decision with a specialized healthcare professional about whether or not to participate in organized breast screening.

1. Introduction

The World Health Organization recommends women with a moderate risk of developing breast cancer have a bilateral mammogram every 2 years [1]. To improve participation in breast screening, as in other countries [2], the French authorities implemented a national breast screening program in 2004 [3].

Nevertheless, participation in breast screening remains a personal

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health choice for each individual woman. In 2016, the National Cancer Institute (INCa), found that women were insufficiently informed about breast screening during a scientific and citizen consultation [4]. Since then, the French Nation health authorities recommend women be appropriately informed to ensure that they are able to make an informed decision as to whether or not to participate in breast screening [4,5].

Similarly, the international medical community has improved the amount and type of information made available to improve patient involvement in the shared decision-making process to undertake health screenings in general [6–8]. While the shared decision-making culture has been the subject of numerous studies in Anglo-Saxon teams [7,9,10], it remains unevenly integrated into clinical practice in France. So, to develop and promote ownership for shared decision-making in France both healthcare professionals and women need to be involved.

Decision aids (DA) can help individuals gain knowledge about breast screening to enable them to make informed decisions consistent with their personal preferences [11]. Although some tools exist to support making breast screening decisions such as the Canadian Task Force [12] as well as the Patient Decision Aid Research Group at the Ottawa Hospital Research Institute [13], few meet international quality standards. However, patient behavior is dependent on the DA quality [14]. Indeed, DA quality standards recommend the content be developed from recent, validated data represented clearly and simply with illustrations, using appropriate patient communication methods [6,15]. Today, no DA in French meets these standards. Therefore, there is a need to provide the French public (healthcare professionals and patients) with adapted DAs about breast screening [13,16].

The objective of this project was to build, validate, and measure the quality of a DA for organized breast screening in France, in line with international standards, intended for both women and healthcare professionals.

2. Materials and methods

This mixed-methods study was conducted in a French primary care research center between January 2017 and June 2022 to develop and evaluate a DA according to the International Patient Decision Aids Standard (IDPAS) approach [17]. A steering group was essential to support the DA development. It consisted of seven general practitioners (GPs) associated with the university who also practice in different cities in France, two breast cancer expert patients involved in associations and medical student training, and two clinical research associates. Also, potential end-users of the DA have been formally involved throughout project, from the creation of the DA to its evaluation. This article describes two stages: (i) Scoping and DA prototype design (ii) alpha testing of the prototype DA (Fig. 1).

Legend: Fig. 1 illustrates the three development stages of this DA. During Stage 1 a prototype was developed from a qualitative study [18], systematic review [16] and targeted review. In Stage 2 the prototype was Alpha tested to obtain a first version, which will be Beta tested in Stage 3. DA: Decision Aid. INCa: National Cancer Institute.

2.1. Scoping and DA prototype design

Scoping for the DA was performed between 2017 and 2019 and included determining the definition and purpose of the DA and its target audience, and performing a qualitative study [18], a systematic review of existing DAs [16], and a targeted literature review. Content for the DA prototype was developed from these studies between January 2019 and April 2020.

The steering group defined the objective and target population according to current recommendations for DA development [1,4] and the National Cancer Institute (NCI) call for projects in January 2017 [5].

The qualitative study conducted between April 2018 and May 2019 among 13 women and 27 healthcare professionals involved in screening (GPs, midwifes, gynacologists, radiologists, screening center managers). It found users expected on-line access, patient appropriate content, ease of use (interactive, intuitive), and graphics [18].

The systematic review of 22 articles conducted between January 2017 and September 2019 evaluated the quality of 23 existing international DAs for eligible women using the International Patient Decision Aid Standards instrument, version 3 (IPDASi) [19]. This review identified the need to include a clearly defined target audience and provide useful information to prepare and use during a consultation with a healthcare professional for both patients and healthcare professionals. Furthermore, a non-biased DA should also provide balanced information about the advantages and disadvantages of screening compared with not screening in terms of scientific evidence and outcome probabilities, whilst also considering patient values and priorities. Lastly, making a DA available online with a printable option, promote progressive thinking, be readable through graphics or videos would be desirable.

The targeted literature review, performed between January 2017

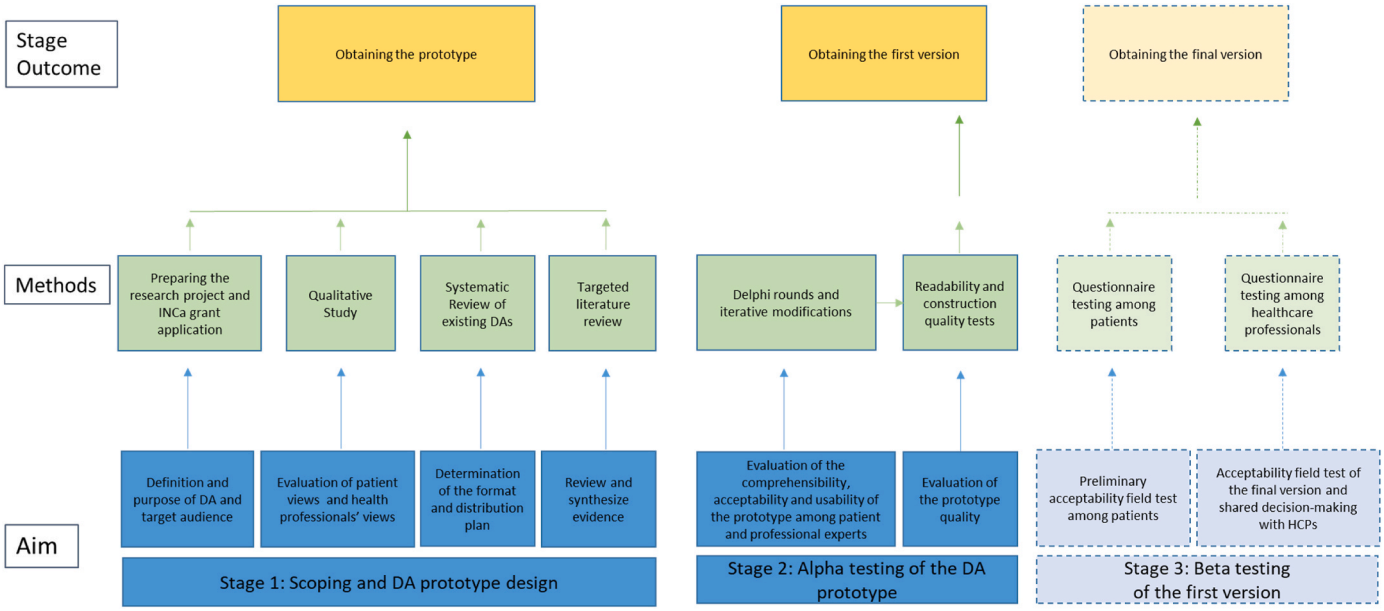

Fig. 1. Development stages for the breast cancer screening decision aid.

and September 2019 identified appropriate sources from which to build the DA content. The review was performed using PubMed, Embase, Cochrane, PsycINFO, the French health agency and national research institute websites [3,20], and international organizations (Agency for Healthcare Research Quality, Ottawa Hospital Research Institute, Canadian Task Force on Preventive Health Care, University de Laval). This review identified ten additional articles, recommendations, documents or websites, which were consulted [19,21–29]. Numerical data from articles were selected if they were: (i) from meta-analyses, (ii) published in the last ten years, (iii) centered on the population of interest (women aged 50 to 74), ideally with provision of data by age groups and covering a period of more than 10 years.

The steering group created the prototype, defined the presentation and chapters, and wrote the content in plain language between January 2019 and April 2020. A graphic designer and a web developer designed illustrations and graphics, and produced the DA website.

2.2. Alpha-testing of the DA prototype

The objective of alpha testing was to explore the comprehensibility, acceptability, and usability of the DA prototype, then the readability and construct quality of the modified prototype was verified. Lastly, any necessary adaptions will be made to obtain a first version. This version will then be evaluated in the final beta-testing evaluation stage (field-testing among patients and healthcare professionals).

The DA prototype was adapted following an iterative process after two modified Delphi survey rounds from 5–November 26, 2020 and 25 march - April 9, 2021 [30–33]. A panel of experts were required to arrive at a consensus before the prototype could be refined. The expert panel consisted of twenty experts from heterogeneous backgrounds, including five non-healthcare professionals and fifteen healthcare professionals from diverse specialties and with experience in breast cancer care. Each expert received an email with a link to a web-based survey to evaluate the prototype. Experts rated their opinion about the graphics, the content (formulation, scientific precision), navigation, readability and understandability, and quantity of information in the DA using a 9-point Likert scale ranging from 1 (strongly disagree) to 9 (strongly agree). Only those experts who participated in the first round could participate in subsequent rounds. Those items with an overall median less than or equal to 3 were invalid. Items scoring >3 and < 7 were equivocal and items with an overall median greater than or equal to 7 (and no disagreement) were scored as valid. Disagreement was defined as the distribution of 30 % of the ratings in both the bottom tercile (1–3) and the top tercile (6–9) [34]. Only invalid or equivocal items at the end of the first Delphi round were resubmitted in the second round. Table 1 lists all items validated during the Delphi process. In the first Delphi round, 27 items were included and 5 in the second round. 1 item was added to the second round. There were 2 items concerning general comments (without a score) in round 1 and 1 in round 2. The number of items that received a score was 25 in round 1 and 4 in round 2 (Table 1). The Delphi process was completed once all items had been validated. Lastly the DA prototype was tested for readability using the Flesch Reading Ease Score [35] and quality according to the IPDASi version 3. The first version will be finalized after the alpha testing process.

3. Results

3.1. Scoping and DA prototype design

The steering group chose to target women aged between 50 and 74, who were eligible for organized breast screening. The group agreed that the DA should provide these women with information about the issues, risks, benefits, and uncertainties of screening, so that they could make an informed choice about whether or not to participate.

Results from the qualitative study, systematic review, and targeted review resulted in a DA prototype, accessible online at www.discutons-mammo.fr (currently unavailable due to an ongoing study) and entitled “Deciding together whether or not to participate in organized breast cancer screening”. Women were free to navigate the site without a code or password. Specific tabs guide women to the home page where the purpose of the DA is explained and the five informative sections [1]; “Does this apply to me?” outlined the eligibility criteria for screening, as well as specific cases, such as having breast symptoms or previous breast cancer [2], “Screening information” defined breast cancer and explained how mammography is performed, possible results and breast cancer treatment [3], “Screening: advantages and disadvantages” described scientific data comparing outcomes associated with and without participating in organized screening [4], “My preferences, my concerns”, outlined 14 barriers and motivations to organized screening, which guides the women to reflect on her preferences and concerns. In the section [5] “Preparing for my discussion with my healthcare professional” the reader can print an information summary sheet to use during a healthcare professional consultation. Lastly, a Frequently Asked Questions section included ten questions about other topics not covered elsewhere on the site.

The source documents selected were pathophysiology, medical examination process/procedure and treatments, which were developed by INCa [22,23]. The description of the advantages and disadvantages of breast cancer screening were taken from the Canadian Task Force recommendations [12]. The figures were taken from the Cochrane review of the Canadian Task Force and included data from the most recent trials up to January 1, 2017, by age group [25]. The value and decision-readiness grids were taken from the Ottawa Hospital Research Institute work [26,27]. The formatting of the numerical data and preferences for women was inspired by those proposed in Agency for Healthcare Research and Quality [28], the University of Laval [36], or DA documents [37,38].

3.2. Alpha testing results from the first delphi round

Overall, among the 25 items with a score, 22 were validated with a median $\geq$7.0 and with no disagreement. Three were equivocal. One of these items targeted the contents of the “treatment” sub-part (part 2; med = 6.5). The other 2 items concerned part 3 “screening: advantages and disadvantages” (med = 6.0) (Table 1). The expert recommendations included the small font size, the difficulty understanding scientific vocabulary, and the anxiety-inducing and detailed description of information relating to breast cancer treatments (“screening information” section). Some experts suggested that certain information such as false positives and overdiagnosis should be limited, so that the DA would encourage the reader to participate in screening.

Subsequently, at the end of the first round, the font size was enlarged, and the editorial content was simplified. In part 2, treatment information was streamlined to direct women to obtain support from health professionals if breast cancer was detected. Part 3 was divided into three sub-sections entitled “numbers”, “participating”, “not participating”. Illustrations represented the outcome probabilities with or without breast screening during a 7-year follow-up period per age group (50–59; 60-60; 70–74 years). The content was checked to ensure that the information provided was in line with the DA objective and remained unbiased in regards to participating or not-participating in organized screening.

3.3. Alpha testing results of the second delphi round

The second Delphi round involved 16 participants out of the 20 invited. The four items with a score were validated with a median $\geq$7.0, without disagreement and results are presented in Table 1. During this round, the experts suggested simplifying the text and highlighting important vocabulary. They also suggested providing detailed directions to navigate the website, and videos to accompany the text. All comments and suggestions were considered. To facilitate the accessibility of complex information, the steering group and a service provider developed four

Table 1
Results of the Delphi evaluation for the DA prototype.

Item	DA section	Item question – ronde 1	Item question – ronde 2	n validation rounds	Results round 1				Results round 2			
					med	% [1–3]	% [7–9]	n comments	med	% [1–3]	% [7–9]	n comments
1	Home page (screen print 1)	What do you think of the layout and graphics of the home page (screenshot below)? Please suggest changes to the layout and graphics of the home page.	NA	1	8.0	0.0	83.3	3	NA			
2	Home page (screen print 1)	What do you think about the content of the home page? Please suggest changes to the content of the home page.	NA	1	8.0	0.0	88.9	2	NA			
3	Home page (screen print 2)	What do you think of the layout and graphics of the home page? Please suggest changes to the layout and graphics of the home page.	NA	1	7.0	0.0	55.6	14	NA			
4	Home page (screen print 2)	What do you think about the content of the home page? Please suggest changes to the content of the home page.	NA	1	8.0	5.6	66.7	14	NA			
5	Section 1 "Does this apply to me?"	What do you think of the layout and design of the "Does this apply to me?" chapter? Please suggest changes to the layout and graphics of the "Does this apply to me?"	NA	1	7.5	0.0	77.8	10	NA			
6	Section 1 "Does this apply to me?"	What do you think about the content of the "Does this apply to me?" chapter? Please suggest changes to the content of the "Does this apply to me?"	NA	1	7.0	16.7	55.6	11	NA			
7	Section 2 "Information about screening"	What do you think of the layout and design of the "Screening information" section? Please suggest changes to the layout and design of the "Screening information" section.	NA	1	8.0	11.1	72.2	11	NA			
8	Section 2 "Information about screening"	What do you think of the content of the "Breast cancer" page? Please suggest changes to the content of the "Breast cancer" page.	NA	1	8.0	5.6	72.2	10	NA			
9	Section 2 "Information about screening"	What do you think of the content of the "screening" page? Please suggest changes to the content of the "screening" page.	NA	1	7.0	11.1	50.0	13	NA			
10	Section 2 "Information about screening"	What do you think of the content of the "mammography" page? Please suggest changes to the content of the "mammography" page.	NA	1	7.5	11.1	61.1	10	NA			
11	Section 2 "Information about screening"	What do you think of the content of the "results" page? Please suggest changes to the content of the "results" page	NA	1	7.5	5.6	77.8	8	NA			
12	Section 2 "Information on screening"	What do you think of the content of the "treatment" page? Please suggest changes to the content of the "treatment" page.	What do you think of the new content of the "treatment" page? Comments	2	6.5	5.6	50.0	13	7.5	0.0	50.0	11

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Table 1 (*continued*)

Item	DA section	Item question – ronde 1	Item question – ronde 2	n validation rounds	Results round 1				Results round 2			
					med	% [1–3]	% [7–9]	n comments	med	% [1–3]	% [7–9]	n comments
13	Section 3 “Screening: advantages and disadvantages”	What do you think of the layout and design of the "advantages/disadvantages" section? Please suggest changes to the layout and design of the "advantages/disadvantages" section.	NA	1	8.0	11.1	72.2	16	NA			
14	Section 3 “Screening: advantages and disadvantages”	What do you think of the content of the "for me" section? Please suggest changes to the content of the "for me" section ("advantages/ disadvantages" chapter)?	What’s your opinion on the new content of the "numbers" page ("advantages/disadvantages" section)? This section used to be called "for me". Comments	2	6.0	11.1	33.3	15	8.0	6.2	43.7	10
15	Section 3 “Screening: advantages and disadvantages”	What do you think of the content of the "for all" section? Please suggest changes to the content of the "for all" section.	What is your opinion on the new content of the two pages entitled " ± participate in organized screening" and " ± do not participate in organized screening" ("advantages/ disadvantages" section)? This section used to be called "for all", and has now been divided into two parts. Comments	2	6.0	11.1	44.4	14	7.0	0.0	37.5	11
16	Section 4 “My preferences, my concerns”	What do you think of the layout and design of the “preferences/concerns” chapter? Please suggest changes to the layout and design of the "preferences/concerns" chapter.	NA	1	8.5	5.6	77.8	13	NA			
17	Section 4 “My preferences, my concerns”	What do you think of the content of the "preferences/ concerns" chapter? Please suggest changes to the content of the "preferences/ concerns" chapter	NA	1	8.0	0.0	72.2	11	NA			
18	Section 5 "Preparing for my exchange with my healthcare professional".	What do you think of the layout and design of the "Preparing for my exchange" chapter? Please suggest changes to the layout and design of the "Preparing for my exchange" chapter.	NA	1	8.5	5.6	77.8	13	NA			
19	Section 5 "Preparing for my exchange with my healthcare professional".	What do you think of the content of the "Preparing for my exchange" chapter? What do you think of the content of the "preparing my exchange" chapter?	NA	1	8.0	16.7	61.1	14	NA			
20	Section 5 "Preparing for my discussion with my healthcare professional".	What do you think of the summary document? You can download it in the section "prepare my exchange". Please suggest changes to the summary document	NA	1	7.5	16.7	66.7	12	NA			
21	Frequently asked questions	What do you think of the layout and design of the frequently asked questions? Please suggest changes to the layout and design of the frequently asked questions.	NA	1	8.0	5.6	77.8	10	NA			
22	Frequently asked questions	What do you think of the content of the frequently asked questions?	NA	1	7.0	16.7	61.1	18	NA			
23	Frequently asked questions	Please suggest changes to the content of the FAQ section. Do you have any other questions?	NA	1	NA	NA	NA	12	NA			

(*continued on next page*)

Table 1 (*continued*)

Item	DA section	Item question – ronde 1	Item question – ronde 2	n validation rounds	Results round 1				Results round 2			
					med	% [1–3]	% [7–9]	n comments	med	% [1–3]	% [7–9]	n comments
24	"About us" tab	What do you think of the "about us" section (presentation and content)? Please suggest changes to the content of the "about us" section. "	NA	1	8.0	0.0	72.2	13	NA			
25	Entire website	What do you think of our site navigation? Please suggest modifications to the site navigation	NA	1	8.0	0.0	83.3	9	NA			
26	Entire website	What's your opinion on the ease of reading and understanding the site? Please suggest changes to make the site easier to read and understand.	NA	1	8.0	5.6	77.8	10	NA			
27	Entire website	Do you have any other comments about this site?	Do you have any other comments about this site?	2	NA	NA	NA	18	NA	NA	NA	11
28*	Entire website		What is your general opinion of the site following the modifications made? Comments	1*	NA	NA	NA	NA	7.5	6.2	43.7	11

Legend.
DA: Decision AID.
Med: median.
% [7–9]: percentage of individual responses between 7 and 9.
% [1–3]: percentage of individual responses between 1 et 3.
NA: not applicable * item added to round 2.

short motion designs. One explained how to use the DA, the second described numerical data with icons for each age group, the third illustrated the advantages and disadvantages of participating in breast screening, and the fourth clarified the advantages and disadvantages of not participating in breast screening. A consensus on the motion design scripts and on the final renderings was obtained within the steering group.

3.4. Quality of the modified prototype

The readability of the prototype, measured with the Flesch readability test showed a Reading Ease score of 65.4, which corresponds to a middle school level (fourth grade) [47].

The construct quality test showed an IPDASi score of 176/188 and 43 of the 47 IPDASi grid items were respected. The four items not achieved in the prototype were a patient field test (development dimension), (ii) the health professional field test (development dimension), (iii) the improved patient knowledge about the options for participating or not participating in screening (DST evaluation dimension), and (iv) improvement of the adequacy between the most important characteristics for informed patients and the chosen option (DST evaluation dimension). Table 2 presents the IPDASi scores of the DA prototype for each of the 10 dimensions.

The first version of the DA was obtained at the end of stage 1 (Appendix A).

4. Discussion

As expected from our research project, this study resulted in a decision aid specifically designed to promote discussions and shared decision-making about organized breast cancer screening between a health professional and a woman, in line with stakeholder expectations [18] The tested version consisted of five sections with text, infographics and videos that highlight the health question, explain the options available, the advantages and disadvantages of each option, and incorporated patient values. The text was written in French and included infographics and videos and will be available online at www.Discutons-mammo.fr.

The DA prototype scored the highest construct quality score among all international DAs targeting breast cancer (IPDASi score of 176 out of 188) according to a recent literature review, which reported that the three best ranked DAs according to this grid were Hersch (172 out of 188) [39], Schonberg (168 out of 188) [40] and Elkin (166 out of 188) [38] and the mean IPDASi score of the 23 ADs studied was 132.6 ± 23.8 [16]. To the best of our knowledge, no other international DA has incorporated video material and verified readability with a recognized readability score. Also, this score is close to that achieved by other DAs recognized in the research field [41].

During the DA development process, the Delphi process identified the unbiased objective and readability as two major challenges to address. Concerning the unbiased objective of the DA, some experts suggested amending the content to encourage patients to choose the breast cancer screening option. This difference of opinion between healthcare professionals was also highlighted in a review by Toledo et al. about implementing shared decision-making for breast cancer screening [42]. However, the DA in our study was specifically designed to provide unbiased, objective information in neutral language that would not influence the reader's decision whether or not to undertake breast screening. This design choice has also been supported in the literature. Feldman et al., reported a study in which, only half of the DAs studied explicitly mentioned that not being tested is a valid option [43]. In this respect, given that so few DAs were designed to provide a balanced representation of the advantages and disadvantages of screening [44], the IPDASi grid authors updated the definition of the "Information" dimension in 2021 and listed indicators of balanced information to guide researchers in providing objective and unbiased information [45].

Concerning readability, the experts highlighted the need to ensure that readers understood the risks and benefits associated with deciding whether or not to undergo breast screening. To this end, the steering group chose to present the raw figures taken from the referenced meta-analysis [25], specifying the time period and the denominator [39]. These numbers were not adapted to French demographics or organization to avoid creating estimation errors [44]. Additionally, as some people find statistics difficult to understand [6], several supports were

Table 2
Results of the IPDASi scores for the DA prototype.

Dimension	Item	Score
Information Providing information about options in sufficient detail for making a specific decision	1. The decision support technology describes the health condition or problem (intervention, procedure, or investigation) for which the index decision is required	4
	2. The decision support technology describes the decision that needs to be considered (the index decision)	4
	3. The decision support technology describes the options available for the index decision	4
	4. The decision support technology describes the natural course of the health condition or problem if no action is taken.	4
	5. The decision support technology describes the positive features (benefits or advantages) of each option	4
	6. The decision aid describes negative features (harms, side effects or disadvantages) of each option.	4
	7. The decision support technology makes it possible to compare the positive and negative features of the available options.	4
	8. The decision support technology shows the negative and positive features of options with equal detail (for example using similar fonts, order, and display of statistical information).	4
	Sub- Total	32/32
Probabilities Presenting outcome probabilities	1. The decision support technology provides information about outcome probabilities associated with the options (i.e. the likely consequences of decisions)	4
	2. The decision support technology specifies the defined group (reference class) of patients for which the outcome probabilities apply.	4
	3. The decision support technology specifies the event rates for the outcome probabilities (in natural frequencies).	4
	4. The decision support technology specifies the time period over which the outcome probabilities apply.	4
	5. The decision support technology allows the user to compare outcome probabilities across options using the same denominator and time period.	4
	6. The decision support technology provides information about the levels of uncertainty around event or outcome probabilities (e.g. by giving a range or by using phrases such as “our best estimate is …”)	4
	7. The decision support technology provides more than one way of viewing the probabilities (e.g. words, numbers, and diagrams).	4
	8. The decision support technology provides balanced information about event or outcome probabilities to limit framing biases.	4
	Sub- Total	32/32
Values Clarifying and expressing values	1. The decision support technology describes the features of options to help patients imagine what it is like to experience the physical effects.	4
	2. The decision support technology describes the features of options to help patients imagine what it is like to experience the psychological effects.	4
	3. The decision support technology describes the features of options to help patients imagine what it is like to experience the social effects.	4
	4. The decision support technology asks patients to think about which positive and negative features of the options matter most to them.	4
	Sub- Total	16/16
Decision Guidance	1. The decision support technology provides a step-by-step way to make a decision.	4
Structured guidance in deliberation and communication	2. The decision support technology includes tools like worksheets or lists of questions to use when discussing options with a practitioner.	4
	Sub- Total	8/8
Development Using a systematic development process	1. The development process included finding out what clients or patients need to prepare them to discuss a specific decision	4
	2. The development process included finding out what health professionals need to prepare them to discuss a specific decision with patients	4
	3. The development process included expert review by clients/patients not involved in producing the decision support technology	4
	4. The development process included expert review by health professionals not involved in producing the decision aid.	4
	5. The decision support technology was field tested with patients who were facing the decision.	1
	6. The decision support technology was field tested with practitioners who counsel patients who face the decision.	1
	Sub- Total	18/24
Evidence Using evidence	1. The decision support technology (or associated documentation) provides citations to the studies selected.	4
	2. The decision support technology (or associated documentation) describes how research evidence was selected or synthesized.	4
	3. The decision support technology (or associated documentation) provides a production or publication date.	4
	4. The decision support technology (or associated documentation) provides information about the proposed update policy.	4
	5. The decision support technology (or associated documentation) describes the quality of the research evidence used.	4
	Sub- Total	20/20
Disclosure Disclosure and transparency	1. The decision support technology (or associated technical documentation) provides information about the funding used for development.	4
	2. The decision support technology includes author/developer credentials or qualifications.	4
	Sub- Total	8/8
Plain Language Using plain language	1. The decision support technology (or associated documentation) reports readability levels (using one or more of the available scales).	4
	Sub- Total	4/4

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Table 2 (*continued*)

Dimension	Item	Score
DST Evaluation	1. There is evidence that the decision support technology improves the match between the features that matter most to the informed patient and the option that is chosen	1
	2. There is evidence that the patient decision support technology helps patients improve their knowledge about options' features	1
	Sub- Total	2/8
Test (for DSTs that are directed at investigations or screening tests)	1. The decision support technology describes what the test is designed to measure.	4
	2. The decision support technology includes information about the chances of having a true positive test result.	4
	3. The decision support technology includes information about the chances of having a true negative test result.	4
	4. The decision support technology includes information about the chances of having a false positive test result.	4
	5. The decision support technology includes information about the chances of having a false negative test result.	4
	6. If the test detects the condition or problem, the decision support technology describes the next steps typically taken.	4
	7. The decision support technology describes the next steps if the condition or problem is not detected.	4
	8. The decision support technology describes the chances that the disease is detected with and without the use of the test.	4
	9. The decision support technology has information about the consequences of detecting the condition or disease that would never have caused problems if screening had not been done (lead time bias).	4
	Sub- Total	36/36
TOTAL		176/188

made to support readers to understand the likelihood of an event occurring whether the reader chose to be screened or not to be screened ("fact box", summary table in full, video) [45].

4.1. Strengths and weaknesses

This DA was developed with a robust, multi-method construction, which complies with the IPDAS Collaboration group recommendations [17]. This methodology generates rigorous evidence that matters to patients [46]. In addition to the theoretical expectations on screening, it was important that the content corresponded to women and health professional's expectations. Like other studies [39,40], this was made possible by preliminary qualitative studies conducted by the research team [18]. The Delphi review with experts from various professions and with diverse points of view, reinforces the content and usefulness as confirmed in other similar research [38–40,47,48]. Furthermore, the steering group included both healthcare professionals and expert patients, which undoubtedly ensured the French National Health Authority requirements for an appropriate DA were well represented [20].

Nevertheless, the results may have been weakened by not integrating the videos in the prototype evaluation process.

4.2. Perspectives and generalizability

The final stage of the DA development process is underway, illustrated in Fig. 1, part 3 of the project research. This final process involves women and health professionals evaluating the acceptability of the first version of the DA, assessing how women make their choices in real-life conditions when using the DA, and evaluating the implementation of shared decision-making with the attending physician. The results will be taken into account in the final DA version [49]. This will be valuable as some studies have described DA development, however few report evaluating a DA to assist patients to decide whether or not to participate in a screening program [6,50]. Nevertheless, it is challenging to measure the performance of a screening tool that provides patient-appropriate information via participation rates in organized screening. Lastly, the continuing DEDICACES research project will evaluate the impact of DAs on the participation rate of women in organized screening for breast cancer through a randomized controlled trial [49]. An ancillary study will assess the determinants of shared decision-making, in particular the level of knowledge and decisional conflict [49].

5. Conclusion

This collegial, robust development process, in line with internationally recognized quality criteria and based on data cross-referencing, led to the development and validation of an online French-language DA "discutons-mammo.fr". This DA aims to help eligible women decide whether or not to participate in organized breast cancer screening and supports shared medical decision-making with a health professional.

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Ethical approval

Ethical approval was not required.

CRediT authorship contribution statement

Sandrine Hild: Data curation, Formal analysis, Investigation, Methodology, Project administration, drafting of the manuscript, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing. **Delphine Teigné:** Project administration, Writing - original draft, Writing - review & editing. **Damien Fairier:** Project administration, Writing - review & editing. **Yannick Ruelle:** Data curation, Formal analysis, Investigation, Methodology, Writing - review & editing. **Isabelle Aubin-Auger:** Data curation, Formal analysis, Investigation, Methodology, Writing - review & editing. **Stéphanie Sidorkiewicz:** Data curation, Formal analysis, Investigation, Methodology, Writing - review & editing. **Marie Citrini:** Data curation, Formal analysis, Investigation, Methodology, Writing - review & editing. **Xavier Gocko:** Data curation, Formal analysis, Investigation, Methodology, Writing - review & editing. **Catherine Cerisey:** Data curation, Formal analysis, Investigation, Methodology, Writing - review & editing. **Emilie Ferrat:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing - review & editing. **Cédric Rat:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Supervision, Validation, Visualization, Writing - review & editing.

Declaration of competing interest

The authors declare no conflict of interest.

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Appendix A. Supplementary data

Presentation of theDecision Aid's first version.
Home Page.

The heading explains women can decide with their healthcare professional about whether or not to participate in organized breast screening. The steps involved in shared decision-making were listed on the home page. The central illustration presents the five tabs: "Des that apply to me?", "Screening information", "Screening: advantages and disadvantages", "My preferences, my concerns" "Preparing my discussion with my healthcare professional"

Next, the woman was told that she could make a decision (to participate or not) or postpone her decision.
Section 1: Does this apply to me?

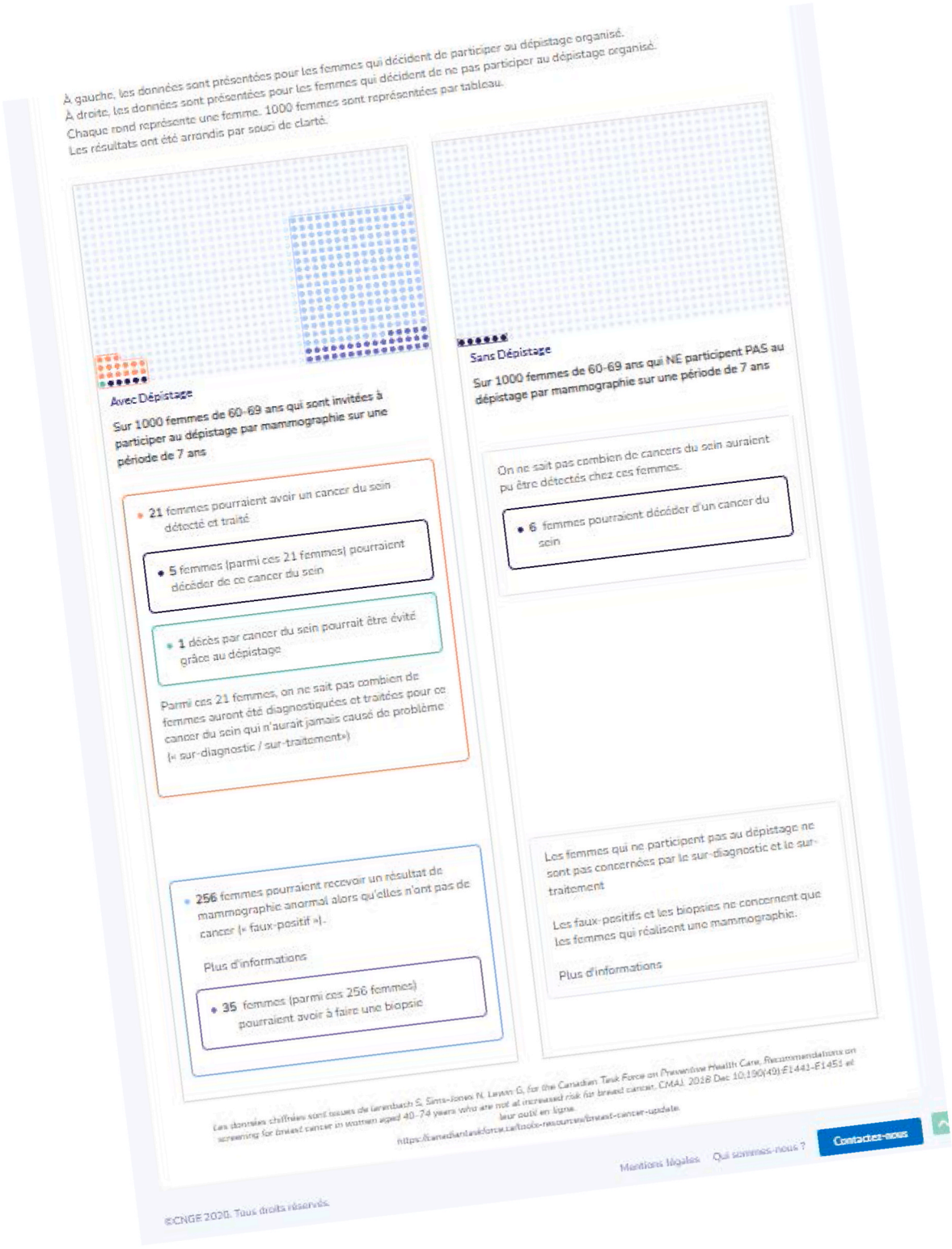
The aim was to ensure that women using the site were indeed eligible for organized screening. The "Does this apply to me?" section lists the criteria leading to an invitation to organized screening, as well as other situations that women may encounter and which could lead to a different type of screening. The information provided was general and valid, and enabled women to take ownership of the subject.

Section 2 "Information on screening"

In the “Information on screening” section, 5 sub-sections were designed. The “Breast cancer” sub-section presented the definition and natural history of “breast cancer”. The “Screening” sub-section explained the benefits of organized screening, as well as its material advantages. The mammography procedure was described and illustrated in the “Mammography” sub-section. The “Results” sub-section suggested actions to be taken depending on the mammogram result. The last sub-section, “Treatments”, dealt with treatments in a general way, the aim of the site being to provide information on screening rather than on the technical aspects of treatments.

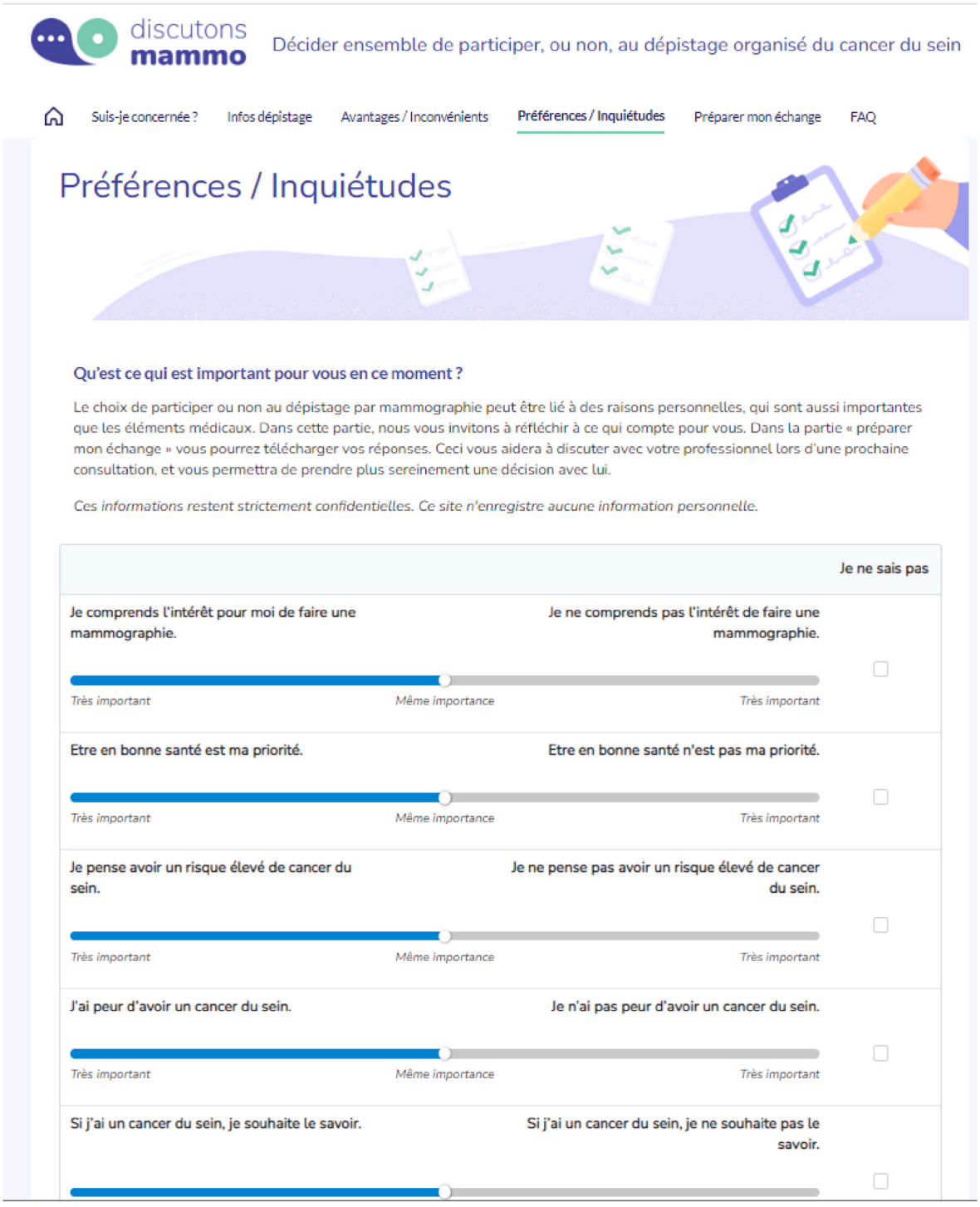
Section 3 “Screening: advantages and disadvantages”

The "Screening: advantages and disadvantages" section describes some outcomes from breast screening. This includes discovering breast cancer, false positive results, biopsies to be performed and overdiagnosis. Other non-quantifiable information such as quality of life, metastases, anxiety are covered in the text. These elements enable the measurement of medico-social and organisational effects.



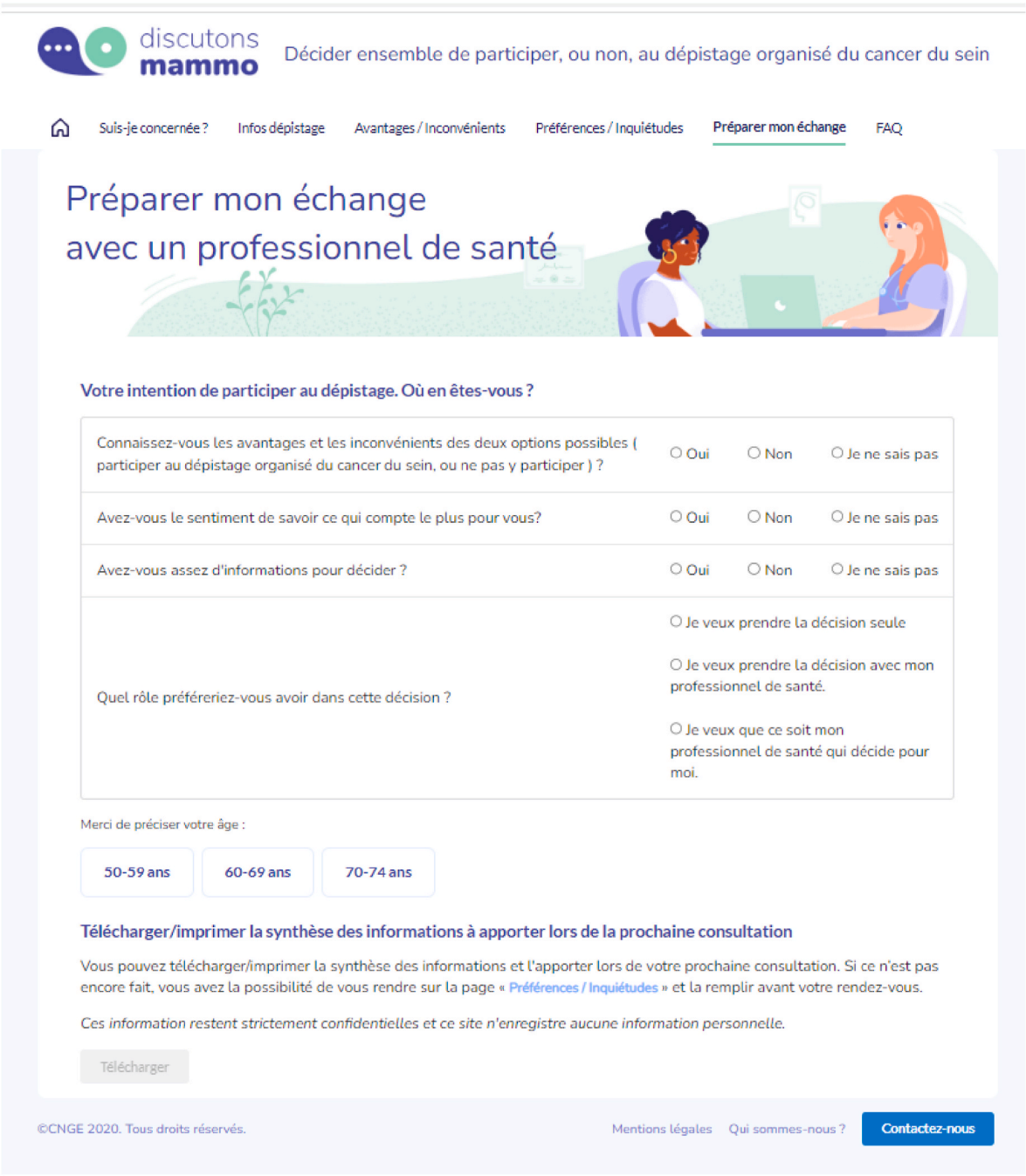
The "Screening: advantages and disadvantages" section combined scientific data with figures on participation and non-participation in organized screening.

Section 4 “My preferences, my concerns”



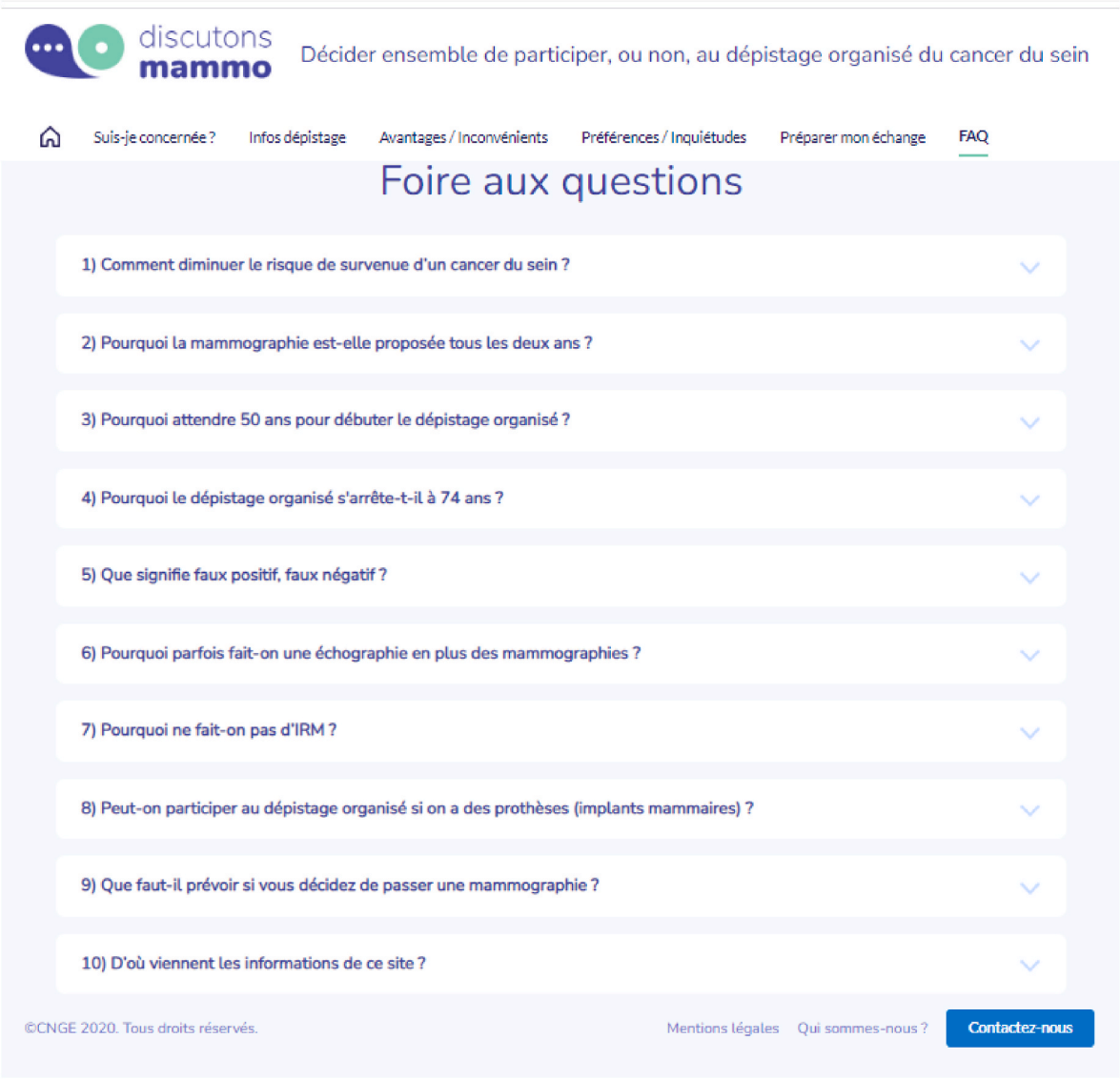
The “My preferences, my concerns” section invited women to reflect on what was important to them. Fourteen items facilitating and limiting screening were formulated based on the barriers and motivations described in qualitative studies, value grids, decision preparation and other tools. A decision scale was associated with each of the 14 items, with opposite statements at either end. The woman had the opportunity to reflect on her preferences and concerns for each item, by moving the cursor on the scale towards the statement that best corresponded to her. This technique made it possible to nuance responses and facilitate reading during the exchange with the healthcare professional. In this section, women also had the opportunity to add any information they felt would be useful during the exchange. A blank field was provided for this purpose.

Section 5 "Preparing for my discussion with my healthcare professional".



In the section entitled “Preparing for my discussion with the healthcare professional”, the woman was asked to evaluate the stage of her decision-making process, using 4 items. All the stages of shared decision-making were covered: existence of a choice, knowledge of the advantages and disadvantages of each option, preferences and concerns. The role the woman wanted to play in the decision was also addressed. Ideally, the decision should be taken after discussion with the professional. In this section, women were given the option of downloading and printing a summary of the information they could bring to the consultation. This summary included the scientific data on participation and non-participation in organized breast screening in her age category (section 3), the woman’s answers to the questions in section 4 “My preferences, my concerns”, and the role she wished to play in the decision-making process (section 5).

Frequently asked questions.



The FAQ was designed to answer some of the more complex questions not covered on the site. It consisted of 10 questions. It was intended to be updated as requests were received via the "contact us" tab.

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