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Complete List of Authors:	Amélie, Aïm-Eusébi; Universite de Paris UFR de Medecine Paris Nord, Ruelle, Yannick; Université Sorbonne Paris Nord, Département Universitaire de Médecine Générale; LEPS Frèche, Bernard; Université de Poitiers, Département de Médecine Générale Houllemare, Mélanie; Université Sorbonne Paris Nord, Département Universitaire de Médecine Générale Bonillo, Aurélie; Université de Poitiers, Département de Médecine Générale Bouaziz, Laurie; Universite de Paris UFR de Medecine Paris Nord RAT, Cédric; Faculty of Medecine, Department of General Practice; French National Institute of Health and Medical Research (INSERM U892) / National Center for Scientific Research (CNRS U6299) - Team 2, Gocko, Xavier; Université Jean-Monnet Saint-Étienne F-42023, Département de Médecine Générale; Université Jean-Monnet Saint-Étienne F-42023 Cerisey, Catherine; LEPS Aubin-Auger, Isabelle; Universite de Paris UFR de Medecine Paris Nord ferrat, emilie; Universite Paris-Est Creteil Val de Marne, CEPIA EA7376
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What do women and healthcare professionals expect of decision aids for breast cancer screening? A qualitative study in France.

Authors: Aïm-Eusébi A[a], Ruelle Y[b,c,d,e], Frèche B[f], Houllemare M[b], Bonillo A[f], Bouaziz L[a], Rat C[e,g,h], Gocko X[h,i,j], Cerisey C[c], Aubin-Auger I[a], Ferrat E[e,k,l], DEDICACES Group, the French National College of General Practitioners.

a. Université de Paris, Département de Médecine Générale, F-75006, Paris, France
b. Université Sorbonne Paris Nord, Département Universitaire de Médecine Générale, DUMG, F-93430, Villetaneuse, France
c. Université Sorbonne Paris Nord, Laboratoire Éducations et Pratiques de Santé, LEPS, UR 3412, F-93430, Villetaneuse, France
d. Centres municipaux de santé universitaires, F-93500, Pantin, France
e. Conseil Scientifique du Collège National des Généralistes Enseignants (CNGE), F-75011, Paris, France
f. Département de Médecine Générale, Faculté de Médecine et Pharmacie, Université de Poitiers, F-86000, Poitiers, France
g. Université de Nantes, Département de Médecine Générale, F-44007, Nantes, France
h. Département de Médecine Générale, Faculté de Médecine Jacques-Lisfranc, Université Jean-Monnet Saint-Étienne, F-42023, Saint-Étienne, France
i. Laboratoire SNA-EPIS EA4607, Université Jean-Monnet Saint-Étienne, F-42023, Saint-Étienne, France
j. HESPER Health Services and Performance Research EA7425, Université Claude Bernard Lyon 1, F-69100 Villeurbanne, France
k. Univ Paris Est Creteil, INSERM, IMRB, CEpiA Team, F-94010 Creteil, France

l. Université Paris-Est Créteil, Département de Médecine Générale, F-94010 Creteil, France

Corresponding Author:

Dr. Amélie Aïm-Eusébi

Université de Paris, Département de Médecine Générale, F-75018, Paris, France

186 boulevard Ney, 75018, Paris, France

amelie.aim-eusebi@u-paris.fr

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ABSTRACT

Objective: Breast cancer screening decision aids (DAs) are designed to help women decide whether or not to participate in mammography-based programs. We aimed to explore women's and healthcare professionals' expectations of a breast cancer screening DA, as part of the French DEDICACES study.

Methods: This French qualitative study was based on semi-structured, individual interviews with women from the general population, general practitioners (GPs), midwives, gynaecologists, radiologists, and screening centre managers. Sampling was purposive and used diversification criteria. The inductive analysis was based on grounded theory.

Results: Between April 2018 and May 2019, we interviewed 40 people: 13 women, 14 GPs, 4 gynaecologists, 3 midwives, 3 radiologists, and 3 screening centre managers. The women and the healthcare professionals considered that a DA could help to improve levels of knowledge, harmonise medical practice, and provide reliable, comprehensive information. Overall, the interviewees wanted an easy-to-use, intuitive, graphic-rich, interactive, computer-based, patient-centred DA. Use of the DA might be limited by a lack of familiarity with SDM, the risk of misuse, and a preference for asymmetric positive information.

Conclusion: The present results are likely to facilitate the development of the first validated tool for SDM support in French breast cancer screening programs.

KEYWORDS: breast cancer screening, decision support, shared decision-making, primary health care, qualitative research

ARTICLE SUMMARY

Strengths and limitations of this study

- Qualitative study, inspired by grounded theory, that complied with the Consolidated Criteria for Reporting Qualitative Research throughout the study.
- The interview guides explored perceptions, attitudes and expectations related to breast cancer, diagnosis, prevention, screening, and the decision aids.
- The data were provided by individual interviews in a diverse sample of both women and healthcare professionals.
- The degree of literacy of interviewed women was insufficiently assessed.
- Several experienced researchers triangulated the data.

BACKGROUND

Breast cancer is the second most common cancer worldwide and constitutes the leading cause of cancer death among women.[1] Most European countries organize mammogram-based breast cancer screening programs.[2] The European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis indicate that a significant decrease in breast cancer mortality requires a participation rate of at least 70%.[2] In France, free organized screening every two years has been available (for women between the ages of 50 and 74) since 2004. A prescription from a general practitioner (GP) or another physician is not required for screening; women can be screened by a radiologist upon presentation of an invitation sent by the local screening coordination centre. However, the participation rate in France's organized screening programme was only 50% in 2018.[3] Even though the results of large, randomized, controlled trials have highlighted a significantly lower breast cancer mortality rate among women undergoing regular mammogram screening,[4, 5] the risk-benefit balance is subject to debate.[6, 7] It has been suggested that shared decision-making (SDM) can help women to weigh up the known benefits and risks of breast cancer screening.[8-10]

By providing information on options and outcomes, decision aids (DAs) can help women to decide whether or not to participate in breast cancer screening. A recent review reported that people exposed to DAs feel more knowledgeable, better informed, and clearer about their values and they probably have a more active role in decision making and more accurate risk perceptions.[11] DAs therefore support the SDM. France currently lacks a breast cancer screening DA that women can use when consulting a visit with their health provider. The French "*Decision Partagée dans le Cadre du Dépistage du Cancer du Sein*" (DEDICACES) study aims at building an online DA for SDM in breast cancer screening

that can be used by both women and healthcare professionals preferentially during a consultation, in compliance with the International Patient Decision Aid Standards.[12]

OBJECTIVE

The objective of our study was to explore women's and healthcare professionals' expectations of a breast cancer screening DA.

METHODS

Study design

This qualitative study, inspired by grounded theory, was based on semi-structured, individual interviews of women, GPs, midwives, gynaecologists, radiologists, and local screening programme managers in three areas of France (the *Oise*, *Val d'Oise* and *Alpes de Haute-Provence* counties). We perform individual interviews because cancer is a delicate subject for some people. Interviews were conducted in French - the mother tongue of all participants. The team of investigators was composed of eight researchers, female and male, trained to lead interviews and perform qualitative analysis *(AAE, EF, BF, AB, MH, LB, IAA,* and *YR*). All semi-structured interviews were led by an investigator.

Participant sampling

The interviewed GPs were recruited from a list provided by the French national public health insurance system (CNAM). The women were recruited by snowball sampling or through their GPs (but not those interviewed for the study). Other healthcare professionals were recruited using snowball sampling. Sampling was purposive for all types of participants. Nobody refused to participate. Diversification criteria were applied in order to obtain a broad range of participants and points of view. Each interviewee gave her/his verbal and written informed consent prior to inclusion.

Data collection

Audiotaped, semi-structured interviews were held face-to-face at the healthcare professional's office or at home. One of the midwives and one of the screening programme managers underwent a phone interview.

The interview guides, developed by the investigators, were similar between the groups interviewed but each had some specificities. They explored perceptions, attitudes and expectations related to breast cancer, diagnosis, prevention, screening, and the DA. In the second part of the interview, published DAs were shown as examples. This enabled participants to state their opinions and expectations with regard to these tools and to describe the tools' strengths and limitations. Field notes were made during and after the interviews. A woman with history of breast cancer helped to build the interview guide of women's group. The interview guide evolved during the study (Supplementary Tables S1 to S4).

Data analysis

All interviews were transcribed verbatim and subjected to an inductive analysis based on grounded theory to analyse social interactions.[13] Next, the interview data were coded jointly by two pairs of investigators (MH+AB, AAE+LB) and, in order to enhance inter-coder reliability, individually by four other investigators (BF, EF, YR, and IA). We used MAXQDA® software (version 12, VERBI Software, Consult-Sozialforschung GmbH, Berlin, Germany) for the analysis. Similarities and differences in the codes from the interviews were assessed and discussed by all the investigators until a consensus was formed. Data sufficiency was achieved.

Patient Involvement

A patient was involved in the design of the study. She was a woman with history of breast cancer and helped to build the interview guide of women's group. She also participated in the evolution of the guide throughout the study. She had access to the results of the study.

RESULTS

Between April 2018 and May 2019, we interviewed 40 people: 13 women, 14 GPs, 4 gynaecologists ("G" in the verbatim below), 3 midwives (M), 3 radiologists (R) and 3 screening programme managers (Table 1). The mean duration of the interviews was 55 minutes and 27 seconds. We used the term "healthcare professionals" to describe the GPs, gynaecologists, midwives, radiologists, and screening programme managers.

Participants	All participants (N = 40)	Women (N = 13)	GPs (N = 14)	Other healthcare profesionnals* (N = 13)
Age mean (range)	53,9 (29-75)	62,9 (42-75)	49,6 (34-68)	49,1 (29-70)
Gender				
Male	11	0	6	5
Female	29	13	8	8
Practices	(N = 27)			
Group	18	-	8	10
Solo	9	-	6	3
Educational level				
Primary school	2	2	0	0
Secondary school	7	7	0	0
Higher education	31	4	14	13
Area				
Rural	8	3	5	0
Semi-rural	10	6	4	0
Urban	22	4	5	13
Previous				

mammography Yes	-	8	-	-
No	-	5	-	-
History of breast cancer Yes	-	2	-	-
No	-	11	-	-
Interview duration	55:27 (7:05-120:00)	69:22 (26:31-120:00)	69:26 (41:13-117:35)	26:33 (7:05-57:23)

Table 1: Characteristics of the study participants
* Gynaecologists, midwives, radiologists screening, programme manager

Purpose of the tool

Women saw the tool as an aid to understand breast cancer screening.

"It would be great to have information about breast cancer: things would be clearer for us." (Women 3)

Healthcare professionals expected the DA to improve their own level of knowledge about breast cancer and breast cancer screening.

"I need objective data that I can rely on when discussing screening with women." (GP6)

Healthcare professionals were interested in a tool that could help them to harmonise their practice with regard to breast cancer screening.

"It would be great to have that sort of tool. It would help to harmonise things." (M3)

The interviewees stated that the decision support tool had to encourage women to visit their doctor and discuss breast cancer screening or to go to a local screening program centre.

"An information poster might prompt women to consult their doctor." (Woman 1)

"[An information leaflet] would be useful if women have questions about mammography and breast cancer screening; they could discuss things with their GP." (GP5)

What kind of DA do people want? (Table 2)

The DA's characteristics

The women and the healthcare professionals wanted the DA to be quick to access and easy to use and understand DA.

"It has to be easy, visual, and simple […] – I'd rather have that sort of tool" (GP10)

"The information has to be concise because otherwise we'll throw it away […]. It would be better to stick to something short and well targeted, with eye-catching stuff…" (Woman 4)

The interviewees expected to have an intuitive tool with diagrams and graphics – something that was almost "fun" to read. The healthcare professionals wanted the statistical information to be of value for the women.

"It's good because there are different sorts of information - numbers but also diagrams; Visual things like that are more meaningful" (Woman 6)

The women and the healthcare professionals also wanted a tool that was designed for all women, regardless of the latter's level of literacy.

"Screening programs are intended to reduce social inequality, rather than increase it" *(Manager 3)*

"The tool's characteristics will depend on who it's targeting. It depends on each woman." (Woman 4)

The medium used for the DA

The women and healthcare professionals suggested that the DA was best presented on a computer or a smartphone or, failing, that on paper (i.e. a leaflet or poster). A video format might be of value for a DA on a computer or a smartphone.

The GPs suggested using the DA as a video or poster to disseminate the information in the medical waiting room. They also suggested that the tool could be directly integrated in their medical software.

"It has to be something visual, something integrated into software. […] It needs to be easy to access." (GP4)

Dissemination of the DA

The healthcare professionals suggested that the DA could be shared over the Internet.

"These days, having an instructive website would be more relevant than handing out leaflets." (M1)

The interviewees stated that word of mouth was also the best means of hearing about the tool. They also reported it would be interesting to use the media and social networks to present the tool.

"It's important that someone talks to me about the tool." (Woman 2)

Use of the tool

The women and the healthcare professionals agreed that the DA could be a useful lever for discussion during normal consultations or dedicated meetings.

"It might also help me to answer questions" (GP6)

"Maybe it would help. It might have an influence and prompt the patient to ask questions that she wouldn't otherwise." (Woman 7)

"If it's during a meeting, we can put the figures on the screen. But then you have to have a discussion; if the woman has questions, you can explain why the information is presented this way." (Manager 1)

For health professionals, their help in commenting and discussing the tool with women is indispensable.

"I wouldn't let them read this by themselves, because... It's scary!" (GP7).

The women were interested in receiving this type of information, along with explanations from their GP. However, they wanted to have the choice to use it or not with their doctor.

"We have an informal discussion, we can... pass on messages.... And then make a decision, saying I'm going or I'm not going. I weigh the pros and cons, that's it." (W3)

Women	Healthcare professionals
Purpose of the tool	
To understand screening	To complete their knowledge
	To harmonize screening / professional practice
To prompt women to visit their GP	To refer women to their doctor
Characteristics of the tool	
With concrete numbers	Give statistical information to women
Easy to understand	Easy to use
Adaptable to different women's profiles	Design for every women
Presence of diagrams	Digital tool
Use of the tool	
A lever for discussion if desired by the woman	A lever for discussion
Have the choice to use it or not with their doctor	The health professional is essential to use the tool

Table 2: Consensus representations

Disagreements about the tool: balanced or biased information? (Table 3)

Shared decision-making

Many of the interviewees were not familiar with the concept of SDM in medicine.

"I didn't really have time to understand everything about this idea of shared decision-making…" (*Woman* 5)

"Support for shared decision-making? What's that?" (GP5)

Some midwives and GPs were in favour of sharing comprehensive, balanced information about screening with women. Hence, DAs could be of value to these healthcare professionals in their daily practice. The healthcare professionals considered themselves to be "screening guides"; they wanted to provide women with reliable scientific data and enabling them to make an informed choice. Indeed, the healthcare professionals wanted to set out the facts and then accept the woman's decision. Furthermore, some of the women actively asked to receive comprehensive information from the healthcare professional so that they could decide for themselves whether or not to be screened.

"I explain things but will never force anyone to be screened - if they don't want to, it's their choice. […] It really is a shared decision and a mutual agreement with the patient." (M2)

"It also depends on the cultural level, we will not work in the same way with a teacher, a nurse, or a woman who lives in the depths of her countryside" (GP4)

"The doctor needs to explain [the screening] properly. I want to be able to weigh up the positive and negative aspects." (*Woman* 6)

Asymmetric information/ Paternalistic model

Some women wanted their physician to help them to understanding information about screening at every step in the process. Some women asked for selective information but

considered that it was not up to them to decide whether or not to go for screening. Other women were afraid of receiving screening results; this is why they did not want to know everything about screening and the risks of cancer in particular.

"You can't let us choose because we don't understand anything about being screened or not" (Woman 2)

Some GPs, gynaecologists and radiologists had the same view about asymmetric information provision, with a focus on the benefits of screening. They considered that giving selected, positive information to women was essential for avoiding fear of screening.

"*We have to explain things quickly and only go into detail if they ask for more information. […] I don't know whether giving lots of impartial information is part of being a physician and above all part of making a diagnosis." (R3)*

"If I tell them to get screened, they'll go without any hesitation." (G1)

Convincing women to participate in screening

Some women thought the tool had to help healthcare professionals to convince everyone to participate in the screening. Similarly, some healthcare professionals stated that convincing women to enter a screening programme was the most important objective. They wanted to reassure women so that they would want to be screened.

"Providing women with information is essential for motivating them to get screened" (GP4)

"Perhaps some women think of having a mammography without being prompted but not me - I wouldn't think of it. But if my doctor suggests it, I'll go!" (*Woman* 2)

Women	Healthcare professionals
Balanced or biased information?	

Shared decision making: Free decision to participate in screening or not after receiving appropriate information	Shared decision making: state the facts in a neutral manner and let the patient decide whether or not she wants to participate in screening
Paternalistic model: the doctor has the knowledge and must tell the women what to do	Asymmetric information: Convince the patient to participate in organized screening because of the responsibility of knowing as a health professional
Lack of interest for such a tool in view of the sufficient data already available	No need for such a tool

Table 3: Dissenting representations

DISCUSSION

Summary of the main findings

Both the women and the healthcare professionals stated that a DA could help to improve knowledge, harmonise medical practice and provide reliable, comprehensive information. They expected the DA's to catalyse discussion between the patient and the physician during a consultation. Women and healthcare professionals wanted an easy-to-use, intuitive interactive computer-based DA, with diagrams and graphics. Some of the health care professionals and some of the women wanted a DA that leads to SDM. Our study highlighted several limitations to the tool, such as a lack of familiarity with SDM, the risk of misuse (i.e. convincing women to participate in a screening programme without engaging an SDM process), and a preference for asymmetric, positive information.

Study strengths and limitations

The study had a number of strengths. Firstly, the investigators complied with the Consolidated Criteria for Reporting Qualitative Research throughout the study.[14] Secondly, the data were provided by a diverse sample of both women (including socioeconomic level) and healthcare professionals; given that the risk-benefit balance for breast cancer screening is currently unclear, SDM appears to be the most ethical approach.[10] Thirdly, the data were triangulated by several experienced researchers. Fourthly, the samples of women and healthcare professionals were particularly diverse.

However, we insufficiently assessed the degree of literacy of interviewed women. Only one woman answered "no" to the question designed to explore the level of literacy *"Do you need someone to help you understand prescriptions or medical information documents given by your doctor or pharmacist?"*. In the future, this may be important for adapting the DA for use with women of different literacy levels.

Comparison with the literature data

As mentioned above, the women interviewed in the present study here knew little or nothing about SDM. When the concept was explained, however, some women thought that it was of value. Similarly, a qualitative study of a DA for breast cancer screening in Spain found that women valued the receipt of information on the benefits and risks of screening.[15] This seems to be true for all women, even though SDM interventions tend to benefit disadvantaged women (e.g. those with a lower level of literacy) more than those with higher literacy or educational/socioeconomic status.[16] Becoming better informed might mean women are less likely to choose screening.

There is a growing body of evidence to show that DAs can improve value-congruent choices. When compared with standard care in a broad variety of decision contexts, women exposed to DAs feel more knowledgeable, better informed, and clearer about their values; as such, they probably have a more active role in decision-making and a more accurate perception of risks.[11] Breast cancer screening DAs are known to improve levels of knowledge and promote informed decisions.[17] For this reason, DAs do not necessarily increase screening participation rates.[18] For example, the large-scale Decideo study of breast cancer screening demonstrated that exposure to the DA reduced the participation rate by almost 2% because the women felt better informed.[19] The above-mentioned Spanish qualitative study found that the provision of information on overdiagnosis is controversial among healthcare professionals.[15] An Australian study about overdetection in breast cancer screening recommended a staged approach to development and piloting of decision aids to further improve understanding of overdetection and support informed decision-

making about screening.[20] The creation and deployment of a DA tool must therefore be accompanied by training for healthcare professionals on SDM.

Several studies have evaluated quality criteria for DAs and the pitfalls to be avoided when designing this type of tool. A review on risk communication developed decision box prototypes, presented them to focus groups of GPs and patients, and explored the participants' perceptions.[21] The model explored seven facets of the user experience: the DA had to be useful, usable (with effectiveness, efficiency and satisfaction), desirable, findable, accessible, credible and valuable (i.e. more frequent SDM). Accordingly, the present study exploring all of these aspects. We found that the study participants wanted an easy-to-use, intuitive, interactive, computer-based DA with diagrams and graphics. In a recent systematic review of the quality of DAs developed for women eligible for mammogram screening, the three best-rated dimensions of standard DAs were disclosure (transparency and conflicts of interest), information (the provision of sufficient detail), and outcome probabilities.[22] The women and the healthcare professionals interviewed in our study also stated that those three dimensions were important to them. We considered that a future DA must focus on all six dimensions, so that women and healthcare professionals engage with the tool.

Implications for clinical practice

The present study explored expectations of a DA for SDM in breast cancer screening before its creation, from the future users themselves. Our work is the first step in the construction of this tool and will thus make it possible to avoid the pitfalls brought to light during the interviews. It's important to take time to acculturate healthcare professionals to the use of the DA to avoid its misuse. Our results should help to create an appropriate, added-value tool for use in this field.

Conclusion

Stakeholders in organized breast cancer screening programmes (women, GPs, gynaecologists, midwives, radiologists and screening programme managers) have a broad range of expectations of a DA. The interviews showed that a DA could help to improve levels of knowledge, harmonise medical practice, and provide reliable, comprehensive information. Overall, the interviewees wanted an easy-to-use, intuitive, graphic-rich, interactive, computer-based and patient-centred DA. The idea of a DA was well received by the interviewees despite the fact the latter were unfamiliar with the concept of SDM. Along with the implementation of this type of tool, it would be useful to raise awareness of SDM among healthcare professionals and breast screening candidates. The present work was the first step in the DEDICACES study and will be followed by the creation and then validation of the first DA for SDM support in France's breast cancer screening programmes.

Data are available upon reasonable request: The deidentified transcripts of the interviews are available from the corresponding author (amelie.aim-eusebi@u-paris.fr). Their reuse is possible for a purpose similar to that of our study, otherwise a new consent from the interviewees will be necessary.

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Ethical approval: The study protocol was approved by a national ethics committee (Collège National des Généralistes Enseignants, Paris, France; reference: 07111732, CNGE. The data collection for the DEDICACES study has been registered with the French National Data Protection Commission (*Commission nationale de l'informatique et des libertés*, Paris, France; reference: 2099780).

Competing interests: None disclosed.

Authors' contributions: AAE, YR, BF, CR, XG, IAA and EF participated to the conception and the design of the study. AAE, YR, MH, AB, LB and EF analyzed the data. All authors contributed in writing the manuscript. All authors read and approved the final manuscript.

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Supplementary files

Table S1: Interview guide (women)

Hello, my name is [first name, family name]. I'm a researcher from the University of Paris 13 [or the University of Poitiers]. Thank you for finding the time for this interview. I am doing a research project about breast cancer screening and, in particular, the information about screening given to women. Our interview will be audio-recorded so that we can collect all the necessary data. Your personal information will be anonymized and then deleted at the end of the study.

1) [BREAST CANCER] **What do you know about breast cancer?**

(Prompt) What can you do to avoid breast cancer or to minimize the likelihood of developing it? To what extent do you feel concerned by breast cancer in your everyday life?

2) [BREAST CANCER SCREENING] **What do you know about breast cancer screening in France?**

(Prompt) What does screening mean for you? Do you feel concerned by breast cancer screening?
(Prompt) What do you think are the differences between organized screening programmes and individual screening?
(Prompt) What do you know about the effectiveness of screening?

3) [PARTICIPATION IN SCREENING] **Have you ever been screened for breast cancer? What did you think about that experience?**

(Prompt) How did you decide whether to get screened or not?
(Prompt) What information did you receive? Who gave you the information? How did you receive it?
(Prompt) How did you feel during the [first] screening?

4) [INFORMATION] **What information about breast cancer screening do you think you should have?**

(Prompt) What information would you have liked to have received but didn't?
(Prompt) How would you like to receive information about breast cancer screening? Who would you like to receive it from?
(Prompt) What format should this information have, in your opinion? Do you think that a healthcare professional should help you to decide?
(Prompt) You told me that you go for regular check-ups with a gynaecologist/general practitioner. Do you discuss breast cancer screening with him/her?
(Prompt) How would you raise the subject with him/her?
(Prompt) What do you expect from him/her?

5) [GENERAL IMPRESSION OF THE DECISION AIDS PRESENTED] **What do you think of these documents?** [*Show the interviewee the documents and let her look at them for 10 minutes or so*]

(Prompt) What do you think about these documents?
(Prompt) What did you get from the documents?
(Prompt) What have you understood from them? Are they easy to understand?
(Prompt) Were you already aware of this information about the advantages and risks [of screening]? If so, how did you receive the information?

6) [CONTENT AND FORMAT] **What do you think about the documents' content?**

(Prompt) And what about the format?
(Prompt) What would you change in these documents? (Prompt) What would you add to or remove from the documents? (Prompt) Which one do you prefer? Why? (Prompt) Which one is least meaningful for you? Why?

7) [SUMMARY OF THE SAMPLES SHOWN] **What do you think about these diagrams/figures /drawings?**

(Prompt) How did they enhance your knowledge about breast cancer screening? (Prompt) What do you think about the figures?
(Prompt) Do they help you to understand not only the advantages but also the risks associated with screening?
(Prompt) What other ways of presenting this information would you suggest?

8) [END PURPOSE OF THE INFORMATION] **How does this information influence your opinion about screening? Are there other things that you'd like to know before being able to make a decision?**

(Prompt) What additional information would you need?

Table S2: Interview guide for GPs

1) [BREAST CANCER SCREENING] **What do you think about breast cancer screening?**

2) [PROFESSIONAL ROLE] **What is your role in breast cancer screening?**

3) [REAL-LIFE EXAMPLE] **Can you tell me about a recent consultation during which you raised this subject with one of your [female] patients?**

(Prompt) How did the consultation go?

(Prompt) What information were you able to give to the patient?

(Prompt) What information were you unable to give to the patient?

(Prompt) In your opinion, what extra information would your patient liked to have received?

How was the decision made?

(Prompt) What was your role and what was the patient's role in the decision?

(Prompt) Did you form a consensus decision with the patient? How do you know that you did?

4) [THE TOOLS] **What do you think about using information tools and/or decision aids for shared decision-making during a consultation?**
And what about [the use of these tools and decision aids in] breast cancer screening?

(Prompt) What do you know about decision aids for shared decision-making? Have you already used any? If so, which ones? And why did you use them?
(Prompt) What do you understand by the term "decision aid"
(Prompt) What format should this type of tool have?
(Prompt) What medium should the tool use, in your opinion?

How could [a decision aid] be integrated into shared decision-making with the patient?

5) [Practical example] **What do you think about these documents?** *(Show the interviewee the documents and let him/her look at them for 10 minutes or so)*

(Prompt) What do you think about the documents' content? And about their form?
(Prompt) What did you learn from them?
(Prompt) Which do you prefer? Why?

(Prompt) Which one is least meaningful for you? Why?
(Prompt) What would you change in these documents?
(Prompt) What would you add to or remove from these documents?
(Prompt) What did you learn [from the documents] about breast cancer screening? Do they help you to better understand not only the advantages but also the risks associated with screening?
(Prompt) How could these documents be used in practice?
(Prompt) Do you think that they are useful for your practice?

Table S3: Interview guides for other healthcare professionals

Hello, my name is [first name, family name]. I'm a house officer in general medicine at the Paris 7 Faculty of Medicine. Thank you for finding the time for this interview. I am doing a research project about breast cancer screening. Our interview will be audio-recorded so that we can collect all the necessary data. Please be aware that there are no right or wrong answers and that your personal information will be anonymized and then deleted at the end of the study.

Background information on the interviewee: age, type of practice, time since qualification, etc.

INTERVIEW GUIDE – GYNAECOLOGISTS and MIDWIVES

1) [BREAST CANCER SCREENING] **How do you address breast cancer screening with your [female] patients?**

2) [REAL-LIFE EXAMPLE] **Can you tell me about a recent consultation during which you raised this subject with one of your patients?**
[*For midwives, if they do not address this subject*]: Why don't you raise the subject of breast cancer screening with your patients?

3) [FEELING] **In your opinion, what do patients feel about this screening?**

(Prompt) What type of information do they ask for?

4) [PROFESSIONAL ROLE] **What information do you give them? What type of document or medium do you use?**

5) [TOOLS] **What do you think about information tools and/or decision aids for shared decision-making with regard to breast cancer screening?**

6) [PRACTICAL EXAMPLE] **What do you think about these documents?** *(Show the interviewee the documents and let him/her look at him/her for 10 minutes or so)*

(Prompt) What type of tools would you like to have at your disposal for advising women about breast cancer screening?

INTERVIEW GUIDE – RADIOLOGISTS

1) [REAL-LIFE EXAMPLE] **What happens when a woman attends your clinic for a mammogram?**

(Prompt) What happens for individual screening and for organized screening?
(Prompt) Do you perform a clinical examination and have a pre-screening interview?
(Prompt) Does this screening create any problems for you (organisational aspects, interpretation, giving the results to the patient, etc.)?

2) [PROFESSIONAL ROLE] **What type of dialogue do you have with the patients?**

(Prompt) Is this before or after you have analyzed the mammogram?
(Prompt) Do you wait for the second analysis?

3) [FEELING] **In your opinion, how do patients feel about this screening?**

(Prompt) If patients ask for more information, what type of tools do you use or would like to use?

4) [PRACTICAL EXAMPLE] **What do you think about these documents?** *(Show the interviewee the documents and let him/her look at them for 10 minutes or so)*

INTERVIEW GUIDE – SCREENING PROGRAMME MANAGER

1) [REAL-LIFE EXAMPLE] **How do you get involved in organized breast cancer screening?**

2) [PROFESSIONAL ROLE] **What sort of information should breast cancer screening candidates be given?**

(Prompt) What do you think about the official document used throughout France?
(Prompt) Have you developed other ways of informing patients?

3) [FEELING **In your opinion, how do patients feel about this screening?**

4) [BREAST CANCER SCREENING] **What do you think about shared decision-making in breast cancer screening?**

5) [PRACTICAL EXAMPLE] **What do you think about these documents?** *(Show the interviewee the documents and let him/her look at them for 10 minutes or so)*

Table S4: Examples of information tools and decision aids

Tool 1

Qu'est-ce que le dépistage?

Dépister, c'est examiner un groupe de personnes afin de détecter une maladie ou de trouver celles à risque accru de développer une maladie.

Dans plusieurs pays, on offre aux femmes de 50 à 69 ans un examen radiographique des seins - mammographie - tous les 2 ou 3 ans. Le but de cet examen de dépistage est de trouver les femmes qui ont un cancer du sein pour leur offrir un traitement à un stade précoce.

Le dépistage par mammographie présente à la fois des bienfaits et des dommages. Le but de cette brochure est d'aider chaque femme à peser le pour et le contre à la lumière de ses propres valeurs et préférences, afin qu'elle puisse prendre une décision personnelle si elle souhaite participer.

Si rien d'anormal n'est trouvé au dépistage, cela permet à une femme de se sentir rassurée sur sa bonne santé. Pourtant, la plupart des femmes se sentent en bonne santé avant d'être invitée au dépistage. En outre, l'invitation elle-même au dépistage peut causer une insécurité. Donc, le dépistage crée autant de sécurité que d'insécurité.

Bienfaits

Réduction du risque de mourir d'un cancer du sein - Le dépistage régulier par mammographie ne peut pas prévenir le cancer du sein, mais il peut réduire peut-être le risque de mourir d'un cancer du sein. Une analyse systématique des études randomisées sur le dépistage par mammographie a révélé que:

> *Si 2000 femmes sont examinées régulièrement pendant 10 ans, une seule d'entre elles bénéficiera réellement du dépistage par le fait qu'on lui évitera la mort par cancer du sein, parce que le dépistage a détecté plus précocement le cancer.*

Depuis que ces essais ont été entrepris, le traitement du cancer du sein s'est considérablement amélioré. Les femmes d'aujourd'hui demandent aussi un avis médical beaucoup plus tôt qu'avant, si elles ont noté quelque chose d'inhabituel dans leurs seins. En outre, diagnostic et traitement ont été centralisés dans de nombreux pays et sont maintenant fournis par des équipes d'experts du cancer du sein.

En raison de ces améliorations, le dépistage est moins efficace aujourd'hui et les dernières études suggèrent que le dépistage par mammographie n'est pas plus efficace pour réduire le risque de mourir d'un cancer du sein (voir la documentation pour les faits et les chiffres ci-dessous).

Le dépistage ne réduit pas le risque global de décès, ou le risque global de décès par cancer (y compris le cancer du sein).

Dommages

Surdiagnostic et surtraitement - Certains des cancers et certaines des modifications cellulaires précoces (carcinome in situ), qui sont découvertes au cours de ce dépistage, grandissent si lentement qu'elles ne se seraient jamais développées en véritable cancer. Beaucoup de ces «pseudo-cancers" détectés grâce au dépistage auraient même disparu spontanément, s'ils avaient été laissés tranquilles, sans traitement.

Puisqu'il n'est pas possible de différencier les modifications cellulaires dangereuses et inoffensives d'un cancer, toutes sont traitées. Par conséquent, le dépistage se solde par le traitement de beaucoup de femmes pour une maladie tumorale qu'elles n'ont pas et qu'elles n'auront pas. Sur la base des essais randomisés, il apparaît que:

Si 2000 femmes sont examinées régulièrement pendant 10 ans,10 femmes en bonne santé seront considérées comme des patientes cancéreuses et seront traitées inutilement. Ces femmes perdront une partie ou la totalité de leur sein et elles recevront souvent une radiothérapie et parfois une chimiothérapie. Le traitement de ces femmes en bonne santé

augmente leur risque de mourir, par exemple d'une maladie cardiaque et d'un cancer.

Malheureusement, certaines de ces modifications cellulaires précoces (carcinome in situ) sont souvent retrouvées en plusieurs endroits du sein. Le sein entier est alors enlevé une fois sur quatre dans ces situations, alors que seule une minorité de ces modifications cellulaires s'est transformée en cancer.

Plus de chirurgie lourde et plus de traitements ultérieurs - Pour les femmes diagnostiquées lors du dépistage avec un «vrai» petit cancer, l'opération et les traitements qui s'en suivent peuvent être moins graves que si ce cancer avait été découvert plus tard. Cependant, comme le dépistage mène aussi au surdiagnostic et au surtraitement de femmes en bonne santé, plus de femmes au total auront un sein opéré dans le cadre du dépistage que si ce dépistage n'avait pas été fait. De même, plus de femmes recevront inutilement de la radiothérapie.

Fausse alerte - Si la radiographie montre quelque chose qui peut être un cancer, la femme est donc rappelée pour des examens complémentaires. Dans quelques cas, il s'avère que ce que la radiographie a vu est bénin et qu'il s'agit donc d'une fausse alerte.

Si 2000 femmes sont examinées régulièrement pendant 10 ans, environ 200 femmes en bonne santé seront victimes d'une fausse alerte. Le stress psychologique de l'attente du résultat pour savoir si elles ont vraiment un cancer peut être sévère. Beaucoup de femmes éprouveront de l'anxiété, des soucis, du découragement, des troubles du sommeil, des problèmes relationnels avec leur famille, leurs amis et leurs connaissances, et des changements dans leur libido. Cela peut durer des mois et à long terme, certaines femmes se sentiront plus vulnérables devant la maladie et consulteront plus souvent un médecin.

La douleur à l'examen - Le sein est pressé entre deux plaques pendant qu'une radiographie est faite. Cela prend peu de temps mais la moitié des femmes environ trouve l'examen douloureux.

Fausse sécurité - Le dépistage par mammographie ne peut pas détecter tous les cancers. Il est important, par conséquent, qu'une femme voit un médecin si elle trouve un nodule dans son sein, même si elle a eu une mammographie récente.

Tool 2

Devrais-je passer une mammographie de dépistage du cancer du sein?

Pour les femmes agées de 40 à 49 ans:

Parmi les femmes ne passant aucune mammographie, le risque de mourir du cancer du sein est de: **1 sur 313**

En passent régulièrement des mammographies, votre risque de mourir du cancer du sein est de: **1 sur 370**

Cela dit, en passant régulièrement des mammographies de dépistage:

... le risque d'erreur de diagnostic (fausse mammographie positive) entraînant d'autres tests de dépistages est de: **1 sur 3**

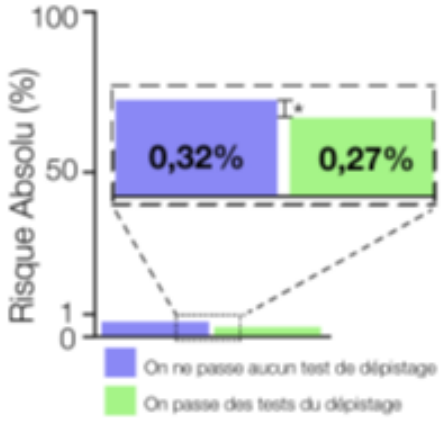
... le risque de subir une biopsie est de: **1 sur 28**

... le risque que l'on vous enlève une partie ou l'ensemble d'un sein inutilement est de: **1 sur 200**

Soyez informée!

Vous entendrez peut-être dure que les risques ou avantages du dépistage du cancer du sein sont décrits comme étant soit **absolus**, soit **relatifs**. Qu'entend-on par cela? En quoi êtes-vous concernée?

La principale différence est que le risque absolu tient compte du fait que peu importe si vous passez un test de dépistage ou recevez des traitements, vous courez tout de même un risque de base de mourir du cancer du sein de: **1 sur 313** ou **0,32%**. En passant régulièrement des tests de dépistage, ce risque passe à: **1 sur 370** ou environ **0,27%**. Le risque relatif ne tient pas compte du risque de base de la même façon et il pourrait semer la confusion quant à la façon dont la participation régulière du dépistage atténue les risques.



Le risque absolu représente simplement la différence de risque entre le fait de passer régulièrement des test de dépistage (0,27%) et le fait de ne passer aucun test de depistage (0,32%).

0,32% - 0,27% = 0,05%

Par conséquent, les femmes âgrées de 40 à 49 ans qui passant des test de dépistage réduisent leur *risque absolu* de mourir du cancer du sein de 0.05%. Ainsi, *l'avantage absolu* du dépistage est de **0,05%**

Le risque relatif tient uniquement compte de la réduction du risque à titre de proportion du risque total (donc, pas du fait que vous courez déjà un risque de cancer, ce qui peut mener à de plus grandes estimations que celles associatées au risque absolu)

0,05%/0,32% = 15%

Par conséquent, les femmes âgrées de 40 à 49 ans qui passent des tests de dépistage réduisent leur *risque relatif* de mourir du cancer du sein de **15%**. Ainsi, l'*avantage relatif* du dépistage est de **15%.**

Alors, que représentent ces probabilités en nombres réels? Parmi 100 000 femmes âgées de 40 à 49 ans qui:

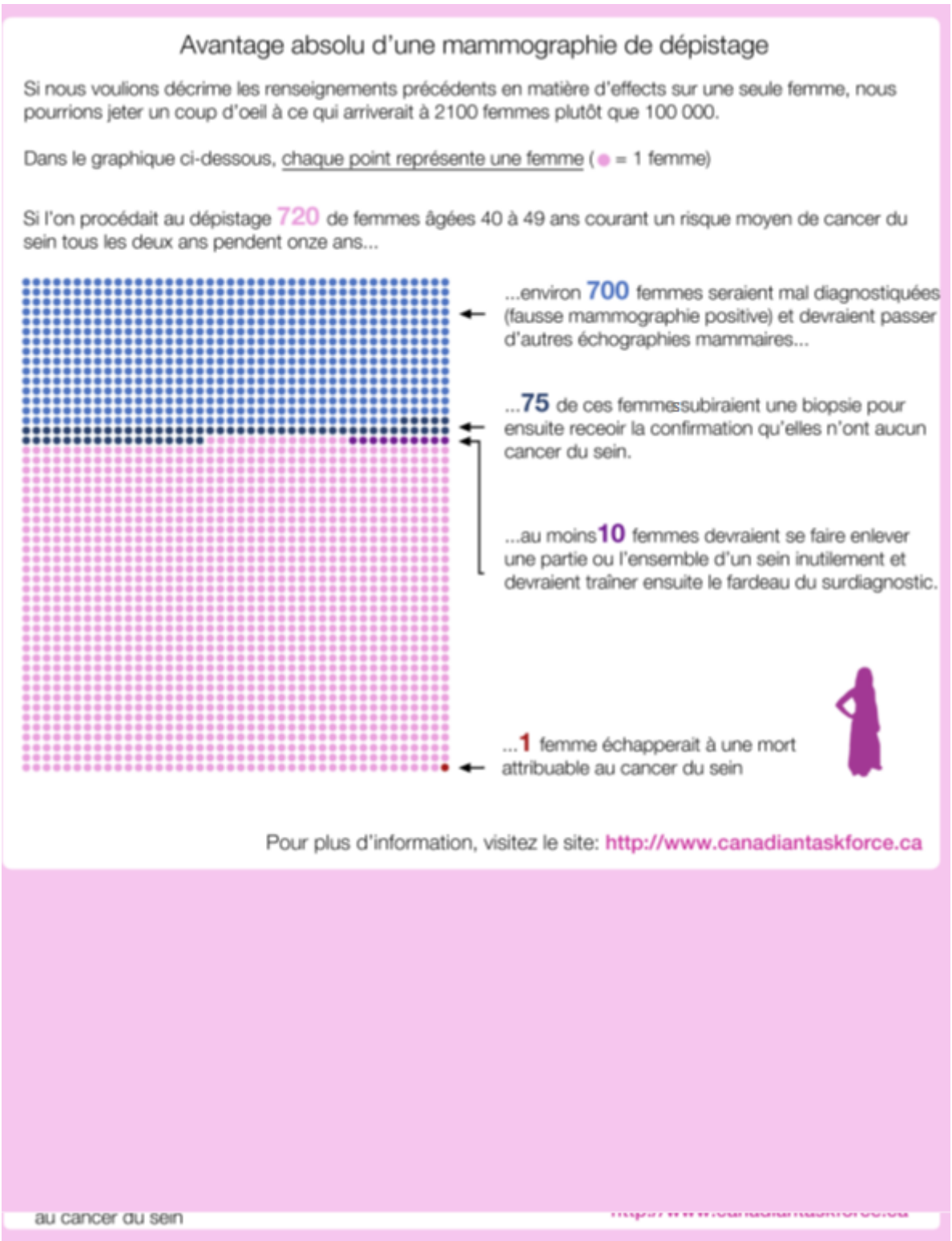
Passent un test de dépistage TOUS les deux ans pendent onze ans:

- **270** femmes mourront du cancer du sein.
- **32 700** femmes obtiendront une fausse alarme.
- **3600** femmes subiront une biopsie.
- **500** femmes se feront enlever une partie ou l'ensemble d'un sein sans avoir un cancer
- **50** femmes échapperont à une mort attribuable au cancer du sein

Ne passent AUCUN test de dépistage pendent onze ans:

- **320** femmes mourront du cancer du sein.
- **99 680** femmes ne mourront pas du cancer du sein.

Pour plus d'information, visitez le site: http://www.canadiantaskforce.ca



Devrais-je passer une mammographie de dépistage du cancer du sein?

Pour les femmes agées de 50 à 69 ans:

Parmi les femmes ne passant aucune mammographie, le risque de mourir du cancer du sein est de: **1 sur 155**

En passent régulièrement des mammographies, votre risque de mourir du cancer du sein est de: **1 sur 196**

Cela dit, en passant régulièrement des mammographies de dépistage:

... le risque d'erreur de diagnostic (fausse mammographie positive) entraînant d'autres tests de dépistages est de: **1 sur 4**

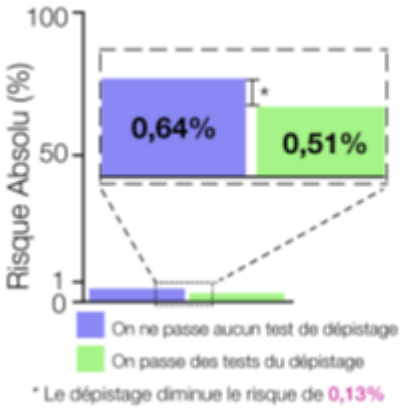
... le risque de subir une biopsie est de: **1 sur 28**

... le risque que l'on vous enlève une partie ou l'ensemble d'un sein inutilement est de: **1 sur 200**

Soyez informée!

Vous entendrez peut-être dure que les risques ou avantages du dépistage du cancer du sein sont décrits comme étant soit **absolus**, soit **relatifs**. Qu'entend-on par cela? En quoi êtes-vous concernée?

La principale différence est que le risque absolu tient compte du fait que peu importe si vous passez un test de dépistage ou recevez des traitements, vous courez tout de même un risque de base de mourir du cancer du sein de: **1 sur 155** ou **0,64%**. En passant régulièrement des tests de dépistage, ce risque passe à: **1 sur 196** ou environ **0,51%**. Le risque relatif ne tient pas compte du risque de base de la même façon et il pourrait semer la confusion quant à la façon dont la participation régulière du dépistage atténue les risques.



Le risque absolu représente simplement la différence de risque entre le fait de passer régulièrement des test de dépistage (0,51%) et le fait de ne passer aucun test de depistage (0,64%).

0,64% - 0,51% = 0,13%

Par conséquent, les femmes âgrées de 50 à 69 ans qui passant des test de dépistage réduisent leur *risque absolu* de mourir du cancer du sein de **0.13%**. Ainsi, *l'avantage absolu* du dépistage est de **0,13%**

Le risque relatif tient uniquement compte de la réduction du risque à titre de proportion du risque total (donc, pas du fait que vous courez déjà un risque de cancer, ce qui peut mener à de plus grandes estimations que celles associatées au risque absolu)

0,13%/0,64% = 21%

Par conséquent, les femmes âgrées de 50 à 69 ans qui passent des tests de dépistage réduisent leur *risque relatif* de mourir du cancer du sein de **21%**. Ainsi, l'*avantage relatif* du dépistage est de **21%.**

Alors, que représentent ces probabilités en nombres réels? Parmi 100 000 femmes âgées de 50 à 69 ans qui:

Passent un test de dépistage TOUS les deux ans pendent onze ans:

- **510** femmes mourront du cancer du sein.
- **28 200** femmes obtiendront une fausse alarme.
- **3700** femmes subiront une biopsie.
- **500** femmes se feront enlever une partie ou l'ensemble d'un sein sans avoir un cancer
- **138** femmes échapperont à une mort attribuable au cancer du sein

Ne passent AUCUN test de dépistage pendent onze ans:

- **640** femmes mourront du cancer du sein.
- **99 360** femmes ne mourront pas du cancer du sein.

Pour plus d'information, visitez le site: http://www.canadiantaskforce.ca

Devrais-je passer une mammographie de dépistage du cancer du sein?

Avantage absolu d'une mammographie de dépistage

Si nous voulions décrire les renseignements précédents en matière d'effects sur une seule femme, nous pourrions jeter un coup d'oeil à ce qui arriverait à 720 femmes plutôt que 100 000.

Dans le graphique ci-dessous, chaque point représente une femme (● = 1 femme)

Si l'on procédait au dépistage 720 femmes âgées de 50 à 69 ans courant un risque moyen de cancer du sein tous les deux ans pendent onze ans...

...environ 204 femmes seraient mal diagnostiquées (fausse mammographie positive) et devraient passer d'autres échographies mammaires...

...26 de ces femmes subiraient une biopsie pour ensuite recevoir la confirmation qu'elles n'ont aucun cancer du sein.

...au moins 4 femmes devraient se faire enlever une partie ou l'ensemble d'un sein inutilement et devraient traîner ensuite le fardeau du surdiagnostic.

...1 femme échapperait à une mort attribuable au cancer du sein

Pour plus d'information, visitez le site: http://www.canadiantaskforce.ca

Devrais-je passer une mammographie de dépistage du cancer du sein?

Pour les femmes agées de 70 à 74 ans:

Parmi les femmes ne passant aucune mammographie, le risque de mourir du cancer du sein est de: **1 sur 146**

En passent régulièrement des mammographies, votre risque de mourir du cancer du sein est de: **1 sur 217**

Cela dit, en passant régulièrement des mammographies de dépistage:

... le risque d'erreur de diagnostic (fausse mammographie positive) entraînant d'autres tests de dépistages est de: **1 sur 5**

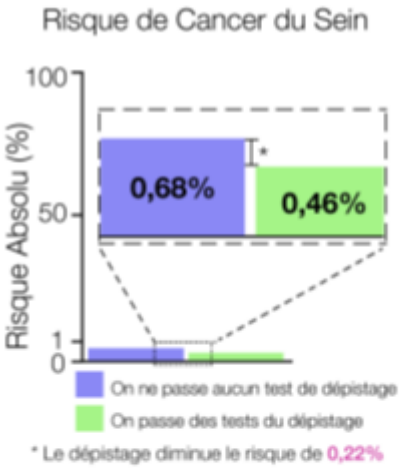
... le risque de subir une biopsie est de: **1 sur 38**

... le risque que l'on vous enlève une partie ou l'ensemble d'un sein inutilement est de: **1 sur 200**

Soyez informée!

Vous entendrez peut-être dure que les risques ou avantages du dépistage du cancer du sein sont décrits comme étant soit **absolus**, soit **relatifs**. Qu'entend-on par cela? En quoi êtes-vous concernée?

La principale différence est que le risque absolu tient compte du fait que peu importe si vous passez un test de dépistage ou recevez des traitements, vous courez tout de même un risque de base de mourir du cancer du sein de: **1 sur 146** ou **0,68%**. En passant régulièrement des tests de dépistage, ce risque passe à: **1 sur 217** ou environ **0,46%**. Le risque relatif ne tient pas compte du risque de base de la même façon et il pourrait semer la confusion quant à la façon dont la participation régulière du dépistage atténue les risques.



Le risque absolu représente simplement la différence de risque entre le fait de passer régulièrement des test de dépistage (0,46%) et le fait de ne passer aucun test de depistage (0,68%).

0,68% - 0,46% = 0,22%

Par conséquent, les femmes âgrées de 70 à 74 ans qui passant des test de dépistage réduisent leur *risque absolu* de mourir du cancer du sein de **0.22%**. Ainsi, *l'avantage absolu* du dépistage est de **0,22%**

Le risque relatif tient uniquement compte de la réduction du risque à titre de proportion du risque total (donc, pas du fait que vous courez déjà un risque de cancer, ce qui peut mener à de plus grandes estimations que celles associatées au risque absolu)

0,22%/0,68% = 32%

Par conséquent, les femmes âgrées de 70 à 74 ans qui passent des tests de dépistage réduisent leur *risque relatif* de mourir du cancer du sein de **32%**. Ainsi, l'*avantage relatif* du dépistage est de **32%.**

Alors, que représentent ces probabilités en nombres réels? Parmi 100 000 femmes âgées de 70 à 74 ans qui:

Passent un test de dépistage TOUS les deux ans pendent onze ans:

- **460** femmes mourront du cancer du sein.
- **21 200** femmes obtiendront une fausse alarme.
- **2600** femmes subiront une biopsie.
- **500** femmes se feront enlever une partie ou l'ensemble d'un sein sans avoir un cancer
- **222** femmes échapperont à une mort attribuable au cancer du sein

Ne passent AUCUN test de dépistage pendent onze ans:

- **680** femmes mourront du cancer du sein.
- **99 320** femmes ne mourront pas du cancer du sein.

Pour plus d'information, visitez le site:
http://www.canadiantaskforce.ca

Devrais-je passer une mammographie de dépistage du cancer du sein?

Avantage absolu d'une mammographie de dépistage

Si nous voulion décrire les renseignements précédents en matière d'effects sure une seule femme, nous pourrions jeter un coup doeil à ce qui arriverait à 450 femmes plutôt que 100 000.

Dans le graphique ci-dessous, chaque point représente une femme (● = 1 femme)

Si l'on procédait au dépistage 450 femme âgées 70 à 74 ans courant un risque moyen de cancer du sein tout less deux ans pendent onze ans...

...environ 90 femmes seraient mal diagnostiquées (fausse mammographie positive) et devraient passer d'autres échographies mammaires...

...11 de ces femmes subiraient une biopsie pour ensuite recevoir la confirmation qu'elles n'ont aucun cancer du sein.

...au moins 2 femmes devraient se faire enlever une partie ou l'ensemble d'un sein inutilement et devraient traîner ensuite le fardeau du surdiagnostic.

...1 femme échapperait à une mort attribuable au cancer du sein

Pour plus d'information, visitez le site: http://www.canadiantaskforce.ca

Tool 3

Rappel

Dépistage individuel :
le médecin prescrit une mammographie sans passer par l'Adémas-69.

Dépistage organisé :
l'Adémas-69 envoie, tous les 2 ans, à toutes les femmes de 50 à 74 ans une lettre d'invitation à pratiquer une mammographie.

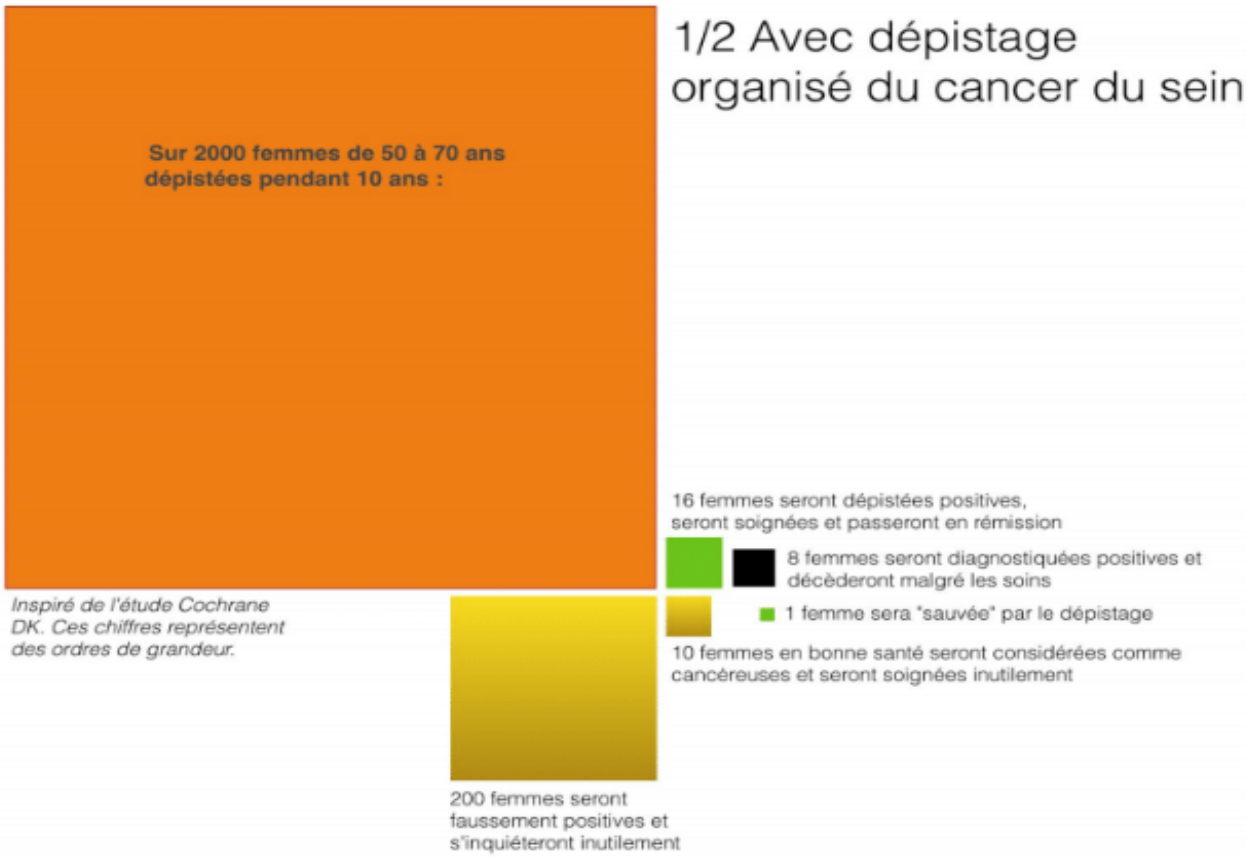
Dépistage organisé (Adémas-69)	*Dépistage individuel*
Rappel régulier et automatique de la date de l'examen	Rappel par le médecin lors d'une visite
Contrôle de la qualité technique des clichés	
Double lecture systématique à l'Adémas-69 des mammographies qui ne sont pas suspectes (cf. verso)	Pas de double lecture systématique
6 cancers sur 100 découverts par la seconde lecture	Pas de données chiffrées
Résultat immédiat et double lecture des clichés remis 15 jours plus tard	Résultat immédiat et pas de double lecture
Relecture possible de la mammographie par le médecin traitant ou le gynécologue	
Pas d'avance des frais pour la mammographie : gratuite	Avance des frais de la mammographie
Avance des frais des examens complémentaires	

Second niveau de décision :
faire le dépistage individuel ou participer au dépistage organisé.

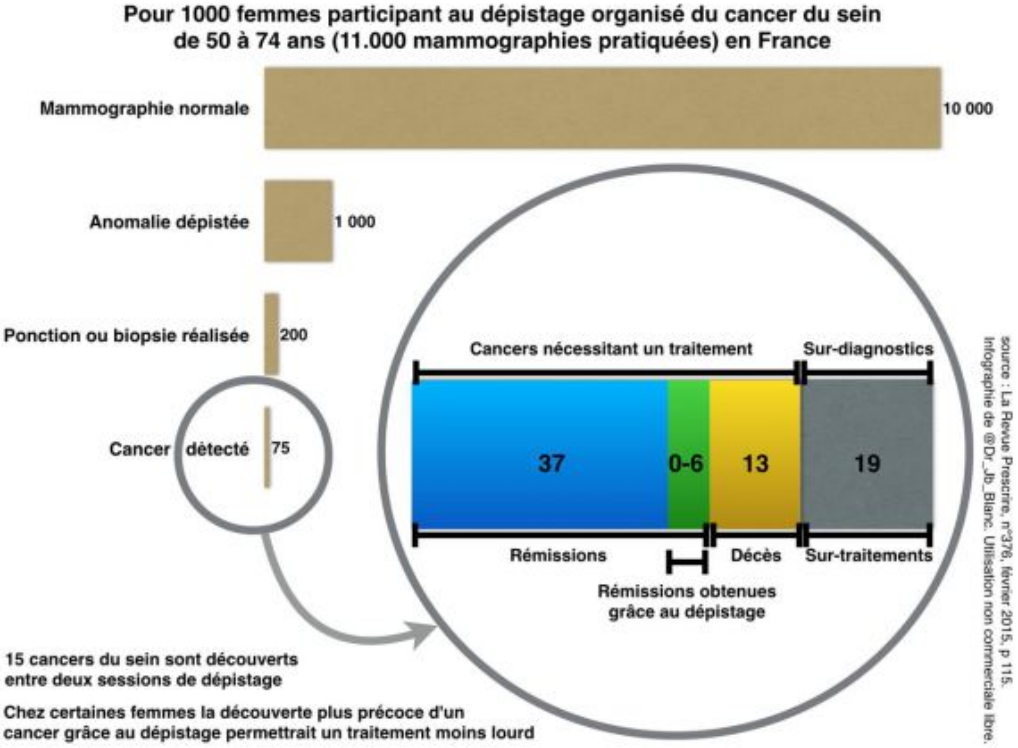
Je suis décidée à participer au dépistage organisé

Questions à poser à mon médecin

Tool 4

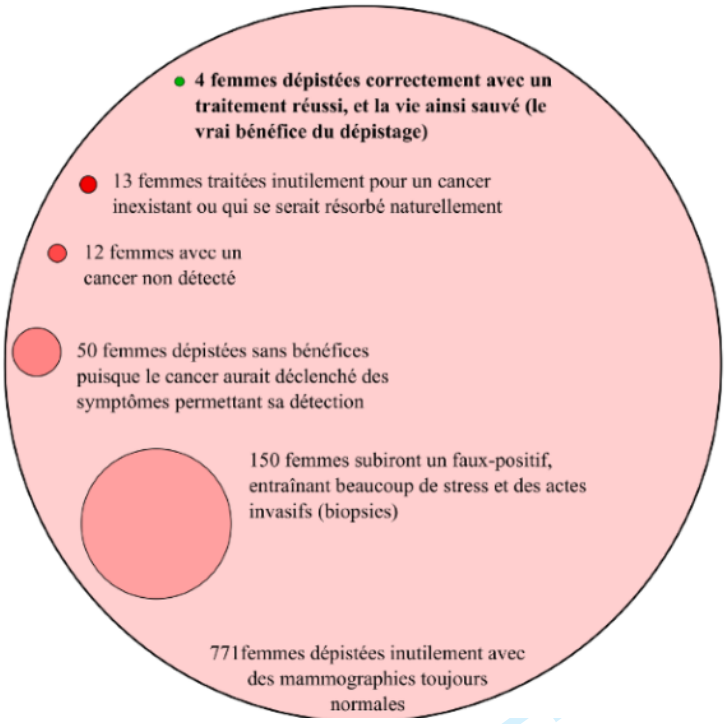


Tool 5

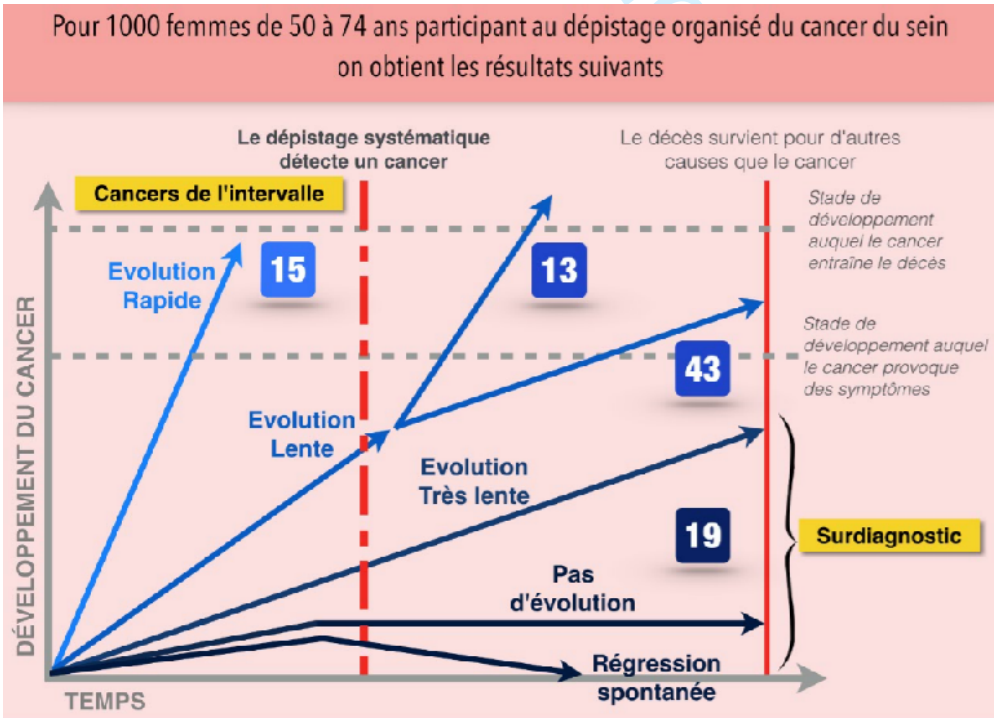


Tool 6

Sur 1000 femmes dépistées pendant 20 ans à raison d'une mammographie tous les deux ans:



Tool 7



Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

No	Item	Guide questions/description
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Ok p7	Interviewer/facilitator	Which author/s conducted the interview or focus group?
2. Ok p7	Credentials	What were the researcher's credentials? *E.g. PhD, MD*
3. Ok p7-p21	Occupation	What was their occupation at the time of the study?
4. Ok p7	Gender	Was the researcher male or female?
5. Ok p7	Experience and training	What experience or training did the researcher have?
Relationship with participants		
6. Ok p8	Relationship established	Was a relationship established prior to study commencement?
7. Ok p8	Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. *personal goals, reasons for doing the research*
8. Ok p7	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic*
Domain 2: study design		
Theoretical framework		
9. Ok p7	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis*
Participant selection		
10. Ok p7	Sampling	How were participants selected? *e.g. purposive, convenience, consecutive, snowball*
11. Ok p7	Method of approach	How were participants approached? e.g. *face-to-face, telephone, mail, email*
12. Ok p9	Sample size	How many participants were in the study?
13. Ok p7	Non-participation	How many people refused to participate or dropped out? Reasons?
Setting		
14. Ok p7	Setting of data collection	Where was the data collected? e.g. *home, clinic, workplace*
15. Ok p7	Presence of non-	Was anyone else present besides the

No	Item	Guide questions/description
	participants	participants and researchers?
16. Ok p9	Description of sample	What are the important characteristics of the sample? *e.g. demographic data, date*
Data collection		
17. Ok p8-Suppelmentary tables	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?
18. Ok p8	Repeat interviews	Were repeat interviews carried out? If yes, how many?
19. Ok p7	Audio/visual recording	Did the research use audio or visual recording to collect the data?
20. Ok p8	Field notes	Were field notes made during and/or after the interview or focus group?
21. Ok p9-10	Duration	What was the duration of the interviews or focus group?
22. Ok p8	Data saturation	Was data saturation discussed?
23. Ok p8	Transcripts returned	Were transcripts returned to participants for comment and/or correction?
Domain 3: analysis and findings		
Data analysis		
24. Ok p8	Number of data coders	How many data coders coded the data?
25. Ok p8	Description of the coding tree	Did authors provide a description of the coding tree?
26. Ok p8	Derivation of themes	Were themes identified in advance or derived from the data?
27. Ok p8	Software	What software, if applicable, was used to manage the data?
28. Ok p8	Participant checking	Did participants provide feedback on the findings?
Reporting		
29. Ok p10-16	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. *participant number*
30. Ok p17-20	Data and findings consistent	Was there consistency between the data presented and the findings?
31. Ok p10-16	Clarity of major themes	Were major themes clearly presented in the findings?
32. Ok p10-16	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes

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What do women and healthcare professionals expect of decision aids for breast cancer screening? A qualitative study in France.

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What do women and healthcare professionals expect of decision aids for breast cancer screening? A qualitative study in France.

Authors: Aïm-Eusébi A[a], Ruelle Y[b,c,d,e], Frèche B[f], Houllemare M[b], Bonillo A[f], Bouaziz L[a], Rat C[e,g,h], Gocko X[h,i,j], Cerisey C[c], Aubin-Auger I[a], Ferrat E[e,k,l], DEDICACES Group, the French National College of General Practitioners.

a. Université de Paris, Département de Médecine Générale, F-75006, Paris, France
b. Université Sorbonne Paris Nord, Département Universitaire de Médecine Générale, DUMG, F-93430, Villetaneuse, France
c. Université Sorbonne Paris Nord, Laboratoire Éducations et Pratiques de Santé, LEPS, UR 3412, F-93430, Villetaneuse, France
d. Centres municipaux de santé universitaires, F-93500, Pantin, France
e. Conseil Scientifique du Collège National des Généralistes Enseignants (CNGE), F-75011, Paris, France
f. Département de Médecine Générale, Faculté de Médecine et Pharmacie, Université de Poitiers, F-86000, Poitiers, France
g. Université de Nantes, Département de Médecine Générale, F-44007, Nantes, France
h. Département de Médecine Générale, Faculté de Médecine Jacques-Lisfranc, Université Jean-Monnet Saint-Étienne, F-42023, Saint-Étienne, France
i. Laboratoire SNA-EPIS EA4607, Université Jean-Monnet Saint-Étienne, F-42023, Saint-Étienne, France
j. HESPER Health Services and Performance Research EA7425, Université Claude Bernard Lyon 1, F-69100 Villeurbanne, France
k. Univ Paris Est Creteil, INSERM, IMRB, CEpiA Team, F-94010 Creteil, France

l. Université Paris-Est Créteil, Département de Médecine Générale, F-94010 Creteil, France

Corresponding Author:

Dr. Amélie Aïm-Eusébi

Université de Paris, Département de Médecine Générale, F-75018, Paris, France

186 boulevard Ney, 75018, Paris, France

amelie.aim-eusebi@u-paris.fr

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ABSTRACT

Objective: Breast cancer screening decision aids (DAs) are designed to help women decide whether or not to participate in mammography-based programs. We aimed to explore women's and healthcare professionals' expectations of a breast cancer screening DA, as part of the French DEDICACES study.

Methods: This French qualitative study was based on semi-structured, individual interviews with women from the general population, general practitioners (GPs), midwives, gynaecologists, radiologists, and screening centre managers. Sampling was purposive and used diversification criteria. The inductive analysis was based on grounded theory.

Results: Between April 2018 and May 2019, we interviewed 40 people: 13 women, 14 GPs, 4 gynaecologists, 3 midwives, 3 radiologists, and 3 screening centre managers. The women and the healthcare professionals considered that a DA could help to improve levels of knowledge, harmonise medical practice, and provide reliable, comprehensive information. Overall, the interviewees wanted an easy-to-use, intuitive, graphic-rich, interactive, computer-based, patient-centred DA. Use of the DA might be limited by a lack of familiarity with SDM, the risk of misuse, and a preference for asymmetric positive information.

Conclusion: The present results are likely to facilitate the development of the first validated tool for SDM support in French breast cancer screening programs.

KEYWORDS: breast cancer screening, decision aid, shared decision-making, primary health care, qualitative research

ARTICLE SUMMARY

Strengths and limitations of this study

- Qualitative study, inspired by grounded theory, that complied with the Consolidated Criteria for Reporting Qualitative Research throughout the study.
- The interview guides explored perceptions, attitudes and expectations related to breast cancer, diagnosis, prevention, screening, and the decision aids.
- The data were provided by individual interviews in a diverse sample of both women and healthcare professionals.
- The degree of literacy of interviewed women was insufficiently assessed.
- Several experienced researchers triangulated the data.

BACKGROUND

Breast cancer is the most common cancer worldwide and constitutes the leading cause of cancer death among women.[1] Most European countries organize mammogram-based breast cancer screening programs.[2] The European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis indicate that a significant decrease in breast cancer mortality requires a participation rate of at least 70%.[2] In France, free organized screening every two years has been available (for women between the ages of 50 and 74) since 2004. A prescription from a general practitioner (GP) or another physician is not required for screening; women can be screened by a radiologist upon presentation of an invitation sent by the local screening coordination centre. However, the participation rate in France's organized screening programme was only 50% in 2018.[3] Even though the results of large, randomized, controlled trials have highlighted a significantly lower breast cancer mortality rate among women undergoing regular mammogram screening,[4-6] the risk-benefit balance is subject to debate.[7, 8] It has been suggested that shared decision-making (SDM) can help women to weigh up the known benefits and risks of breast cancer screening.[9-11]

By providing information on options and outcomes, decision aids (DAs) can help women to decide whether or not to participate in breast cancer screening. A recent review reported that people exposed to DAs feel more knowledgeable, better informed, and clearer about their values and they probably have a more active role in decision making and more accurate risk perceptions.[12] DAs therefore support the SDM. France currently lacks a breast cancer screening DA that women can use when consulting a visit with their health provider. The French "*Decision Partagée dans le Cadre du Dépistage du Cancer du Sein*" (DEDICACES) study aims at building an online DA for SDM in breast cancer screening that can be used by both women and healthcare professionals preferentially during a consultation, in compliance with the International Patient Decision Aid Standards.[13]

OBJECTIVE

The objective of our study was to explore women's and healthcare professionals' expectations of a breast cancer screening DA.

METHODS

Study design

This qualitative study, inspired by grounded theory, was based on semi-structured, individual interviews of women, GPs, midwives, gynaecologists, radiologists, and local screening programme managers in three areas of France (the *Oise*, *Val d'Oise* and *Alpes de Haute-Provence* counties). We perform individual interviews because cancer is a delicate subject for some people. Interviews were conducted in French - the mother tongue of all participants. The team of investigators was composed of eight researchers, female and male, trained to lead interviews and perform qualitative analysis *(AAE, EF, BF, AB, MH, LB, IAA,* and *YR*). All semi-structured interviews were led by an investigator. MH and AB led women's interviews; AB and MH led GP's interviews and LB led healthcare professionals' interviews.

Participant sampling

The interviewed GPs were recruited from a list provided by the French national public health insurance system (CNAM). The women were recruited by snowball sampling or through their GPs (but not those interviewed for the study). Other healthcare professionals were recruited using snowball sampling. Sampling was purposive for all types of participants. Nobody refused to participate. Diversification criteria were applied in order to obtain a broad range of participants and points of view. Diversification criteria were discussed with the research team for all participants and were completed during data collection (Table 1). Each interviewee gave her/his verbal and written informed consent prior to inclusion.

Data collection

Audiotaped, semi-structured interviews were held face-to-face at the healthcare professional's office or at home. One of the midwives and one of the screening programme managers underwent a phone interview.

The interview guides, developed by the investigators, were similar between the groups interviewed but each had some specificities. They explored perceptions, attitudes and expectations related to breast cancer, diagnosis, prevention, screening, and the DA. In the second part of the interview, published DAs were shown as examples (14-20). This enabled participants to state their opinions and expectations with regard to these tools and to describe the tools' strengths and limitations. Field notes were made during and after the interviews. A woman with history of breast cancer helped to build the interview guide of women's and GPs' groups and pilot tested it. The interview guide evolved during the study (Supplementary Tables S1 to S4).

Data analysis

All interviews were transcribed verbatim and subjected to an inductive analysis based on grounded theory to analyse social interactions.[21] Next, the interview data were coded jointly by two pairs of investigators (MH+AB, AAE+LB) and, in order to enhance inter-coder reliability, individually by four other investigators (BF, EF, YR, and IA). We used MAXQDA® software (version 12, VERBI Software, Consult-Sozialforschung GmbH, Berlin, Germany) for the analysis. Similarities and differences in the codes from the interviews were assessed and discussed by all the investigators until a consensus was formed. Data collection was achieved for each kind of participants after two interviews without new codes.

Patient Involvement

A patient was involved in the design of the study. She was a woman with history of breast cancer and helped to build the interview guide of women's group. She also participated in the evolution of the guide throughout the study. She had access to the results of the study.

RESULTS

Between April 2018 and May 2019, we interviewed 40 people: 13 women, 14 GPs, 4 gynaecologists ("G" in the verbatim below), 3 midwives (M), 3 radiologists (R) and 3 screening programme managers (Table 1). The mean duration of the interviews was 55 minutes and 27 seconds. We used the term "healthcare professionals" to describe the GPs, gynaecologists, midwives, radiologists, and screening programme managers.

Participants	All participants (N = 40)	Women (N = 13)	GPs (N = 14)	Other healthcare profesionnals* (N = 13)
Age mean (range)	53.9 (29-75)	62.9 (42-75)	49.6 (34-68)	49.1 (29-70)
Gender Female N (%)	29 (72.5)	13 (100)	8 (57.1)	8 (61.5)
Practices	(N = 27)			
Group	18	-	8	10
Solo	9	-	6	3
Educational level				
Primary school	2	2	0	0
Secondary school	7	7	0	0
Higher education	31	4	14	13
Area				
Rural	8	3	5	0
Semi-rural	10	6	4	0
Urban	22	4	5	13
Previous mammography (Y/N)	-	8/5	-	-

History of breast cancer (Y/N)	-	2/11	-	-
Interview mean duration in minutes (range)	55 min (7 min-120 min)	69 min (27 min-120 min)	69 min (41 min-118 min)	27 min (7 min-57 min)

Table 1: Characteristics of the study participants
* Gynaecologists, midwives, radiologists screening, programme manager

Purpose of the tool

Women saw the tool as an aid to understand breast cancer screening.

"It would be great to have information about breast cancer: things would be clearer for us." (Women 3)

Healthcare professionals expected the DA to improve their own level of knowledge about breast cancer and breast cancer screening.

"I need objective data that I can rely on when discussing screening with women." (GP 6)

Healthcare professionals were interested in a tool that could help them to harmonise their practice with regard to breast cancer screening.

"It would be great to have that sort of tool. It would help to harmonise things." (Midwife 3)

The interviewees stated that the decision support tool had to encourage women to visit their doctor and discuss breast cancer screening or to go to a local screening program centre.

"An information poster might prompt women to consult their doctor." (Woman 1)

"[An information leaflet] would be useful if women have questions about mammography and breast cancer screening; they could discuss things with their GP." (GP 5)

What kind of DA do people want? (Table 2)

The DA's characteristics

The women and the healthcare professionals wanted the DA to be quick to access and easy to use and understand DA.

"It has to be easy, visual, and simple […] – I'd rather have that sort of tool" (GP 10)

"The information has to be concise because otherwise we'll throw it away […]. It would be better to stick to something short and well targeted, with eye-catching stuff…" (Woman 4)

The interviewees expected to have an intuitive tool with diagrams and graphics – something that was almost "fun" to read. The healthcare professionals wanted the statistical information to be of value for the women.

"It's good because there are different sorts of information - numbers but also diagrams; Visual things like that are more meaningful" (Woman 6)

The women and the healthcare professionals also wanted a tool that was designed for all women, regardless of the latter's level of literacy.

"Screening programs are intended to reduce social inequality, rather than increase it" (Manager 3)

"The tool's characteristics will depend on who it's targeting. It depends on each woman." (Woman 4)

The medium used for the DA

The women and healthcare professionals suggested that the DA was best presented on a computer or a smartphone or, failing, that on paper (i.e. a leaflet or poster). A video format might be of value for a DA on a computer or a smartphone.

The GPs suggested using the DA as a video or poster to disseminate the information in the medical waiting room. They also suggested that the tool could be directly integrated in their medical software.

"It has to be something visual, something integrated into software. […] It needs to be easy to access." (GP 4)

Dissemination of the DA

The healthcare professionals suggested that the DA could be shared over the Internet.

"These days, having an instructive website would be more relevant than handing out leaflets." (Midwife 1)

The interviewees stated that word of mouth was also the best means of hearing about the tool. They also reported it would be interesting to use the media and social networks to present the tool.

"It's important that someone talks to me about the tool." (Woman 2)

Use of the tool

The women and the healthcare professionals agreed that the DA could be a useful lever for discussion during normal consultations or dedicated meetings.

"It might also help me to answer questions" (GP 6)

"Maybe it would help. It might have an influence and prompt the patient to ask questions that she wouldn't otherwise." (Woman 7)

"If it's during a meeting, we can put the figures on the screen. But then you have to have a discussion; if the woman has questions, you can explain why the information is presented this way." (Manager 1)

For health professionals, their help in commenting and discussing the tool with women is indispensable.

"I wouldn't let them read this by themselves, because... It's scary!" (GP 7).

The women were interested in receiving this type of information, along with explanations from their GP. However, they wanted to have the choice to use it or not with their doctor.

"We have an informal discussion, we can... pass on messages.... And then make a decision, saying I'm going or I'm not going. I weigh the pros and cons, that's it." (Woman 3)

Women	Healthcare professionals
Purpose of the tool	
To understand screening	To complete their knowledge
	To harmonize screening / professional practice
To prompt women to visit their GP	To refer women to their doctor
Characteristics of the tool	
With concrete numbers	Give statistical information to women
Easy to understand	Easy to use
Adaptable to different women's profiles	Design for every women
Presence of diagrams	Digital tool
Use of the tool	
A lever for discussion if desired by the woman	A lever for discussion
Have the choice to use it or not with their doctor	The health professional is essential to use the tool

Table 2: Consensus representations

Disagreements about the tool: balanced or biased information? (Table 3)

Opinions on breast cancer screening

The participants pointed out the sub-optimal effectiveness of breast cancer screening because of the harms associated with overdiagnosis and overtreatment.

"What surprised me was the ability to diagnose something that wasn't there and treat someone who didn't need it." (Woman 12, before the presentation of the tools)

"I am devastated by the results of the mammogram. Despite the double reading which I was inclined to give credit to..." (GP 3, before the presentation of the tools)

On the other hand, overtreatment could be seen as acceptable either because it applies to small tumours treatment or because it could save lives.

"They are cared for anyway, it's not useless…" (Woman 9, after the presentation of the tools)

"I don't play the game of overdiagnosis. [...] Honestly, I don't believe in overdiagnosis." (Radiologist 3, before the presentation of the tools)

Sometimes it is even difficult for professionals to distance themselves from their personal experience.

"If it's someone in my family or even me personally, I'd rather know about something and do a biopsy for nothing" (Gynaecologist 4, before the presentation of the tools),

Some participants considered the benefit-risk balance favourable, while others found it questionable. In this second case, the attitudes towards the tool differed according to the participants.

Shared decision-making

Many of the interviewees were not familiar with the concept of SDM in medicine.

"I didn't really have time to understand everything about this idea of shared decision-making…" (*Woman* 5)

"Support for shared decision-making? What's that?" (GP 5)

Some midwives and GPs were in favour of sharing comprehensive, balanced information about screening with women. Hence, DAs could be of value to these healthcare professionals in their daily practice. The healthcare professionals considered themselves to be "screening guides"; they wanted to provide women with reliable scientific data and enabling them to make an informed choice. Indeed, the healthcare professionals wanted to set out the facts and then accept the woman's decision. Furthermore, some of the women actively asked to receive comprehensive information from the healthcare professional so that they could decide for themselves whether or not to be screened.

"I explain things but will never force anyone to be screened - if they don't want to, it's their choice. […] It really is a shared decision and a mutual agreement with the patient." (Mifwife 2)

"It also depends on the cultural level, we will not work in the same way with a teacher, a nurse, or a woman who lives in the depths of her countryside" (GP 4)

"The doctor needs to explain [the screening] properly. I want to be able to weigh up the positive and negative aspects." (*Woman* 6)

Asymmetric information/ Paternalistic model

Some women wanted their physician to help them to understanding information about screening at every step in the process. Some women asked for selective information but considered that it was not up to them to decide whether or not to go for screening. Other women were afraid of receiving screening results; this is why they did not want to know everything about screening and the risks of cancer in particular.

"You can't let us choose because we don't understand anything about being screened or not" (Woman 2, after the presentation of the tools)

Some GPs, gynaecologists and radiologists had the same view about asymmetric information provision, with a focus on the benefits of screening. They considered that giving selected, positive information to women was essential for avoiding fear of screening.

"*We have to explain things quickly and only go into detail if they ask for more information. […] I don't know whether giving lots of impartial information is part of being a physician and above all part of making a diagnosis." (Radiologist 3, after the presentation of the tools)*

"If I tell them to get screened, they'll go without any hesitation." (Gynaecologist 1, before the presentation of the tools)

Convincing women to participate in screening

Some women thought the tool had to help healthcare professionals to convince everyone to participate in the screening. Similarly, some healthcare professionals stated that convincing women to enter a screening programme was the most important objective. They wanted to reassure women so that they would want to be screened.

"Providing women with information is essential for motivating them to get screened" (GP 4, before the presentation of the tools)

"Perhaps some women think of having a mammography without being prompted but not me - I wouldn't think of it. But if my doctor suggests it, I'll go!" (*Woman* 2, before the presentation of the tools)

Women	Healthcare professionals
Balanced or biased information?	
Shared decision making: Free decision to participate in screening or not after receiving appropriate information	Shared decision making: state the facts in a neutral manner and let the patient decide whether or not she wants to participate in screening

Paternalistic model: the doctor has the knowledge and must tell the women what to do	Asymmetric information: Convince the patient to participate in organized screening because of the responsibility of knowing as a health professional
Lack of interest for such a tool in view of the sufficient data already available	No need for such a tool

Table 3: Dissenting representations

DISCUSSION

Summary of the main findings

Both the women and the healthcare professionals stated that a DA could help to improve knowledge, harmonise medical practice and provide reliable, comprehensive information. They expected the DA's to catalyse discussion between the patient and the physician during a consultation. Women and healthcare professionals wanted an easy-to-use, intuitive interactive computer-based DA, with diagrams and graphics. Some of the health care professionals and some of the women wanted a DA that leads to SDM. Our study highlighted several limitations to the tool, such as a lack of familiarity with SDM, the risk of misuse (i.e. convincing women to participate in a screening programme without engaging an SDM process), and a preference for asymmetric, positive information.

Study strengths and limitations

The study had a number of strengths. Firstly, the investigators complied with the Consolidated Criteria for Reporting Qualitative Research throughout the study.[22] Secondly, the data were provided by a diverse sample of both women (including socioeconomic level) and healthcare professionals; given that the risk-benefit balance for breast cancer screening is currently unclear, SDM appears to be the most ethical approach.[11] Thirdly, the data were triangulated by several experienced researchers. Fourthly, the samples of women and healthcare professionals were particularly diverse. Fifthly, nobody refused to participate to the study; we think that snowball sampling was a good way to engage participants.

However, we insufficiently assessed the degree of literacy of interviewed women. Only one woman answered "no" to the question designed to explore the level of literacy *"Do you need someone to help you understand prescriptions or medical information documents given by*

your doctor or pharmacist?". In the future, this may be important for adapting the DA for use with women of different literacy levels.

Comparison with the literature data

As mentioned above, the women interviewed in the present study here knew little or nothing about SDM. When the concept was explained, however, some women thought that it was of value. Similarly, a qualitative study of a DA for breast cancer screening in Spain found that women valued the receipt of information on the benefits and risks of screening.[23] This seems to be true for all women, even though SDM interventions tend to benefit disadvantaged women (e.g. those with a lower level of literacy) more than those with higher literacy or educational/socioeconomic status.[24] Becoming better informed might mean women are less likely to choose screening.

There is a growing body of evidence to show that DAs can improve value-congruent choices. In our study, the perception of screening seems to be modified by the presentation of the tools. Indeed, participants tend to cite the harms of screening more often after the tools have been presented to them. On the contrary, the presentation of the tools may have strengthened some participants in their conviction that screening was essential and its value indisputable. The latter found it questionable to tell women about the adverse effects of screening as this could reduce their motivation to undergo screening. These data are consistent with the literature. When compared with standard care in a broad variety of decision contexts, women exposed to DAs feel more knowledgeable, better informed, and clearer about their values; as such, they probably have a more active role in decision-making and a more accurate perception of risks.[12] Breast cancer screening DAs are known to improve levels of knowledge and promote informed decisions.[10] For this reason, DAs do not necessarily

increase screening participation rates.[25] For example, the large-scale Decideo study of breast cancer screening demonstrated that exposure to the DA reduced the participation rate by almost 2% because the women felt better informed.[16] The above-mentioned Spanish qualitative study found that the provision of information on overdiagnosis is controversial among healthcare professionals.[23] An Australian study about overdetection in breast cancer screening recommended a staged approach to development and piloting of decision aids to further improve understanding of overdetection and support informed decision-making about screening.[26] The creation and deployment of a DA tool must therefore be accompanied by training for healthcare professionals on SDM.

Several studies have evaluated quality criteria for DAs and the pitfalls to be avoided when designing this type of tool. A review on risk communication developed decision box prototypes, presented them to focus groups of GPs and patients, and explored the participants' perceptions.[27] The model explored seven facets of the user experience: the DA had to be useful, usable (with effectiveness, efficiency and satisfaction), desirable, findable, accessible, credible and valuable (i.e. more frequent SDM). Accordingly, the present study exploring all of these aspects. We found that the study participants wanted an easy-to-use, intuitive, interactive, computer-based DA with diagrams and graphics. In a recent systematic review of the quality of DAs developed for women eligible for mammogram screening, the three best-rated dimensions of standard DAs were disclosure (transparency and conflicts of interest), information (the provision of sufficient detail), and outcome probabilities.[28] The women and the healthcare professionals interviewed in our study also stated that those three dimensions were important to them. We considered that a future DA must focus on all six dimensions, so that women and healthcare professionals engage with the tool.

Implications for clinical practice

The present study explored expectations of a DA for SDM in breast cancer screening before its creation, from the future users themselves. Our work is the first step in the construction of this tool and will thus make it possible to avoid the pitfalls brought to light during the interviews. The future tool will allow adapting the information according to the age group of the patient. It's important to take time to acculturate healthcare professionals to the use of the DA to avoid its misuse. Our results should help to create an appropriate, added-value tool for use in this field and adapted to French context.

Conclusion

Stakeholders in organized breast cancer screening programmes (women, GPs, gynaecologists, midwives, radiologists and screening programme managers) have a broad range of expectations of a DA. The interviews showed that a DA could help to improve levels of knowledge, harmonise medical practice, and provide reliable, comprehensive information. Overall, the interviewees wanted an easy-to-use, intuitive, graphic-rich, interactive, computer-based and patient-centred DA. The idea of a DA was well received by the interviewees despite the fact the latter were unfamiliar with the concept of SDM. Along with the implementation of this type of tool, it would be useful to raise awareness of SDM among healthcare professionals and breast screening candidates. The present work was the first step in the DEDICACES study and will be followed by the creation and then validation of the first DA for SDM support in France's breast cancer screening programmes.

Data are available upon reasonable request: The deidentified transcripts of the interviews are available from the corresponding author (amelie.aim-eusebi@u-paris.fr). Their reuse is possible for a purpose similar to that of our study, otherwise a new consent from the interviewees will be necessary.

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What do women and healthcare professionals expect of decision aids for breast cancer screening? A qualitative study in France.

Authors: Aïm-Eusébi A[a], Ruelle Y[b,c,d,e], Frèche B[f], Houllemare M[b], Bonillo A[f], Bouaziz L[a], Rat C[e,g,h], Gocko X[h,i,j], Cerisey C[c], Aubin-Auger I[a], Ferrat E[e,k,l], DEDICACES Group, the French National College of General Practitioners.

a. Université de Paris, Département de Médecine Générale, F-75006, Paris, France
b. Université Sorbonne Paris Nord, Département Universitaire de Médecine Générale, DUMG, F-93430, Villetaneuse, France
c. Université Sorbonne Paris Nord, Laboratoire Éducations et Pratiques de Santé, LEPS, UR 3412, F-93430, Villetaneuse, France
d. Centres municipaux de santé universitaires, F-93500, Pantin, France
e. Conseil Scientifique du Collège National des Généralistes Enseignants (CNGE), F-75011, Paris, France
f. Département de Médecine Générale, Faculté de Médecine et Pharmacie, Université de Poitiers, F-86000, Poitiers, France
g. Université de Nantes, Département de Médecine Générale, F-44007, Nantes, France
h. Département de Médecine Générale, Faculté de Médecine Jacques-Lisfranc, Université Jean-Monnet Saint-Étienne, F-42023, Saint-Étienne, France
i. Laboratoire SNA-EPIS EA4607, Université Jean-Monnet Saint-Étienne, F-42023, Saint-Étienne, France
j. HESPER Health Services and Performance Research EA7425, Université Claude Bernard Lyon 1, F-69100 Villeurbanne, France
k. Univ Paris Est Creteil, INSERM, IMRB, CEpiA Team, F-94010 Creteil, France

l. Université Paris-Est Créteil, Département de Médecine Générale, F-94010 Creteil, France

Corresponding Author:

Dr. Amélie Aïm-Eusébi

Université de Paris, Département de Médecine Générale, F-75018, Paris, France

186 boulevard Ney, 75018, Paris, France

amelie.aim-eusebi@u-paris.fr

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ABSTRACT

Objective: Breast cancer screening decision aids (DAs) are designed to help women decide whether or not to participate in mammography-based programs. We aimed to explore women's and healthcare professionals' expectations of a breast cancer screening DA, as part of the French DEDICACES study.

Methods: This French qualitative study was based on semi-structured, individual interviews with women from the general population, general practitioners (GPs), midwives, gynaecologists, radiologists, and screening centre managers. Sampling was purposive and used diversification criteria. The inductive analysis was based on grounded theory.

Results: Between April 2018 and May 2019, we interviewed 40 people: 13 women, 14 GPs, 4 gynaecologists, 3 midwives, 3 radiologists, and 3 screening centre managers. The women and the healthcare professionals considered that a DA could help to improve levels of knowledge, harmonise medical practice, and provide reliable, comprehensive information. Overall, the interviewees wanted an easy-to-use, intuitive, graphic-rich, interactive, computer-based, patient-centred DA. Use of the DA might be limited by a lack of familiarity with SDM, the risk of misuse, and a preference for asymmetric positive information.

Conclusion: The present results are likely to facilitate the development of the first validated tool for SDM support in French breast cancer screening programs.

KEYWORDS: breast cancer screening, decision ~~support~~aid, shared decision-making, primary health care, qualitative research

ARTICLE SUMMARY

Strengths and limitations of this study

- Qualitative study, inspired by grounded theory, that complied with the Consolidated Criteria for Reporting Qualitative Research throughout the study.
- The interview guides explored perceptions, attitudes and expectations related to breast cancer, diagnosis, prevention, screening, and the decision aids.
- The data were provided by individual interviews in a diverse sample of both women and healthcare professionals.
- The degree of literacy of interviewed women was insufficiently assessed.
- Several experienced researchers triangulated the data.

BACKGROUND

Breast cancer is the ~~second~~ most common cancer worldwide and constitutes the leading cause of cancer death among women.[1] Most European countries organize mammogram-based breast cancer screening programs.[2] The European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis indicate that a significant decrease in breast cancer mortality requires a participation rate of at least 70%.[2] In France, free organized screening every two years has been available (for women between the ages of 50 and 74) since 2004. A prescription from a general practitioner (GP) or another physician is not required for screening; women can be screened by a radiologist upon presentation of an invitation sent by the local screening coordination centre. However, the participation rate in France's organized screening programme was only 50% in 2018.[3] Even though the results of large, randomized, controlled trials have highlighted a significantly lower breast cancer mortality rate among women undergoing regular mammogram screening,[4-6, ~~5~~] the risk-benefit balance is subject to debate.[7~~6~~, 8~~7~~] It has been suggested that shared decision-making (SDM) can help women to weigh up the known benefits and risks of breast cancer screening.[9~~8~~-11~~0~~]

By providing information on options and outcomes, decision aids (DAs) can help women to decide whether or not to participate in breast cancer screening. A recent review reported that people exposed to DAs feel more knowledgeable, better informed, and clearer about their values and they probably have a more active role in decision making and more accurate risk perceptions.[12~~1~~] DAs therefore support the SDM. France currently lacks a breast cancer screening DA that women can use when consulting a visit with their health provider. The French "*Decision Partagée dans le Cadre du Dépistage du Cancer du Sein*" (DEDICACES) study aims at building an online DA for SDM in breast cancer screening

that can be used by both women and healthcare professionals preferentially during a consultation, in compliance with the International Patient Decision Aid Standards.[132]

OBJECTIVE

The objective of our study was to explore women's and healthcare professionals' expectations of a breast cancer screening DA.

METHODS

Study design

This qualitative study, inspired by grounded theory, was based on semi-structured, individual interviews of women, GPs, midwives, gynaecologists, radiologists, and local screening programme managers in three areas of France (the *Oise*, *Val d'Oise* and *Alpes de Haute-Provence* counties). We perform individual interviews because cancer is a delicate subject for some people. Interviews were conducted in French - the mother tongue of all participants. The team of investigators was composed of eight researchers, female and male, trained to lead interviews and perform qualitative analysis *(AAE, EF, BF, AB, MH, LB, IAA,* and *YR*). All semi-structured interviews were led by an investigator. MH and AB led women's interviews; AB and MH led GP's interviews and LB led healthcare professionals' interviews.

Participant sampling

The interviewed GPs were recruited from a list provided by the French national public health insurance system (CNAM). The women were recruited by snowball sampling or through their GPs (but not those interviewed for the study). Other healthcare professionals were recruited using snowball sampling. Sampling was purposive for all types of participants. Nobody refused to participate. Diversification criteria were applied in order to obtain a broad range of participants and points of view. Diversification criteria were discussed with the research team for all participants and were completed during data collection (Table 1). Each interviewee gave her/his verbal and written informed consent prior to inclusion.

Data collection

Audiotaped, semi-structured interviews were held face-to-face at the healthcare professional's office or at home. One of the midwives and one of the screening programme managers underwent a phone interview.

The interview guides, developed by the investigators, were similar between the groups interviewed but each had some specificities. They explored perceptions, attitudes and expectations related to breast cancer, diagnosis, prevention, screening, and the DA. In the second part of the interview, published DAs were shown as examples (14-20). This enabled participants to state their opinions and expectations with regard to these tools and to describe the tools' strengths and limitations. Field notes were made during and after the interviews. A woman with history of breast cancer helped to build the interview guide of women's and GPs' groups and pilot tested it. The interview guide evolved during the study (Supplementary Tables S1 to S4).

Data analysis

All interviews were transcribed verbatim and subjected to an inductive analysis based on grounded theory to analyse social interactions.[21~~13~~] Next, the interview data were coded jointly by two pairs of investigators (MH+AB, AAE+LB) and, in order to enhance inter-coder reliability, individually by four other investigators (BF, EF, YR, and IA). We used MAXQDA® software (version 12, VERBI Software, Consult-Sozialforschung GmbH, Berlin, Germany) for the analysis. Similarities and differences in the codes from the interviews were assessed and discussed by all the investigators until a consensus was formed. Data ~~sufficiency~~ collection was achieved for each kind of participants after two interviews without new codes.

Patient Involvement

A patient was involved in the design of the study. She was a woman with history of breast cancer and helped to build the interview guide of women's group. She also participated in the evolution of the guide throughout the study. She had access to the results of the study.

RESULTS

Between April 2018 and May 2019, we interviewed 40 people: 13 women, 14 GPs, 4 gynaecologists ("G" in the verbatim below), 3 midwives (M), 3 radiologists (R) and 3 screening programme managers (Table 1). The mean duration of the interviews was 55 minutes and 27 seconds. We used the term "healthcare professionals" to describe the GPs, gynaecologists, midwives, radiologists, and screening programme managers.

Participants	All participants (N = 40)	Women (N = 13)	GPs (N = 14)	Other healthcare profesionnals* (N = 13)
Age mean (range)	53,9 (29-75)	62,9 (42-75)	49,6 (34-68)	49,1 (29-70)
Gender Female N (%)	29 (72.5)	13 (100)	8 (57.1)	8 (61.5)
Practices	(N = 27)			
Group	18	-	8	10
Solo	9	-	6	3
Educational level				
Primary school	2	2	0	0
Secondary school	7	7	0	0
Higher education	31	4	14	13
Area				
Rural	8	3	5	0
Semi-rural	10	6	4	0
Urban	22	4	5	13
Previous mammography (Y/N)	-	8/5	-	-

History of breast cancer (Y/N)	-	2/11	-	-
Interview mean duration in minutes (range)	55 min:27 (7 min:05-120 min:00)	69 min:22 (27 min6:31-120 min:00)	69 min:26 (41 min:13-118 min7:35)	27 min6:33 (7 min:05-57 min:23)

Table 1: Characteristics of the study participants
* Gynaecologists, midwives, radiologists screening, programme manager

Purpose of the tool

Women saw the tool as an aid to understand breast cancer screening.

"It would be great to have information about breast cancer: things would be clearer for us." (Women 3)

Healthcare professionals expected the DA to improve their own level of knowledge about breast cancer and breast cancer screening.

"I need objective data that I can rely on when discussing screening with women." (GP 6)

Healthcare professionals were interested in a tool that could help them to harmonise their practice with regard to breast cancer screening.

"It would be great to have that sort of tool. It would help to harmonise things." (Midwife 3)

The interviewees stated that the decision support tool had to encourage women to visit their doctor and discuss breast cancer screening or to go to a local screening program centre.

"An information poster might prompt women to consult their doctor." (Woman 1)

"[An information leaflet] would be useful if women have questions about mammography and breast cancer screening; they could discuss things with their GP." (GP 5)

What kind of DA do people want? (Table 2)

The DA's characteristics

The women and the healthcare professionals wanted the DA to be quick to access and easy to use and understand DA.

"It has to be easy, visual, and simple […] – I'd rather have that sort of tool" (GP 10)

"The information has to be concise because otherwise we'll throw it away […]. It would be better to stick to something short and well targeted, with eye-catching stuff…" (Woman 4)

The interviewees expected to have an intuitive tool with diagrams and graphics – something that was almost "fun" to read. The healthcare professionals wanted the statistical information to be of value for the women.

"It's good because there are different sorts of information - numbers but also diagrams; Visual things like that are more meaningful" (Woman 6)

The women and the healthcare professionals also wanted a tool that was designed for all women, regardless of the latter's level of literacy.

"Screening programs are intended to reduce social inequality, rather than increase it" (Manager 3)

"The tool's characteristics will depend on who it's targeting. It depends on each woman." (Woman 4)

The medium used for the DA

The women and healthcare professionals suggested that the DA was best presented on a computer or a smartphone or, failing, that on paper (i.e. a leaflet or poster). A video format might be of value for a DA on a computer or a smartphone.

The GPs suggested using the DA as a video or poster to disseminate the information in the medical waiting room. They also suggested that the tool could be directly integrated in their medical software.

"It has to be something visual, something integrated into software. […] It needs to be easy to access." (GP 4)

Dissemination of the DA

The healthcare professionals suggested that the DA could be shared over the Internet.

"These days, having an instructive website would be more relevant than handing out leaflets." (Midwife 1)

The interviewees stated that word of mouth was also the best means of hearing about the tool. They also reported it would be interesting to use the media and social networks to present the tool.

"It's important that someone talks to me about the tool." (Woman 2)

Use of the tool

The women and the healthcare professionals agreed that the DA could be a useful lever for discussion during normal consultations or dedicated meetings.

"It might also help me to answer questions" (GP 6)

"Maybe it would help. It might have an influence and prompt the patient to ask questions that she wouldn't otherwise." (Woman 7)

"If it's during a meeting, we can put the figures on the screen. But then you have to have a discussion; if the woman has questions, you can explain why the information is presented this way." (Manager 1)

For health professionals, their help in commenting and discussing the tool with women is indispensable.

"I wouldn't let them read this by themselves, because... It's scary!" (GP 7).

The women were interested in receiving this type of information, along with explanations from their GP. However, they wanted to have the choice to use it or not with their doctor.

"We have an informal discussion, we can... pass on messages.... And then make a decision, saying I'm going or I'm not going. I weigh the pros and cons, that's it." (Woman 3)

Women	Healthcare professionals
Purpose of the tool	
To understand screening	To complete their knowledge
	To harmonize screening / professional practice
To prompt women to visit their GP	To refer women to their doctor
Characteristics of the tool	
With concrete numbers	Give statistical information to women
Easy to understand	Easy to use
Adaptable to different women's profiles	Design for every women
Presence of diagrams	Digital tool
Use of the tool	
A lever for discussion if desired by the woman	A lever for discussion
Have the choice to use it or not with their doctor	The health professional is essential to use the tool

Table 2: Consensus representations

Disagreements about the tool: balanced or biased information? (Table 3)

Opinions on breast cancer screening

The participants pointed out the sub-optimal effectiveness of breast cancer screening because of the harms associated with overdiagnosis and overtreatment.

"What surprised me was the ability to diagnose something that wasn't there and treat someone who didn't need it." (Woman 12, before the presentation of the tools)

"I am devastated by the results of the mammogram. Despite the double reading which I was inclined to give credit to..." (GP 3, before the presentation of the tools)

On the other hand, overtreatment could be seen as acceptable either because it applies to small tumours treatment or because it could save lives.

"They are cared for anyway, it's not useless…" (Woman 9, after the presentation of the tools)

"I don't play the game of overdiagnosis. [...] Honestly, I don't believe in overdiagnosis." (Radiologist 3, before the presentation of the tools)

Sometimes it is even difficult for professionals to distance themselves from their personal experience.

"If it's someone in my family or even me personally, I'd rather know about something and do a biopsy for nothing" (Gynaecologist 4, before the presentation of the tools),

Some participants considered the benefit-risk balance favourable, while others found it questionable. In this second case, the attitudes towards the tool differed according to the participants.

Shared decision-making

Many of the interviewees were not familiar with the concept of SDM in medicine.

"I didn't really have time to understand everything about this idea of shared decision-making…" (*Woman* 5)

"Support for shared decision-making? What's that?" (GP 5)

Some midwives and GPs were in favour of sharing comprehensive, balanced information about screening with women. Hence, DAs could be of value to these healthcare professionals in their daily practice. The healthcare professionals considered themselves to be "screening guides"; they wanted to provide women with reliable scientific data and enabling them to make an informed choice. Indeed, the healthcare professionals wanted to set out the facts and then accept the woman's decision. Furthermore, some of the women actively asked to receive comprehensive information from the healthcare professional so that they could decide for themselves whether or not to be screened.

"I explain things but will never force anyone to be screened - if they don't want to, it's their choice. […] It really is a shared decision and a mutual agreement with the patient." (Mifwife 2)

"It also depends on the cultural level, we will not work in the same way with a teacher, a nurse, or a woman who lives in the depths of her countryside" (GP 4)

"The doctor needs to explain [the screening] properly. I want to be able to weigh up the positive and negative aspects." (*Woman* 6)

Asymmetric information/ Paternalistic model

Some women wanted their physician to help them to understanding information about screening at every step in the process. Some women asked for selective information but considered that it was not up to them to decide whether or not to go for screening. Other women were afraid of receiving screening results; this is why they did not want to know everything about screening and the risks of cancer in particular.

"You can't let us choose because we don't understand anything about being screened or not" (Woman 2, after the presentation of the tools)

Some GPs, gynaecologists and radiologists had the same view about asymmetric information provision, with a focus on the benefits of screening. They considered that giving selected, positive information to women was essential for avoiding fear of screening.

"*We have to explain things quickly and only go into detail if they ask for more information. […] I don't know whether giving lots of impartial information is part of being a physician and above all part of making a diagnosis." (Radiologist 3, after the presentation of the tools)*

"If I tell them to get screened, they'll go without any hesitation." (Gynaecologist 1, before the presentation of the tools)

Convincing women to participate in screening

Some women thought the tool had to help healthcare professionals to convince everyone to participate in the screening. Similarly, some healthcare professionals stated that convincing women to enter a screening programme was the most important objective. They wanted to reassure women so that they would want to be screened.

"Providing women with information is essential for motivating them to get screened" (GP 4, before the presentation of the tools)

"Perhaps some women think of having a mammography without being prompted but not me - I wouldn't think of it. But if my doctor suggests it, I'll go!" (*Woman* 2, before the presentation of the tools)

Women	Healthcare professionals
Balanced or biased information?	
Shared decision making: Free decision to participate in screening or not after receiving appropriate information	Shared decision making: state the facts in a neutral manner and let the patient decide whether or not she wants to participate in

	screening
Paternalistic model: the doctor has the knowledge and must tell the women what to do	Asymmetric information: Convince the patient to participate in organized screening because of the responsibility of knowing as a health professional
Lack of interest for such a tool in view of the sufficient data already available	No need for such a tool

Table 3: Dissenting representations

DISCUSSION

Summary of the main findings

Both the women and the healthcare professionals stated that a DA could help to improve knowledge, harmonise medical practice and provide reliable, comprehensive information. They expected the DA's to catalyse discussion between the patient and the physician during a consultation. Women and healthcare professionals wanted an easy-to-use, intuitive interactive computer-based DA, with diagrams and graphics. Some of the health care professionals and some of the women wanted a DA that leads to SDM. Our study highlighted several limitations to the tool, such as a lack of familiarity with SDM, the risk of misuse (i.e. convincing women to participate in a screening programme without engaging an SDM process), and a preference for asymmetric, positive information.

Study strengths and limitations

The study had a number of strengths. Firstly, the investigators complied with the Consolidated Criteria for Reporting Qualitative Research throughout the study.[22~~14~~] Secondly, the data were provided by a diverse sample of both women (including socioeconomic level) and healthcare professionals; given that the risk-benefit balance for breast cancer screening is currently unclear, SDM appears to be the most ethical approach.[1~~1~~0] Thirdly, the data were triangulated by several experienced researchers. Fourthly, the samples of women and healthcare professionals were particularly diverse. Fifthly, nobody refused to participate to the study; we think that snowball sampling was a good way to engage participants.

However, we insufficiently assessed the degree of literacy of interviewed women. Only one woman answered "no" to the question designed to explore the level of literacy *"Do you need someone to help you understand prescriptions or medical information documents*

given by your doctor or pharmacist?". In the future, this may be important for adapting the DA for use with women of different literacy levels.

Comparison with the literature data

As mentioned above, the women interviewed in the present study here knew little or nothing about SDM. When the concept was explained, however, some women thought that it was of value. Similarly, a qualitative study of a DA for breast cancer screening in Spain found that women valued the receipt of information on the benefits and risks of screening.[2315] This seems to be true for all women, even though SDM interventions tend to benefit disadvantaged women (e.g. those with a lower level of literacy) more than those with higher literacy or educational/socioeconomic status.[2416] Becoming better informed might mean women are less likely to choose screening.

There is a growing body of evidence to show that DAs can improve value-congruent choices. In our study, the perception of screening seems to be modified by the presentation of the tools. Indeed, participants tend to cite the harms of screening more often after the tools have been presented to them. On the contrary, the presentation of the tools may have strengthened some participants in their conviction that screening was essential and its value indisputable. The latter found it questionable to tell women about the adverse effects of screening as this could reduce their motivation to undergo screening. These data are consistent with the literature. When compared with standard care in a broad variety of decision contexts, women exposed to DAs feel more knowledgeable, better informed, and clearer about their values; as such, they probably have a more active role in decision-making and a more accurate perception of risks.[121] Breast cancer screening DAs are known to improve levels of knowledge and promote informed decisions.[1017] For this

reason, DAs do not necessarily increase screening participation rates.[25~~18~~] For example, the large-scale Decideo study of breast cancer screening demonstrated that exposure to the DA reduced the participation rate by almost 2% because the women felt better informed.[~~1~~169] The above-mentioned Spanish qualitative study found that the provision of information on overdiagnosis is controversial among healthcare professionals.[2315~~15~~] An Australian study about overdetection in breast cancer screening recommended a staged approach to development and piloting of decision aids to further improve understanding of overdetection and support informed decision-making about screening.[260~~0~~] The creation and deployment of a DA tool must therefore be accompanied by training for healthcare professionals on SDM.

Several studies have evaluated quality criteria for DAs and the pitfalls to be avoided when designing this type of tool. A review on risk communication developed decision box prototypes, presented them to focus groups of GPs and patients, and explored the participants' perceptions.[27~~1~~] The model explored seven facets of the user experience: the DA had to be useful, usable (with effectiveness, efficiency and satisfaction), desirable, findable, accessible, credible and valuable (i.e. more frequent SDM). Accordingly, the present study exploring all of these aspects. We found that the study participants wanted an easy-to-use, intuitive, interactive, computer-based DA with diagrams and graphics. In a recent systematic review of the quality of DAs developed for women eligible for mammogram screening, the three best-rated dimensions of standard DAs were disclosure (transparency and conflicts of interest), information (the provision of sufficient detail), and outcome probabilities.[28~~22~~] The women and the healthcare professionals interviewed in our study also stated that those three dimensions were important to them. We considered that a future DA must focus on all six dimensions, so that women and healthcare professionals engage with the tool.

Implications for clinical practice

The present study explored expectations of a DA for SDM in breast cancer screening before its creation, from the future users themselves. Our work is the first step in the construction of this tool and will thus make it possible to avoid the pitfalls brought to light during the interviews. The future tool will allow adapting the information according to the age group of the patient. It's important to take time to acculturate healthcare professionals to the use of the DA to avoid its misuse. Our results should help to create an appropriate, added-value tool for use in this field and adapted to French context.

Conclusion

Stakeholders in organized breast cancer screening programmes (women, GPs, gynaecologists, midwives, radiologists and screening programme managers) have a broad range of expectations of a DA. The interviews showed that a DA could help to improve levels of knowledge, harmonise medical practice, and provide reliable, comprehensive information. Overall, the interviewees wanted an easy-to-use, intuitive, graphic-rich, interactive, computer-based and patient-centred DA. The idea of a DA was well received by the interviewees despite the fact the latter were unfamiliar with the concept of SDM. Along with the implementation of this type of tool, it would be useful to raise awareness of SDM among healthcare professionals and breast screening candidates. The present work was the first step in the DEDICACES study and will be followed by the creation and then validation of the first DA for SDM support in France's breast cancer screening programmes.

Data are available upon reasonable request: The deidentified transcripts of the interviews are available from the corresponding author (amelie.aim-eusebi@u-paris.fr). Their reuse is possible for a purpose similar to that of our study, otherwise a new consent from the interviewees will be necessary.

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Ethical approval: The study protocol was approved by a national ethics committee (Collège National des Généralistes Enseignants, Paris, France; reference: 07111732, CNGE. The data collection for the DEDICACES study has been registered with the French National Data Protection Commission (*Commission nationale de l'informatique et des libertés*, Paris, France; reference: 2099780).

Competing interests: None disclosed.

Authors' contributions: AAE, YR, BF, CR, XG, IAA and EF participated to the conception and the design of the study. AAE, YR, MH, AB, LB and EF analyzed the data. All authors contributed in writing the manuscript. All authors read and approved the final manuscript.

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Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

No	Item	Guide questions/description
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Ok p7	Interviewer/facilitator	Which author/s conducted the interview or focus group?
2. Ok p7	Credentials	What were the researcher's credentials? *E.g. PhD, MD*
3. Ok p7-p21	Occupation	What was their occupation at the time of the study?
4. Ok p7	Gender	Was the researcher male or female?
5. Ok p7	Experience and training	What experience or training did the researcher have?
Relationship with participants		
6. Ok p8	Relationship established	Was a relationship established prior to study commencement?
7. Ok p8	Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. *personal goals, reasons for doing the research*
8. Ok p7	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic*
Domain 2: study design		
Theoretical framework		
9. Ok p7	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis*
Participant selection		
10. Ok p7	Sampling	How were participants selected? *e.g. purposive, convenience, consecutive, snowball*
11. Ok p7	Method of approach	How were participants approached? e.g. *face-to-face, telephone, mail, email*
12. Ok p9	Sample size	How many participants were in the study?
13. Ok p7	Non-participation	How many people refused to participate or dropped out? Reasons?
Setting		
14. Ok p7	Setting of data collection	Where was the data collected? e.g. *home, clinic, workplace*
15. Ok p7	Presence of non-	Was anyone else present besides the

No	Item	Guide questions/description
	participants	participants and researchers?
16. Ok p9	Description of sample	What are the important characteristics of the sample? *e.g. demographic data, date*
Data collection		
17. Ok p8-Suppelmentary tables	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?
18. Ok p8	Repeat interviews	Were repeat interviews carried out? If yes, how many?
19. Ok p7	Audio/visual recording	Did the research use audio or visual recording to collect the data?
20. Ok p8	Field notes	Were field notes made during and/or after the interview or focus group?
21. Ok p9-10	Duration	What was the duration of the interviews or focus group?
22. Ok p8	Data saturation	Was data saturation discussed?
23. Ok p8	Transcripts returned	Were transcripts returned to participants for comment and/or correction?
Domain 3: analysis and findings		
Data analysis		
24. Ok p8	Number of data coders	How many data coders coded the data?
25. Ok p8	Description of the coding tree	Did authors provide a description of the coding tree?
26. Ok p8	Derivation of themes	Were themes identified in advance or derived from the data?
27. Ok p8	Software	What software, if applicable, was used to manage the data?
28. Ok p8	Participant checking	Did participants provide feedback on the findings?
Reporting		
29. Ok p10-16	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. *participant number*
30. Ok p17-20	Data and findings consistent	Was there consistency between the data presented and the findings?
31. Ok p10-16	Clarity of major themes	Were major themes clearly presented in the findings?
32. Ok p10-16	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes

Supplementary files

Table S1: Interview guide (women)

Hello, my name is [first name, family name]. I'm a researcher from the University of Paris 13 [or the University of Poitiers]. Thank you for finding the time for this interview. I am doing a research project about breast cancer screening and, in particular, the information about screening given to women. Our interview will be audio-recorded so that we can collect all the necessary data. Your personal information will be anonymized and then deleted at the end of the study.

1) [BREAST CANCER] **What do you know about breast cancer?**

(Prompt) What can you do to avoid breast cancer or to minimize the likelihood of developing it? To what extent do you feel concerned by breast cancer in your everyday life?

2) [BREAST CANCER SCREENING] **What do you know about breast cancer screening in France?**

(Prompt) What does screening mean for you? Do you feel concerned by breast cancer screening?
(Prompt) What do you think are the differences between organized screening programmes and individual screening?
(Prompt) What do you know about the effectiveness of screening?

3) [PARTICIPATION IN SCREENING] **Have you ever been screened for breast cancer? What did you think about that experience?**

(Prompt) How did you decide whether to get screened or not?
(Prompt) What information did you receive? Who gave you the information? How did you receive it?
(Prompt) How did you feel during the [first] screening?

4) [INFORMATION] **What information about breast cancer screening do you think you should have?**

(Prompt) What information would you have liked to have received but didn't?
(Prompt) How would you like to receive information about breast cancer screening? Who would you like to receive it from?
(Prompt) What format should this information have, in your opinion? Do you think that a healthcare professional should help you to decide?
(Prompt) You told me that you go for regular check-ups with a gynaecologist/general practitioner. Do you discuss breast cancer screening with him/her?
(Prompt) How would you raise the subject with him/her?
(Prompt) What do you expect from him/her?

5) [GENERAL IMPRESSION OF THE DECISION AIDS PRESENTED] **What do you think of these documents?** [*Show the interviewee the documents and let her look at them for 10 minutes or so*]

(Prompt) What do you think about these documents?
(Prompt) What did you get from the documents?
(Prompt) What have you understood from them? Are they easy to understand?
(Prompt) Were you already aware of this information about the advantages and risks [of screening]? If so, how did you receive the information?

6) [CONTENT AND FORMAT] **What do you think about the documents' content?**

(Prompt) And what about the format?
(Prompt) What would you change in these documents? (Prompt) What would you add to or remove from the documents? (Prompt) Which one do you prefer? Why? (Prompt) Which one is least meaningful for you? Why?

7) [SUMMARY OF THE SAMPLES SHOWN] **What do you think about these diagrams/figures /drawings?**

(Prompt) How did they enhance your knowledge about breast cancer screening? (Prompt) What do you think about the figures?
(Prompt) Do they help you to understand not only the advantages but also the risks associated with screening?
(Prompt) What other ways of presenting this information would you suggest?

8) [END PURPOSE OF THE INFORMATION] **How does this information influence your opinion about screening? Are there other things that you'd like to know before being able to make a decision?**

(Prompt) What additional information would you need?

Table S2: Interview guide for GPs

1) [BREAST CANCER SCREENING] **What do you think about breast cancer screening?**

2) [PROFESSIONAL ROLE] **What is your role in breast cancer screening?**

3) [REAL-LIFE EXAMPLE] **Can you tell me about a recent consultation during which you raised this subject with one of your [female] patients?**

(Prompt) How did the consultation go?

(Prompt) What information were you able to give to the patient?

(Prompt) What information were you unable to give to the patient?

(Prompt) In your opinion, what extra information would your patient liked to have received?

How was the decision made?

(Prompt) What was your role and what was the patient's role in the decision?

(Prompt) Did you form a consensus decision with the patient? How do you know that you did?

4) [THE TOOLS] **What do you think about using information tools and/or decision aids for shared decision-making during a consultation?**
And what about [the use of these tools and decision aids in] breast cancer screening?

(Prompt) What do you know about decision aids for shared decision-making? Have you already used any? If so, which ones? And why did you use them?
(Prompt) What do you understand by the term "decision aid"
(Prompt) What format should this type of tool have?
(Prompt) What medium should the tool use, in your opinion?

How could [a decision aid] be integrated into shared decision-making with the patient?

5) [Practical example] **What do you think about these documents?** *(Show the interviewee the documents and let him/her look at them for 10 minutes or so)*

(Prompt) What do you think about the documents' content? And about their form?
(Prompt) What did you learn from them?
(Prompt) Which do you prefer? Why?

(Prompt) Which one is least meaningful for you? Why?
(Prompt) What would you change in these documents?
(Prompt) What would you add to or remove from these documents?
(Prompt) What did you learn [from the documents] about breast cancer screening? Do they help you to better understand not only the advantages but also the risks associated with screening?
(Prompt) How could these documents be used in practice?
(Prompt) Do you think that they are useful for your practice?

Table S3: Interview guides for other healthcare professionals

Hello, my name is [first name, family name]. I'm a house officer in general medicine at the Paris 7 Faculty of Medicine. Thank you for finding the time for this interview. I am doing a research project about breast cancer screening. Our interview will be audio-recorded so that we can collect all the necessary data. Please be aware that there are no right or wrong answers and that your personal information will be anonymized and then deleted at the end of the study.

Background information on the interviewee: age, type of practice, time since qualification, etc.

INTERVIEW GUIDE – GYNAECOLOGISTS and MIDWIVES

1) [BREAST CANCER SCREENING] **How do you address breast cancer screening with your [female] patients?**

2) [REAL-LIFE EXAMPLE] **Can you tell me about a recent consultation during which you raised this subject with one of your patients?**
[*For midwives, if they do not address this subject*]: Why don't you raise the subject of breast cancer screening with your patients?

3) [FEELING] **In your opinion, what do patients feel about this screening?**

(Prompt) What type of information do they ask for?

4) [PROFESSIONAL ROLE] **What information do you give them? What type of document or medium do you use?**

5) [TOOLS] **What do you think about information tools and/or decision aids for shared decision-making with regard to breast cancer screening?**

6) [PRACTICAL EXAMPLE] **What do you think about these documents?** *(Show the interviewee the documents and let him/her look at him/her for 10 minutes or so)*

(Prompt) What type of tools would you like to have at your disposal for advising women about breast cancer screening?

INTERVIEW GUIDE – RADIOLOGISTS

1) [REAL-LIFE EXAMPLE] **What happens when a woman attends your clinic for a mammogram?**

(Prompt) What happens for individual screening and for organized screening?
(Prompt) Do you perform a clinical examination and have a pre-screening interview?
(Prompt) Does this screening create any problems for you (organisational aspects, interpretation, giving the results to the patient, etc.)?

2) [PROFESSIONAL ROLE] **What type of dialogue do you have with the patients?**

(Prompt) Is this before or after you have analyzed the mammogram?
(Prompt) Do you wait for the second analysis?

3) [FEELING] **In your opinion, how do patients feel about this screening?**

(Prompt) If patients ask for more information, what type of tools do you use or would like to use?

4) [PRACTICAL EXAMPLE] **What do you think about these documents?** *(Show the interviewee the documents and let him/her look at them for 10 minutes or so)*

INTERVIEW GUIDE – SCREENING PROGRAMME MANAGER

1) [REAL-LIFE EXAMPLE] **How do you get involved in organized breast cancer screening?**

2) [PROFESSIONAL ROLE] **What sort of information should breast cancer screening candidates be given?**

(Prompt) What do you think about the official document used throughout France?
(Prompt) Have you developed other ways of informing patients?

3) [FEELING **In your opinion, how do patients feel about this screening?**

4) [BREAST CANCER SCREENING] **What do you think about shared decision-making in breast cancer screening?**

5) [PRACTICAL EXAMPLE] **What do you think about these documents?** *(Show the interviewee the documents and let him/her look at them for 10 minutes or so)*

Table S4: Examples of information tools and decision aids

Tool 1

What is screening?

Screening means examining a group of people in order to detect disease or to find people at increased risk of disease.

In many countries, women between 50 and 69 years of age are offered an X-ray examination of the breasts – screening with mammography - every second or third year. The purpose of the screening examination is to find women who have breast cancer in order to offer them earlier treatment.

Screening with mammography has both benefits and harms. The aim of this leaflet is to help each woman weigh up the pros and cons in the light of her own values and preferences, in order that she can make a personal decision whether she wishes to attend.

If nothing abnormal is found by screening, it makes the woman feel reassured that she is healthy. But almost all women feel healthy before they are invited to screening. Furthermore, the invitation itself may cause insecurity. Therefore, screening creates both security and insecurity.

Benefits

Reduced risk of dying from breast cancer - Regular screening with mammography cannot prevent breast cancer, but it can perhaps reduce the risk of dying from breast cancer. A systematic review of the randomised trials of mammography screening found that:

> *If 2000 women are screened regularly for 10 years, one will benefit from screening, as she will avoid dying from breast cancer because the screening detected the cancer earlier.*

Since these trials were undertaken, treatment of breast cancer has improved considerably. Women today also seek medical advice much earlier than previously, if they have noted anything unusual in their breasts. In addition, diagnosis and treatment have been centralised in many countries and are now provided by teams of breast cancer experts.

Because of these improvements, screening is less effective today and newer studies suggest that mammography screening is no longer effective in reducing the risk of dying from breast cancer (see *Documentation for the facts and figures* below).

Screening does not reduce the overall risk of dying, or the overall risk of dying from cancer (including breast cancer).

Harms

Overdiagnosis and overtreatment - Some of the cancers and some of the early cell changes (carcinoma in situ) that are found by screening grow so slowly that they would never have developed into a real cancer. Many of these screen-detected "pseudo-cancers" would even have disappeared spontaneously, if they had been left alone, without treatment.

Since it is not possible to tell the difference between the dangerous and the harmless cell changes and cancers, all of them are treated. Therefore, screening results in treatment of many women for a cancer disease they do not have, and that they will not get. Based on the randomised trials, it appears that:

> *If 2000 women are screened regularly for 10 years, 10 healthy women will be turned into cancer patients and will be treated unnecessarily. These women will have either a part of their breast or the whole breast removed, and they will often receive radiotherapy, and sometimes chemotherapy. Treatment of these healthy women increases their risk of dying, e.g. from heart disease and cancer.*
>
> *Unfortunately, some of the early cell changes (carcinoma in situ) are often found in several places in the breast. Therefore, the whole breast is removed in one out of four of these cases, although only a minority of the cell changes would have developed into cancer.*

More extensive surgery and aftertreatment - For women diagnosed at screening with a small “true” cancer, the operation and aftertreatment may be less extensive than if the cancer had been detected at a later time. However, as screening also leads to overdiagnosis and subsequent overtreatment of healthy women,

more women in total will have a breast removed when there is screening than if there had not been screening. Also, more women will receive radiotherapy unnecessarily.

False alarm - If the X-ray shows something that might be cancer, the woman is recalled for additional investigations. In some cases it turns out that what was seen on the X-ray was benign, and that it was therefore a false alarm.

> *If 2000 women are screened regularly for 10 years, about 200 healthy women will experience a false alarm. The psychological strain until it is known whether or not there is a cancer can be severe. Many women experience anxiety, worry, despondency, sleeping problems, changes in the relationships with family, friends and acquaintances, and a change in sex drive. This can go on for months, and in the long term some women will feel more vulnerable about disease and will see a doctor more often.*

Pain at the examination - The breast is squeezed flat between two plates while an X-ray is taken. It only takes a moment, but about half of the women find it painful.

False reassurance - Mammography screening cannot detect all cancers. It is important, therefore, that the woman sees a doctor if she finds a lump in her breast, even if she has had a mammogram recently.

Gøtzsche PC, Hartling OJ, Nielsen M, et al. Mammography screening leaflet. Copenhagen: Nordic Cochrane Centre 2012. https://www.cochrane.dk/mammography-screening-leaflet (accessed Janv 2022)

Tool 2

Should I be screened with mammography for breast cancer?

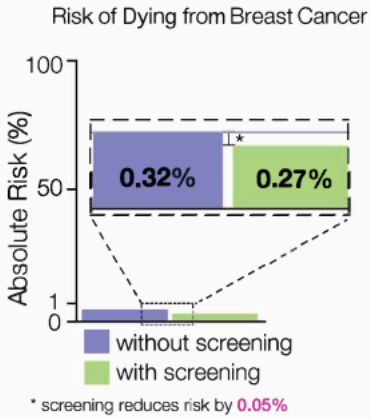
For women between 40 and 49 years of age:

Among women who do not screen, the risk of dying from breast cancer is:	**1 in 313**
With regular screening your risk of dying of breast cancer is:	**1 in 370**
However, with regular screening:	
... your risk of having a false positive mammogram requiring further screening is:	**1 in 3**
... your risk of having a biopsy is:	**1 in 28**
... your risk of having part or all of a breast removed unnecessarily is:	**1 in 200**

Be informed!

You may hear the risks or benefits of breast cancer screening described as either **absolute** or **relative**. But what does all this mean and how does it apply to you?

The main difference is that absolute risk takes into consideration the fact that whether or not you get screened or treated, you still have a baseline risk of dying of breast cancer: **1 in 313** or **0.32%**. With regular screening that risk changes to: **1 in 370** or about **0.27%**. Relative risk does not consider baseline risk in the same way and may lead to confusion about how regular screening reduces risk.



The absolute risk is simply the difference in risk between regular screening (0.27%) and no screening (0.32%).
0.32% - 0.27% = 0.05%
Therefore screening in women aged 40-49 reduces your ***absolute risk*** of dying of breast cancer by **0.05%**.
So the ***absolute benefit*** of screening is **0.05%**.

Relative risk only looks at the reduction in risk as a proportion of the total risk (so it doesn't consider that you are already at risk of cancer, this can lead to larger values than absolute risk).
0.05%/0.32% = 15%
Thus, screening in women aged 40-49 reduces your ***relative risk*** of dying of breast cancer by **15%**. So the ***relative benefit*** of screening is **15%**.

So how does this translate into actual numbers? Among 100 000 women aged 40 to 49 who are:

Screened **EVERY** 2 years for 11 years:
- **270** would die of breast cancer
- **32 700** would experience a false alarm
- **3600** would have a biopsy
- **500** would have part or all of a breast removed without having cancer
- **50** would escape a breast cancer death

NOT screened for 11 years:
- **320** would die of breast cancer
- **99 680** would not

For more info visit:
http://www.canadiantaskforce.ca

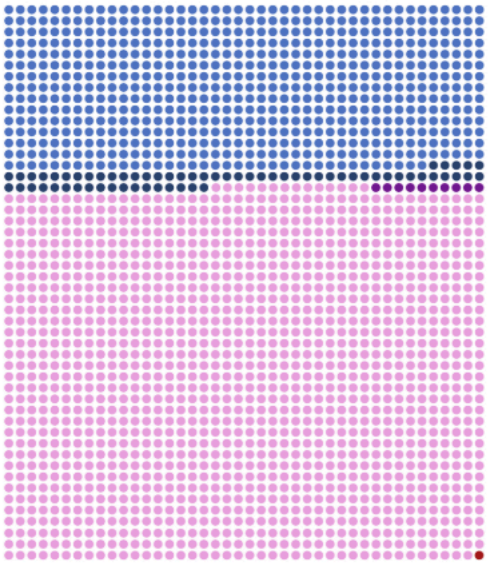
Should I be screened with mammography for breast cancer?

Absolute Benefit of Screening with Mammography

If we wanted to describe the previous information in regards to the effect on an individual woman then we can look at what would occur in a base of 2100 women instead of 100 000.

In the graphic below, each dot represents 1 woman (● = 1 woman)

If we screened **2100** women, aged 40-49 years, at average risk of breast cancer every two years for 11 years...



...about **700** women would experience a false positive mamogram requiring further imaging...

...**75** of these women would have a biopsy, all to confirm that they do not have breast cancer

...at least **10** women would have part or all of a breast unnecessarily removed and bear the burden of over- diagnosis

...**1** woman would escape a breast cancer death

For more information visit: **http://www.canadiantaskforce.ca**

Should I be screened with mammography for breast cancer?

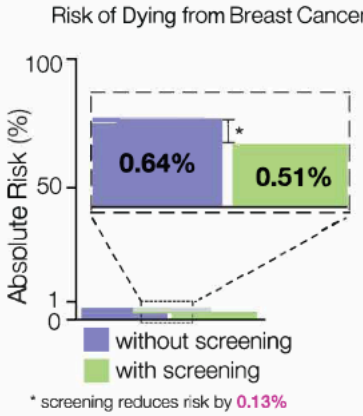
For women between 50 and 69 years of age:

Among women who do not screen, the risk of dying from breast cancer is:	**1 in 155**
With regular screening your risk of dying of breast cancer is:	**1 in 196**
However, with regular screening:	
... your risk of having a false positive mammogram requiring further screening is:	**1 in 4**
... your risk of having a biopsy is:	**1 in 28**
... your risk of having part or all of a breast removed unnecessarily is:	**1 in 200**

Be informed!

You may hear the risks or benefits of breast cancer screening described as either **absolute** or **relative**. But what does all this mean and how does it apply to you?

The main difference is that absolute risk takes into consideration the fact that whether or not you get screened or treated, you still have a baseline risk of dying of breast cancer: **1 in 155** or **0.64%**. With regular screening that risk changes to: **1 in 196** or about **0.51%**. Relative risk does not consider baseline risk in the same way and may lead to confusion about how regular screening reduces risk.



The absolute risk is simply the difference in risk between regular screening (0.47%) and no screening (0.64%).
0.64% - 0.51% = 0.13%
Therefore screening in women aged 50-69 reduces your ***absolute risk*** of dying of breast cancer by **0.13%**.
So the ***absolute benefit*** of screening is **0.13%**.

Relative risk only looks at the reduction in risk as a proportion of the total risk (so it doesn't consider that you are already at risk of cancer, this can lead to larger values than absolute risk).
0.13%/0.64% = 21%
Thus, screening in women aged 50-69 reduces your ***relative risk*** of dying of breast cancer by **21%**. So the ***relative benefit*** of screening is **21%**.

So how does this translate into actual numbers? Among 100 000 women aged 50 to 69 who are:

Screened **EVERY** 2 years for 11 years:
- **510** would die of breast cancer
- **28 200** would experience a false alarm
- **3700** would have a biopsy
- **500** would have part or all of a breast removed without having cancer
- **138** would escape a breast cancer death

NOT screened for 11 years:
- **640** would die of breast cancer
- **99 360** would not

For more info visit:
http://www.canadiantaskforce.ca

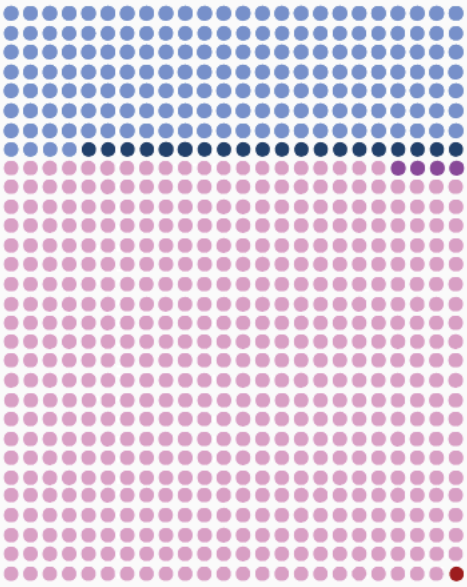
Should I be screened with mammography for breast cancer?

Absolute Benefit of Screening with Mammography

If we wanted to describe the previous information in regards to the effect on an individual woman then we can look at what would occur in a base of 720 women instead of 100 000.

In the graphic below, each dot represents 1 woman (● = 1 woman)

If we screened **720** women, aged 50-69 years, at average risk of breast cancer every two years for 11 years...



. .. about **204** women would experience a false positive mammogram requiring further imaging...

...**26** of these women would have a biopsy, all to confirm that they do not have breast cancer

...at least **4** women would have part or all of a breast unnecessarily removed and bear the burden of over- diagnosis

...**1** woman would escape a breast cancer death

For more information visit: **http://www.canadiantaskforce.ca**

Should I be screened with mammography for breast cancer?

For women between 70 and 74 years of age:

Among women who do not screen, the risk of dying from breast cancer is:	**1 in 146**
With regular screening your risk of dying of breast cancer is:	**1 in 217**

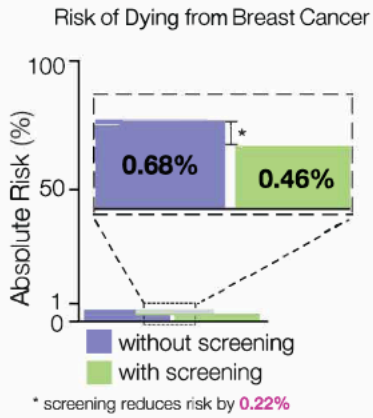
However, with regular screening:

... your risk of having a false positive mammogram requiring further screening is:	**1 in 5**
... your risk of having a biopsy is:	**1 in 38**
... your risk of having part or all of a breast unnecessarily removed is:	**1 in 200**

Be informed!

You may hear the risks or benefits of breast cancer screening described as either **absolute** or **relative**. But what does all this mean and how does it apply to you?

The main difference is that absolute risk takes into consideration the fact that whether or not you get screened or treated, you still have a baseline risk of dying of breast cancer: **1 in 146** or **0.68%**. With regular screening that risk changes to: **1 in 217** or **0.46%**. Relative risk does not consider baseline risk in the same way and may lead to confusion about how regular screening reduces risk.



The absolute risk is simply the difference in risk between regular screening (0.46%) and no screening (0.68%).
0.68% - 0.46% = 0.22%
Therefore screening in women aged 70-74 reduces your ***absolute risk*** of dying of breast cancer by **0.22%**.
So the ***absolute benefit*** of screening is **0.22%**.

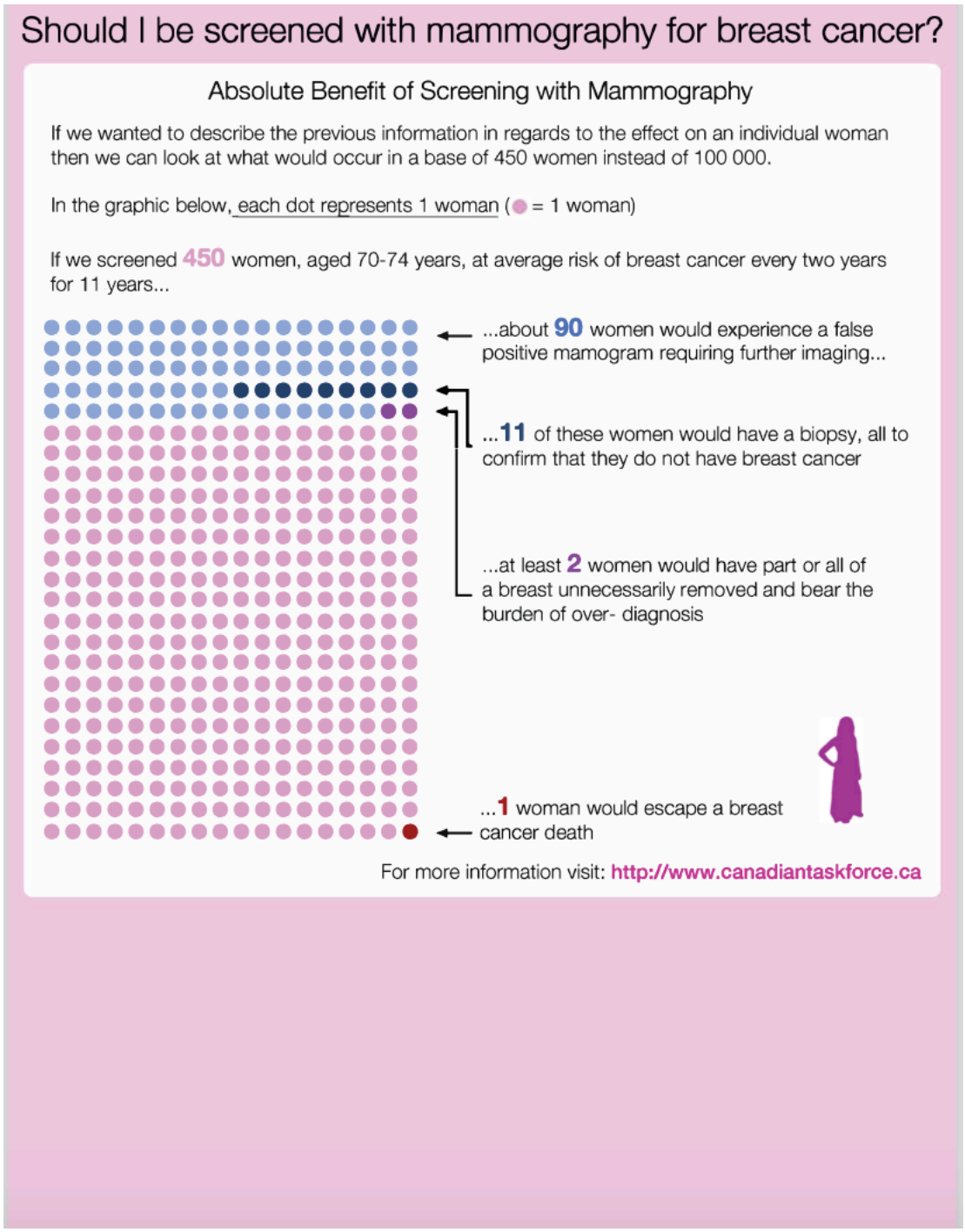
Relative risk only looks at the reduction in risk as a proportion of the total risk (so it doesn't consider that you are already at risk of cancer, this can lead to larger values than absolute risk).
0.22%/0.68% = 32%
Thus, screening in women aged 70-74 reduces your ***relative risk*** of dying of breast cancer by **32%**. So the ***relative benefit*** of screening is **32%**.

So how does this translate into actual numbers? Among 100 000 women aged 70 to 74 who are:

Screened **EVERY** 2 years for 11 years:
- **460** would die of breast cancer
- **21 200** would experience a false alarm
- **2600** would have a biopsy
- **500** would have part or all of a breast removed without having cancer
- **222** would escape a breast cancer death

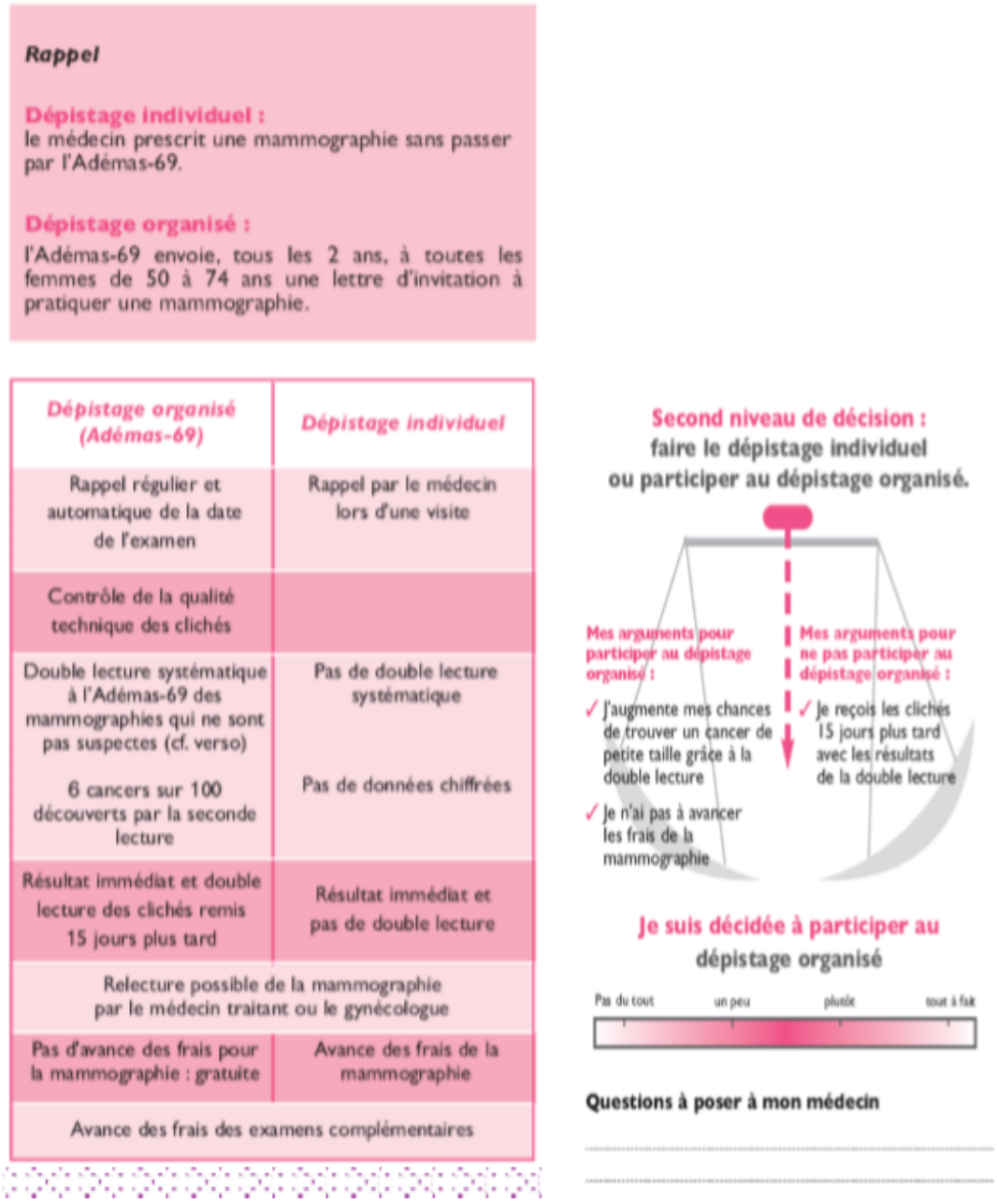
NOT screened for 11 years:
- **680** would die of breast cancer
- **99 320** would not

For more info visit:
http://www.canadiantaskforce.ca



Canadian Task Force on Preventive Health Care. Breast Cancer (2011). Montreal: CTFPHC 2011. https://canadiantaskforce.ca/tools-resources/breast-cancer-2/ (accesses Janv 2022)

Tool 3



Rappel

Dépistage individuel :
le médecin prescrit une mammographie sans passer par l'Adémas-69.

Dépistage organisé :
l'Adémas-69 envoie, tous les 2 ans, à toutes les femmes de 50 à 74 ans une lettre d'invitation à pratiquer une mammographie.

Dépistage organisé (Adémas-69)	*Dépistage individuel*
Rappel régulier et automatique de la date de l'examen	Rappel par le médecin lors d'une visite
Contrôle de la qualité technique des clichés	
Double lecture systématique à l'Adémas-69 des mammographies qui ne sont pas suspectes (cf. verso)	Pas de double lecture systématique
6 cancers sur 100 découverts par la seconde lecture	Pas de données chiffrées
Résultat immédiat et double lecture des clichés remis 15 jours plus tard	Résultat immédiat et pas de double lecture
Relecture possible de la mammographie par le médecin traitant ou le gynécologue	
Pas d'avance des frais pour la mammographie : gratuite	Avance des frais de la mammographie
Avance des frais des examens complémentaires	

Second niveau de décision :
faire le dépistage individuel ou participer au dépistage organisé.

Mes arguments pour participer au dépistage organisé :
- ✓ J'augmente mes chances de trouver un cancer de petite taille grâce à la double lecture
- ✓ Je n'ai pas à avancer les frais de la mammographie

Mes arguments pour ne pas participer au dépistage organisé :
- ✓ Je reçois les clichés 15 jours plus tard avec les résultats de la double lecture

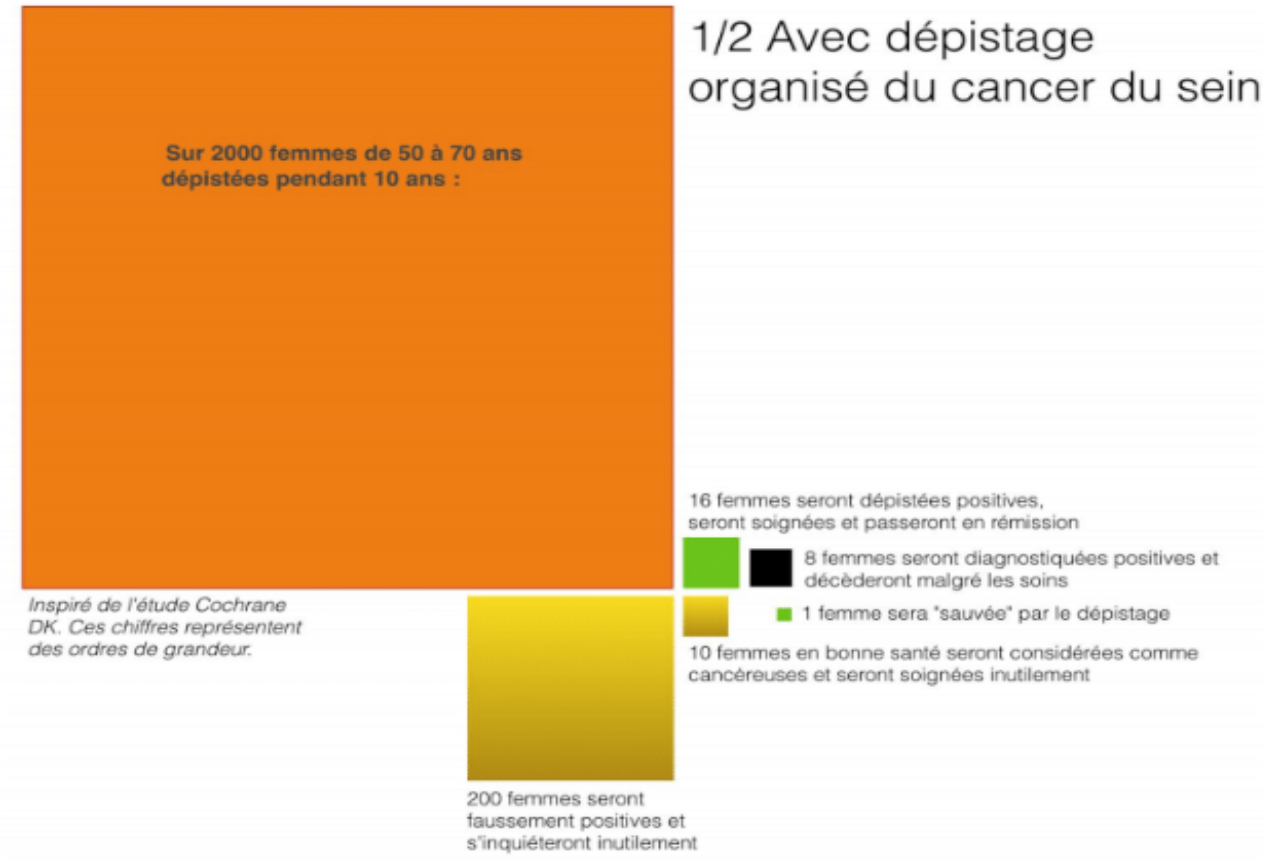
Je suis décidée à participer au dépistage organisé

Pas du tout | un peu | plutôt | tout à fait

Questions à poser à mon médecin

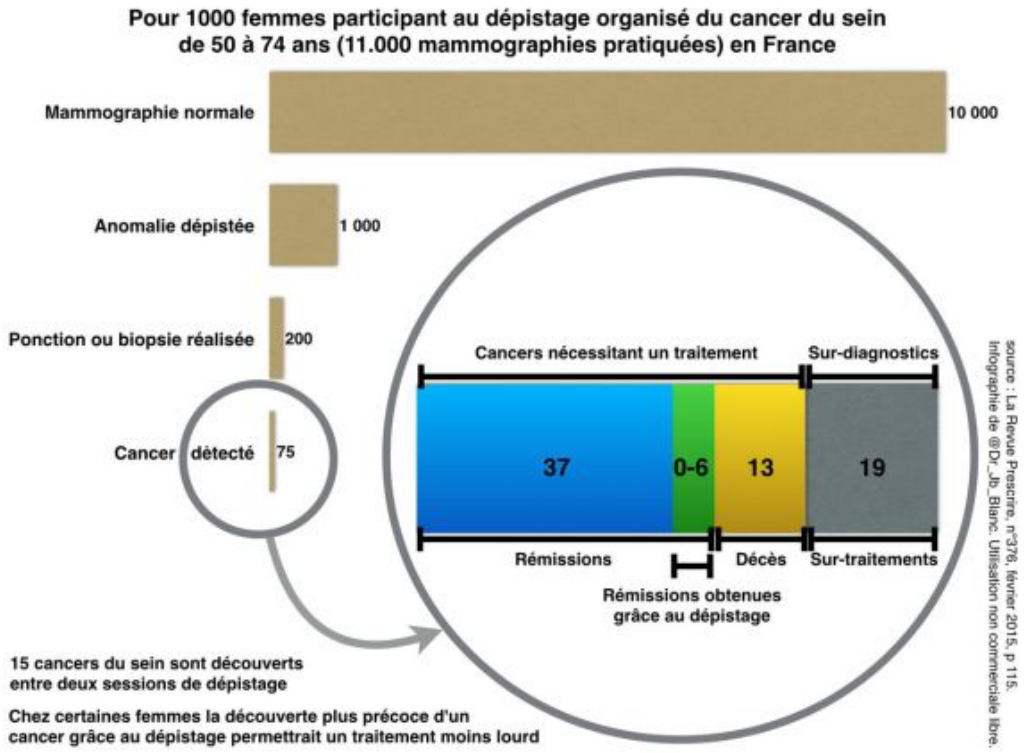
Bourmaud A, Soler-Michel P, Oriol M, et al. Decision aid on breast cancer screening reduces attendance rate: results of a large-scale, randomized, controlled study by the DECIDEO group. Oncotarget 201615;7(11):12885-92.

Tool 4



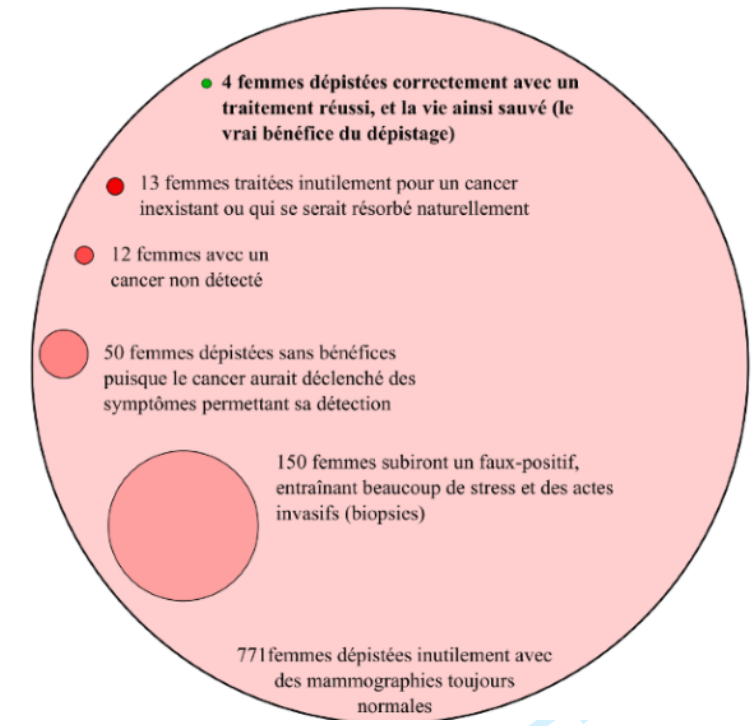
Blanc JB. Comment pratiquer la prise de décision partagée en médecine générale? [Mémoire en vue du diplôme inter universitaire de requalification à la pratique de la médecine générale]. Université de Rennes1 2015. https://sites.google.com/site/ladecisionpartagee/home (accesses Janv 2022)

Tool 5



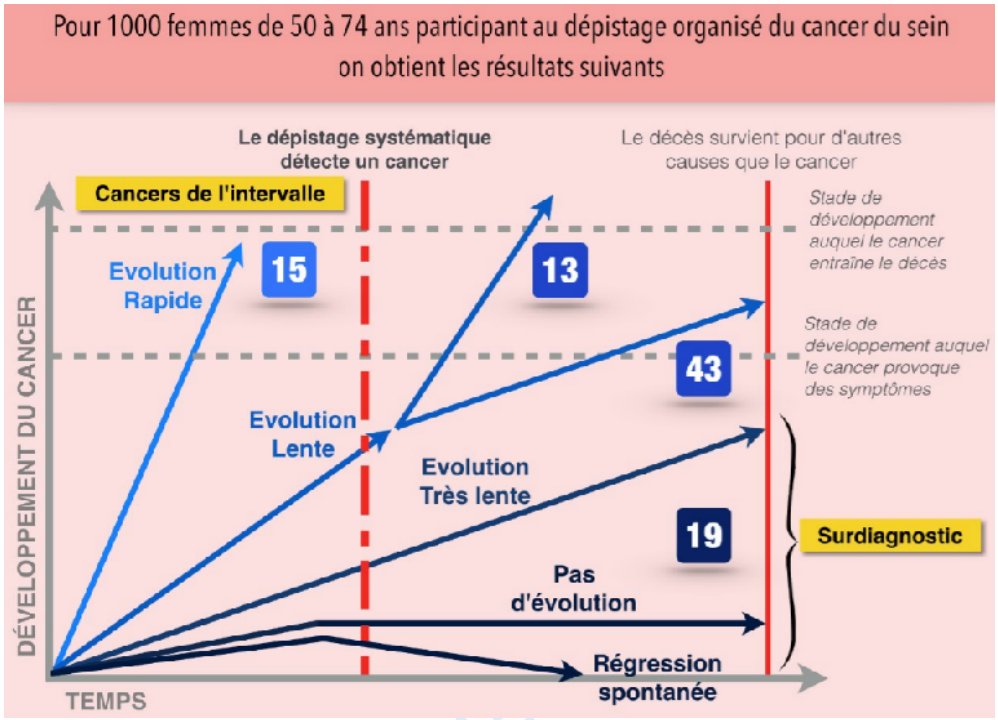
Prescrire. Partager avec les femmes les informations utiles pour décider de participer ou non au dépistage des cancers du sein. Rev Prescrire 2015;35(376):115.

Tool 6



Dur à avaler. La mammographie de dépistage pour le cancer du sein : inutile et dangereuse ? Noumea: Dur à avaler 2016. https://www.dur-a-avaler.com/la-mammographie-de-depistage-pour-le-cancer-du-sein-inutile-et-dangereuse/ (accessed Janv 2022)

Tool 7



PDQ® Screening and Prevention Editorial Board. PDQ Breast Cancer Screening. Bethesda, MD: National Cancer Institute 2021. https://www.cancer.gov/types/breast/patient/breast-screening-pdq (accessed Janv 2022)

BMJ Open

What do women and healthcare professionals expect of decision aids for breast cancer screening? A qualitative study in France.

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Keywords:	QUALITATIVE RESEARCH, Breast tumours < ONCOLOGY, PRIMARY CARE, PREVENTIVE MEDICINE

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What do women and healthcare professionals expect of decision aids for breast cancer screening? A qualitative study in France.

Authors: Aïm-Eusébi A[a], Ruelle Y[b,c,d,e], Frèche B[f], Houllemare M[b], Bonillo A[f], Bouaziz L[a], Rat C[e,g,h], Gocko X[h,i,j], Cerisey C[c], Aubin-Auger I[a], Ferrat E[e,k,l], DEDICACES Group, the French National College of General Practitioners.

a. Université de Paris, Département de Médecine Générale, F-75006, Paris, France
b. Université Sorbonne Paris Nord, Département Universitaire de Médecine Générale, DUMG, F-93430, Villetaneuse, France
c. Université Sorbonne Paris Nord, Laboratoire Éducations et Pratiques de Santé, LEPS, UR 3412, F-93430, Villetaneuse, France
d. Centres municipaux de santé universitaires, F-93500, Pantin, France
e. Conseil Scientifique du Collège National des Généralistes Enseignants (CNGE), F-75011, Paris, France
f. Département de Médecine Générale, Faculté de Médecine et Pharmacie, Université de Poitiers, F-86000, Poitiers, France
g. Université de Nantes, Département de Médecine Générale, F-44007, Nantes, France
h. Département de Médecine Générale, Faculté de Médecine Jacques-Lisfranc, Université Jean-Monnet Saint-Étienne, F-42023, Saint-Étienne, France
i. Laboratoire SNA-EPIS EA4607, Université Jean-Monnet Saint-Étienne, F-42023, Saint-Étienne, France
j. HESPER Health Services and Performance Research EA7425, Université Claude Bernard Lyon 1, F-69100 Villeurbanne, France
k. Univ Paris Est Creteil, INSERM, IMRB, CEpiA Team, F-94010 Creteil, France

l. Université Paris-Est Créteil, Département de Médecine Générale, F-94010 Creteil, France

Corresponding Author:

Dr. Amélie Aïm-Eusébi

Université de Paris, Département de Médecine Générale, F-75006, Paris, France

186 boulevard Ney, 75018, Paris, France

amelie.aim-eusebi@u-paris.fr

Word count: 3885

ABSTRACT

Objective: Breast cancer screening decision aids (DAs) are designed to help women decide whether or not to participate in mammography-based programs. We aimed to explore women's and healthcare professionals' expectations of a breast cancer screening DA, as part of the French DEDICACES study.

Methods: This French qualitative study was based on semi-structured, individual interviews with women from the general population, general practitioners (GPs), midwives, gynaecologists, radiologists, and screening centre managers. Sampling was purposive and used diversification criteria. The inductive analysis was based on grounded theory.

Results: Between April 2018 and May 2019, we interviewed 40 people: 13 women, 14 GPs, 4 gynaecologists, 3 midwives, 3 radiologists, and 3 screening centre managers. The women and the healthcare professionals considered that a DA could help to improve levels of knowledge, harmonise medical practice, and provide reliable, comprehensive information. Overall, the interviewees wanted an easy-to-use, intuitive, graphic-rich, interactive, computer-based, patient-centred DA. Use of the DA might be limited by a lack of familiarity with SDM, the risk of misuse, and a preference for asymmetric positive information.

Conclusion: The present results are likely to facilitate the development of the first validated tool for SDM support in French breast cancer screening programs.

KEYWORDS: breast cancer screening, decision aid, shared decision-making, primary health care, qualitative research

ARTICLE SUMMARY

Strengths and limitations of this study

- Qualitative study, inspired by grounded theory, that complied with the Consolidated Criteria for Reporting Qualitative Research throughout the study.
- The interview guides explored perceptions, attitudes and expectations related to breast cancer, diagnosis, prevention, screening, and the decision aids.
- The data were provided by individual interviews in a diverse sample of both women and healthcare professionals.
- The degree of literacy of interviewed women was insufficiently assessed.
- Several experienced researchers triangulated the data.

BACKGROUND

Breast cancer is the most common cancer worldwide and constitutes the leading cause of cancer death among women.[1] Most European countries organize mammogram-based breast cancer screening programs.[2] The European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis indicate that a significant decrease in breast cancer mortality requires a participation rate of at least 70%.[2] In France, free organized screening every two years has been available (for women between the ages of 50 and 74) since 2004. A prescription from a general practitioner (GP) or another physician is not required for screening; women can be screened by a radiologist upon presentation of an invitation sent by the local screening coordination centre. However, the participation rate in France's organized screening programme was only 50% in 2018.[3] Even though the results of large, randomized, controlled trials have highlighted a significantly lower breast cancer mortality rate among women undergoing regular mammogram screening,[4-6] the risk-benefit balance is subject to debate.[7, 8] It has been suggested that shared decision-making (SDM) can help women to weigh up the known benefits and risks of breast cancer screening.[9-12]

By providing information on options and outcomes, decision aids (DAs) can help women to decide whether or not to participate in breast cancer screening. A recent review reported that people exposed to DAs feel more knowledgeable, better informed, and clearer about their values and they probably have a more active role in decision making and more accurate risk perceptions.[13] DAs therefore support the SDM. France currently lacks a breast cancer screening DA that women can use when consulting a visit with their health provider. The French "*Decision Partagée dans le Cadre du Dépistage du Cancer du Sein*" (DEDICACES) study aims at building an online DA for SDM in breast cancer screening that can be used by both women and healthcare professionals preferentially during a consultation, in compliance with the International Patient Decision Aid Standards.[14]

OBJECTIVE

The objective of our study was to explore women's and healthcare professionals' expectations of a breast cancer screening DA.

METHODS

Study design

This qualitative study, inspired by grounded theory, was based on semi-structured, individual interviews of women, GPs, midwives, gynaecologists, radiologists, and local screening programme managers in three areas of France (the *Oise*, *Val d'Oise* and *Alpes de Haute-Provence* counties). We perform individual interviews because cancer is a delicate subject for some people. Interviews were conducted in French - the mother tongue of all participants. The team of investigators was composed of eight researchers, female and male, trained to lead interviews and perform qualitative analysis *(AAE, EF, BF, AB, MH, LB, IAA,* and *YR*). All semi-structured interviews were led by an investigator. MH and AB led women's interviews; AB and MH led GP's interviews and LB led healthcare professionals' interviews.

Participant sampling

The interviewed GPs were recruited from a list provided by the French national public health insurance system (CNAM). The women were recruited by snowball sampling or through their GPs (but not those interviewed for the study). Other healthcare professionals were recruited using snowball sampling. Sampling was purposive for all types of participants. Nobody refused to participate. Diversification criteria were applied in order to obtain a broad range of participants and points of view. Diversification criteria were discussed with the research team for all participants and were completed during data collection (Table 1). Each interviewee gave her/his verbal and written informed consent prior to inclusion.

Data collection

Audiotaped, semi-structured interviews were held face-to-face at the healthcare professional's office or at home. One of the midwives and one of the screening programme managers underwent a phone interview.

The interview guides, developed by the investigators, were similar between the groups interviewed but each had some specificities. They explored perceptions, attitudes and expectations related to breast cancer, diagnosis, prevention, screening, and the DA. In the second part of the interview, published DAs were shown as examples (15-21). This enabled participants to state their opinions and expectations with regard to these tools and to describe the tools' strengths and limitations. Field notes were made during and after the interviews. A woman with history of breast cancer helped to build the interview guide of women's and GPs' groups and pilot tested it. The interview guide evolved during the study (Supplementary Tables S1 to S4).

Data analysis

All interviews were transcribed verbatim and subjected to an inductive analysis based on grounded theory to analyse social interactions.[22] Next, the interview data were coded jointly by two pairs of investigators (MH+AB, AAE+LB) and, in order to enhance inter-coder reliability, individually by four other investigators (BF, EF, YR, and IA). We used MAXQDA® software (version 12, VERBI Software, Consult-Sozialforschung GmbH, Berlin, Germany) for the analysis. Similarities and differences in the codes from the interviews were assessed and discussed by all the investigators until a consensus was formed. Data collection was achieved for each kind of participants after two interviews without new codes.

Patient Involvement

A patient was involved in the design of the study. She was a woman with history of breast cancer and helped to build the interview guide of women's group. She also participated in the evolution of the guide throughout the study. She had access to the results of the study.

RESULTS

Between April 2018 and May 2019, we interviewed 40 people: 13 women, 14 GPs, 4 gynaecologists ("G" in the verbatim below), 3 midwives (M), 3 radiologists (R) and 3 screening programme managers (Table 1). The mean duration of the interviews was 55 minutes and 27 seconds. We used the term "healthcare professionals" to describe the GPs, gynaecologists, midwives, radiologists, and screening programme managers.

Participants	All participants (N = 40)	Women (N = 13)	GPs (N = 14)	Other healthcare profesionnals* (N = 13)
Age mean (range)	53.9 (29-75)	62.9 (42-75)	49.6 (34-68)	49.1 (29-70)
Gender Female N (%)	29 (72.5)	13 (100)	8 (57.1)	8 (61.5)
Practices	(N = 27)			
Group	18	-	8	10
Solo	9	-	6	3
Educational level				
Primary school	2	2	0	0
Secondary school	7	7	0	0
Higher education	31	4	14	13
Area				
Rural	8	3	5	0
Semi-rural	10	6	4	0
Urban	22	4	5	13
Previous mammography (Y/N)	-	8/5	-	-

History of breast cancer (Y/N)	-	2/11	-	-
Interview mean duration in minutes (range)	55 (7-120)	69 (27-120)	69 (41-118)	27 (7-57)

Table 1: Characteristics of the study participants
* Gynaecologists, midwives, radiologists screening, programme manager

Purpose of the tool

Women saw the tool as an aid to understand breast cancer screening.

"It would be great to have information about breast cancer: things would be clearer for us." (Women 3)

Healthcare professionals expected the DA to improve their own level of knowledge about breast cancer and breast cancer screening.

"I need objective data that I can rely on when discussing screening with women." (GP 6)

Healthcare professionals were interested in a tool that could help them to harmonise their practice with regard to breast cancer screening.

"It would be great to have that sort of tool. It would help to harmonise things." (Midwife 3)

The interviewees stated that the decision support tool had to encourage women to visit their doctor and discuss breast cancer screening or to go to a local screening program centre.

"An information poster might prompt women to consult their doctor." (Woman 1)

"[An information leaflet] would be useful if women have questions about mammography and breast cancer screening; they could discuss things with their GP." (GP 5)

What kind of DA do people want?

The DA's characteristics

The women and the healthcare professionals wanted the DA to be quick to access and easy to use and understand DA.

"It has to be easy, visual, and simple […] – I'd rather have that sort of tool" (GP 10)

"The information has to be concise because otherwise we'll throw it away […]. It would be better to stick to something short and well targeted, with eye-catching stuff…" (Woman 4)

The interviewees expected to have an intuitive tool with diagrams and graphics – something that was almost "fun" to read. The healthcare professionals wanted the statistical information to be of value for the women.

"It's good because there are different sorts of information - numbers but also diagrams; Visual things like that are more meaningful" (Woman 6)

The women and the healthcare professionals also wanted a tool that was designed for all women, regardless of the latter's level of literacy.

"Screening programs are intended to reduce social inequality, rather than increase it" (Manager 3)

"The tool's characteristics will depend on who it's targeting. It depends on each woman." (Woman 4)

The medium used for the DA

The women and healthcare professionals suggested that the DA was best presented on a computer or a smartphone or, failing, that on paper (i.e. a leaflet or poster). A video format might be of value for a DA on a computer or a smartphone.

The GPs suggested using the DA as a video or poster to disseminate the information in the medical waiting room. They also suggested that the tool could be directly integrated in their medical software.

"It has to be something visual, something integrated into software. […] It needs to be easy to access." (GP 4)

Dissemination of the DA

The healthcare professionals suggested that the DA could be shared over the Internet.

"These days, having an instructive website would be more relevant than handing out leaflets." (Midwife 1)

The interviewees stated that word of mouth was also the best means of hearing about the tool. They also reported it would be interesting to use the media and social networks to present the tool.

"It's important that someone talks to me about the tool." (Woman 2)

Use of the tool

The women and the healthcare professionals agreed that the DA could be a useful lever for discussion during normal consultations or dedicated meetings.

"It might also help me to answer questions" (GP 6)

"Maybe it would help. It might have an influence and prompt the patient to ask questions that she wouldn't otherwise." (Woman 7)

"If it's during a meeting, we can put the figures on the screen. But then you have to have a discussion; if the woman has questions, you can explain why the information is presented this way." (Manager 1)

For health professionals, their help in commenting and discussing the tool with women is indispensable.

"I wouldn't let them read this by themselves, because... It's scary!" (GP 7).

The women were interested in receiving this type of information, along with explanations from their GP. However, they wanted to have the choice to use it or not with their doctor (Table 2).

"We have an informal discussion, we can... pass on messages.... And then make a decision, saying I'm going or I'm not going. I weigh the pros and cons, that's it." (Woman 3)

Women	Healthcare professionals
Purpose of the tool	
To understand screening	To complete their knowledge
	To harmonize screening / professional practice
To prompt women to visit their GP	To refer women to their doctor
Characteristics of the tool	
With concrete numbers	Give statistical information to women
Easy to understand	Easy to use
Adaptable to different women's profiles	Design for every women
Presence of diagrams	Digital tool
Use of the tool	
A lever for discussion if desired by the woman	A lever for discussion
Have the choice to use it or not with their doctor	The health professional is essential to use the tool

Table 2: Consensus representations

Disagreements about the tool: balanced or biased information?

Opinions on breast cancer screening

The participants pointed out the sub-optimal effectiveness of breast cancer screening because of the harms associated with overdiagnosis and overtreatment.

"What surprised me was the ability to diagnose something that wasn't there and treat someone who didn't need it." (Woman 12, before the presentation of the tools)

"I am devastated by the results of the mammogram. Despite the double reading which I was inclined to give credit to..." (GP 3, before the presentation of the tools)

On the other hand, overtreatment could be seen as acceptable either because it applies to small tumours treatment or because it could save lives.

"They are cared for anyway, it's not useless…" (Woman 9, after the presentation of the tools)

"I don't play the game of overdiagnosis. [...] Honestly, I don't believe in overdiagnosis." (Radiologist 3, before the presentation of the tools)

Sometimes it is even difficult for professionals to distance themselves from their personal experience.

"If it's someone in my family or even me personally, I'd rather know about something and do a biopsy for nothing" (Gynaecologist 4, before the presentation of the tools),

Some participants considered the benefit-risk balance favourable, while others found it questionable. In this second case, the attitudes towards the tool differed according to the participants.

Shared decision-making

Many of the interviewees were not familiar with the concept of SDM in medicine.

"I didn't really have time to understand everything about this idea of shared decision-making…" (*Woman* 5)

"Support for shared decision-making? What's that?" (GP 5)

Some midwives and GPs were in favour of sharing comprehensive, balanced information about screening with women. Hence, DAs could be of value to these healthcare professionals in their daily practice. The healthcare professionals considered themselves to be "screening guides"; they wanted to provide women with reliable scientific data and enabling them to make an informed choice. Indeed, the healthcare professionals wanted to set out the facts and then accept the woman's decision. Furthermore, some of the women actively asked to receive comprehensive information from the healthcare professional so that they could decide for themselves whether or not to be screened.

"I explain things but will never force anyone to be screened - if they don't want to, it's their choice. […] It really is a shared decision and a mutual agreement with the patient." (Mifwife 2)

"It also depends on the cultural level, we will not work in the same way with a teacher, a nurse, or a woman who lives in the depths of her countryside" (GP 4)

"The doctor needs to explain [the screening] properly. I want to be able to weigh up the positive and negative aspects." (*Woman* 6)

Asymmetric information/ Paternalistic model

Some women wanted their physician to help them to understanding information about screening at every step in the process. Some women asked for selective information but considered that it was not up to them to decide whether or not to go for screening. Other women were afraid of receiving screening results; this is why they did not want to know everything about screening and the risks of cancer in particular.

"You can't let us choose because we don't understand anything about being screened or not" (Woman 2, after the presentation of the tools)

Some GPs, gynaecologists and radiologists had the same view about asymmetric information provision, with a focus on the benefits of screening. They considered that giving selected, positive information to women was essential for avoiding fear of screening.

"*We have to explain things quickly and only go into detail if they ask for more information. […] I don't know whether giving lots of impartial information is part of being a physician and above all part of making a diagnosis." (Radiologist 3, after the presentation of the tools)*

"If I tell them to get screened, they'll go without any hesitation." (Gynaecologist 1, before the presentation of the tools)

Convincing women to participate in screening

Some women thought the tool had to help healthcare professionals to convince everyone to participate in the screening. Similarly, some healthcare professionals stated that convincing women to enter a screening programme was the most important objective. They wanted to reassure women so that they would want to be screened (Table 3).

"Providing women with information is essential for motivating them to get screened" (GP 4, before the presentation of the tools)

"Perhaps some women think of having a mammography without being prompted but not me - I wouldn't think of it. But if my doctor suggests it, I'll go!" (*Woman* 2, before the presentation of the tools)

Women	Healthcare professionals
Balanced or biased information?	
Shared decision making: Free decision to participate in screening or not after receiving appropriate information	Shared decision making: state the facts in a neutral manner and let the patient decide whether or not she wants to participate in screening

Paternalistic model: the doctor has the knowledge and must tell the women what to do	Asymmetric information: Convince the patient to participate in organized screening because of the responsibility of knowing as a health professional
Lack of interest for such a tool in view of the sufficient data already available	No need for such a tool

Table 3: Dissenting representations

DISCUSSION

Summary of the main findings

Both the women and the healthcare professionals stated that a DA could help to improve knowledge, harmonise medical practice and provide reliable, comprehensive information. They expected the DA's to catalyse discussion between the patient and the physician during a consultation. Women and healthcare professionals wanted an easy-to-use, intuitive interactive computer-based DA, with diagrams and graphics. Some of the health care professionals and some of the women wanted a DA that leads to SDM. Our study highlighted several limitations to the tool, such as a lack of familiarity with SDM, the risk of misuse (i.e. convincing women to participate in a screening programme without engaging an SDM process), and a preference for asymmetric, positive information.

Study strengths and limitations

The study had a number of strengths. Firstly, the investigators complied with the Consolidated Criteria for Reporting Qualitative Research throughout the study.[23] Secondly, the data were provided by a diverse sample of both women (including socioeconomic level) and healthcare professionals; given that the risk-benefit balance for breast cancer screening is currently unclear, SDM appears to be the most ethical approach.[11] Thirdly, the data were triangulated by several experienced researchers. Fourthly, the samples of women and healthcare professionals were particularly diverse. Fifthly, nobody refused to participate to the study; we think that snowball sampling was a good way to engage participants.

However, we insufficiently assessed the degree of literacy of interviewed women. Only one woman answered "no" to the question designed to explore the level of literacy *"Do you need someone to help you understand prescriptions or medical information documents given by*

your doctor or pharmacist?". In the future, this may be important for adapting the DA for use with women of different literacy levels.

Comparison with the literature data

As mentioned above, the women interviewed in the present study here knew little or nothing about SDM. When the concept was explained, however, some women thought that it was of value. Similarly, a qualitative study of a DA for breast cancer screening in Spain found that women valued the receipt of information on the benefits and risks of screening.[24] This seems to be true for all women, even though SDM interventions tend to benefit disadvantaged women (e.g. those with a lower level of literacy) more than those with higher literacy or educational/socioeconomic status.[25] Becoming better informed might mean women are less likely to choose screening.

There is a growing body of evidence to show that DAs can improve value-congruent choices. In our study, the perception of screening seems to be modified by the presentation of the tools. Indeed, participants tend to cite the harms of screening more often after the tools have been presented to them. On the contrary, the presentation of the tools may have strengthened some participants in their conviction that screening was essential and its value indisputable. The latter found it questionable to tell women about the adverse effects of screening as this could reduce their motivation to undergo screening. These data are consistent with the literature. When compared with standard care in a broad variety of decision contexts, women exposed to DAs feel more knowledgeable, better informed, and clearer about their values; as such, they probably have a more active role in decision-making and a more accurate perception of risks.[13] Breast cancer screening DAs are known to improve levels of knowledge and promote informed decisions.[10] For this reason, DAs do not necessarily

increase screening participation rates.[26] For example, the large-scale Decideo study of breast cancer screening demonstrated that exposure to the DA reduced the participation rate by almost 2% because the women felt better informed.[17] The above-mentioned Spanish qualitative study found that the provision of information on overdiagnosis is controversial among healthcare professionals.[24] An Australian study about overdetection in breast cancer screening recommended a staged approach to development and piloting of decision aids to further improve understanding of overdetection and support informed decision-making about screening.[27] The creation and deployment of a DA tool must therefore be accompanied by training for healthcare professionals on SDM.

Several studies have evaluated quality criteria for DAs and the pitfalls to be avoided when designing this type of tool. A review on risk communication developed decision box prototypes, presented them to focus groups of GPs and patients, and explored the participants' perceptions.[28] The model explored seven facets of the user experience: the DA had to be useful, usable (with effectiveness, efficiency and satisfaction), desirable, findable, accessible, credible and valuable (i.e. more frequent SDM). Accordingly, the present study exploring all of these aspects. We found that the study participants wanted an easy-to-use, intuitive, interactive, computer-based DA with diagrams and graphics. In a recent systematic review of the quality of DAs developed for women eligible for mammogram screening, the three best-rated dimensions of standard DAs were disclosure (transparency and conflicts of interest), information (the provision of sufficient detail), and outcome probabilities.[29] The women and the healthcare professionals interviewed in our study also stated that those three dimensions were important to them. We considered that a future DA must focus on all six dimensions, so that women and healthcare professionals engage with the tool.

Implications for clinical practice

The present study explored expectations of a DA for SDM in breast cancer screening before its creation, from the future users themselves. Our work is the first step in the construction of this tool and will thus make it possible to avoid the pitfalls brought to light during the interviews. The future tool will allow adapting the information according to the age group of the patient. It's important to take time to acculturate healthcare professionals to the use of the DA to avoid its misuse. Our results should help to create an appropriate, added-value tool for use in this field and adapted to French context.

Conclusion

Stakeholders in organized breast cancer screening programmes (women, GPs, gynaecologists, midwives, radiologists and screening programme managers) have a broad range of expectations of a DA. The interviews showed that a DA could help to improve levels of knowledge, harmonise medical practice, and provide reliable, comprehensive information. Overall, the interviewees wanted an easy-to-use, intuitive, graphic-rich, interactive, computer-based and patient-centred DA. The idea of a DA was well received by the interviewees despite the fact the latter were unfamiliar with the concept of SDM. Along with the implementation of this type of tool, it would be useful to raise awareness of SDM among healthcare professionals and breast screening candidates. The present work was the first step in the DEDICACES study and will be followed by the creation and then validation of the first DA for SDM support in France's breast cancer screening programmes.

Data are available upon reasonable request: The deidentified transcripts of the interviews are available from the corresponding author (amelie.aim-eusebi@u-paris.fr). Their reuse is possible for a purpose similar to that of our study, otherwise a new consent from the interviewees will be necessary.

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Ethical approval: The study protocol was approved by a national ethics committee (Collège National des Généralistes Enseignants, Paris, France; reference: 07111732, CNGE. The data collection for the DEDICACES study has been registered with the French National Data Protection Commission (*Commission nationale de l'informatique et des libertés*, Paris, France; reference: 2099780).

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Authors' contributions: AAE, YR, BF, CR, XG, CC, IAA and EF participated to the conception and the design of the study. AAE, YR, MH, AB, LB and EF analyzed the data. All authors contributed in writing the manuscript. All authors read and approved the final manuscript.

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Supplementary files

Table S1: Interview guide (women)

Hello, my name is [first name, family name]. I'm a researcher from the University of Paris 13 [or the University of Poitiers]. Thank you for finding the time for this interview. I am doing a research project about breast cancer screening and, in particular, the information about screening given to women. Our interview will be audio-recorded so that we can collect all the necessary data. Your personal information will be anonymized and then deleted at the end of the study.

1) [BREAST CANCER] **What do you know about breast cancer?**

(Prompt) What can you do to avoid breast cancer or to minimize the likelihood of developing it? To what extent do you feel concerned by breast cancer in your everyday life?

2) [BREAST CANCER SCREENING] **What do you know about breast cancer screening in France?**

(Prompt) What does screening mean for you? Do you feel concerned by breast cancer screening?
(Prompt) What do you think are the differences between organized screening programmes and individual screening?
(Prompt) What do you know about the effectiveness of screening?

3) [PARTICIPATION IN SCREENING] **Have you ever been screened for breast cancer? What did you think about that experience?**

(Prompt) How did you decide whether to get screened or not?
(Prompt) What information did you receive? Who gave you the information? How did you receive it?
(Prompt) How did you feel during the [first] screening?

4) [INFORMATION] **What information about breast cancer screening do you think you should have?**

(Prompt) What information would you have liked to have received but didn't?
(Prompt) How would you like to receive information about breast cancer screening? Who would you like to receive it from?
(Prompt) What format should this information have, in your opinion? Do you think that a healthcare professional should help you to decide?
(Prompt) You told me that you go for regular check-ups with a gynaecologist/general practitioner. Do you discuss breast cancer screening with him/her?
(Prompt) How would you raise the subject with him/her?
(Prompt) What do you expect from him/her?

5) [GENERAL IMPRESSION OF THE DECISION AIDS PRESENTED] **What do you think of these documents?** [*Show the interviewee the documents and let her look at them for 10 minutes or so*]

(Prompt) What do you think about these documents?
(Prompt) What did you get from the documents?
(Prompt) What have you understood from them? Are they easy to understand?
(Prompt) Were you already aware of this information about the advantages and risks [of screening]? If so, how did you receive the information?

6) [CONTENT AND FORMAT] **What do you think about the documents' content?**

(Prompt) And what about the format?
(Prompt) What would you change in these documents? (Prompt) What would you add to or remove from the documents? (Prompt) Which one do you prefer? Why? (Prompt) Which one is least meaningful for you? Why?

7) [SUMMARY OF THE SAMPLES SHOWN] **What do you think about these diagrams/figures /drawings?**

(Prompt) How did they enhance your knowledge about breast cancer screening? (Prompt) What do you think about the figures?
(Prompt) Do they help you to understand not only the advantages but also the risks associated with screening?
(Prompt) What other ways of presenting this information would you suggest?

8) [END PURPOSE OF THE INFORMATION] **How does this information influence your opinion about screening? Are there other things that you'd like to know before being able to make a decision?**

(Prompt) What additional information would you need?

Table S2: Interview guide for GPs

1) [BREAST CANCER SCREENING] **What do you think about breast cancer screening?**

2) [PROFESSIONAL ROLE] **What is your role in breast cancer screening?**

3) [REAL-LIFE EXAMPLE] **Can you tell me about a recent consultation during which you raised this subject with one of your [female] patients?**

(Prompt) How did the consultation go?

(Prompt) What information were you able to give to the patient?

(Prompt) What information were you unable to give to the patient?

(Prompt) In your opinion, what extra information would your patient liked to have received?

How was the decision made?

(Prompt) What was your role and what was the patient's role in the decision?

(Prompt) Did you form a consensus decision with the patient? How do you know that you did?

4) [THE TOOLS] **What do you think about using information tools and/or decision aids for shared decision-making during a consultation?**
And what about [the use of these tools and decision aids in] breast cancer screening?

(Prompt) What do you know about decision aids for shared decision-making? Have you already used any? If so, which ones? And why did you use them?
(Prompt) What do you understand by the term "decision aid"
(Prompt) What format should this type of tool have?
(Prompt) What medium should the tool use, in your opinion?

How could [a decision aid] be integrated into shared decision-making with the patient?

5) [Practical example] **What do you think about these documents?** *(Show the interviewee the documents and let him/her look at them for 10 minutes or so)*

(Prompt) What do you think about the documents' content? And about their form?
(Prompt) What did you learn from them?
(Prompt) Which do you prefer? Why?

(Prompt) Which one is least meaningful for you? Why?
(Prompt) What would you change in these documents?
(Prompt) What would you add to or remove from these documents?
(Prompt) What did you learn [from the documents] about breast cancer screening? Do they help you to better understand not only the advantages but also the risks associated with screening?
(Prompt) How could these documents be used in practice?
(Prompt) Do you think that they are useful for your practice?

Table S3: Interview guides for other healthcare professionals

Hello, my name is [first name, family name]. I'm a house officer in general medicine at the Paris 7 Faculty of Medicine. Thank you for finding the time for this interview. I am doing a research project about breast cancer screening. Our interview will be audio-recorded so that we can collect all the necessary data. Please be aware that there are no right or wrong answers and that your personal information will be anonymized and then deleted at the end of the study.

Background information on the interviewee: age, type of practice, time since qualification, etc.

INTERVIEW GUIDE – GYNAECOLOGISTS and MIDWIVES

1) [BREAST CANCER SCREENING] **How do you address breast cancer screening with your [female] patients?**

2) [REAL-LIFE EXAMPLE] **Can you tell me about a recent consultation during which you raised this subject with one of your patients?**
[*For midwives, if they do not address this subject*]: Why don't you raise the subject of breast cancer screening with your patients?

3) [FEELING] **In your opinion, what do patients feel about this screening?**

(Prompt) What type of information do they ask for?

4) [PROFESSIONAL ROLE] **What information do you give them? What type of document or medium do you use?**

5) [TOOLS] **What do you think about information tools and/or decision aids for shared decision-making with regard to breast cancer screening?**

6) [PRACTICAL EXAMPLE] **What do you think about these documents?** *(Show the interviewee the documents and let him/her look at him/her for 10 minutes or so)*

(Prompt) What type of tools would you like to have at your disposal for advising women about breast cancer screening?

INTERVIEW GUIDE – RADIOLOGISTS

1) [REAL-LIFE EXAMPLE] **What happens when a woman attends your clinic for a mammogram?**

(Prompt) What happens for individual screening and for organized screening?
(Prompt) Do you perform a clinical examination and have a pre-screening interview?
(Prompt) Does this screening create any problems for you (organisational aspects, interpretation, giving the results to the patient, etc.)?

2) [PROFESSIONAL ROLE] **What type of dialogue do you have with the patients?**

(Prompt) Is this before or after you have analyzed the mammogram?
(Prompt) Do you wait for the second analysis?

3) [FEELING] **In your opinion, how do patients feel about this screening?**

(Prompt) If patients ask for more information, what type of tools do you use or would like to use?

4) [PRACTICAL EXAMPLE] **What do you think about these documents?** *(Show the interviewee the documents and let him/her look at them for 10 minutes or so)*

INTERVIEW GUIDE – SCREENING PROGRAMME MANAGER

1) [REAL-LIFE EXAMPLE] **How do you get involved in organized breast cancer screening?**

2) [PROFESSIONAL ROLE] **What sort of information should breast cancer screening candidates be given?**

(Prompt) What do you think about the official document used throughout France?
(Prompt) Have you developed other ways of informing patients?

3) [FEELING **In your opinion, how do patients feel about this screening?**

4) [BREAST CANCER SCREENING] **What do you think about shared decision-making in breast cancer screening?**

5) [PRACTICAL EXAMPLE] **What do you think about these documents?** *(Show the interviewee the documents and let him/her look at them for 10 minutes or so)*

Table S4: Examples of information tools and decision aids

Tool 1

What is screening?

Screening means examining a group of people in order to detect disease or to find people at increased risk of disease.

In many countries, women between 50 and 69 years of age are offered an X-ray examination of the breasts – screening with mammography - every second or third year. The purpose of the screening examination is to find women who have breast cancer in order to offer them earlier treatment.

Screening with mammography has both benefits and harms. The aim of this leaflet is to help each woman weigh up the pros and cons in the light of her own values and preferences, in order that she can make a personal decision whether she wishes to attend.

If nothing abnormal is found by screening, it makes the woman feel reassured that she is healthy. But almost all women feel healthy before they are invited to screening. Furthermore, the invitation itself may cause insecurity. Therefore, screening creates both security and insecurity.

Benefits

Reduced risk of dying from breast cancer - Regular screening with mammography cannot prevent breast cancer, but it can perhaps reduce the risk of dying from breast cancer. A systematic review of the randomised trials of mammography screening found that:

> *If 2000 women are screened regularly for 10 years, one will benefit from screening, as she will avoid dying from breast cancer because the screening detected the cancer earlier.*

Since these trials were undertaken, treatment of breast cancer has improved considerably. Women today also seek medical advice much earlier than previously, if they have noted anything unusual in their breasts. In addition, diagnosis and treatment have been centralised in many countries and are now provided by teams of breast cancer experts.

Because of these improvements, screening is less effective today and newer studies suggest that mammography screening is no longer effective in reducing the risk of dying from breast cancer (see *Documentation for the facts and figures* below).

Screening does not reduce the overall risk of dying, or the overall risk of dying from cancer (including breast cancer).

Harms

Overdiagnosis and overtreatment - Some of the cancers and some of the early cell changes (carcinoma in situ) that are found by screening grow so slowly that they would never have developed into a real cancer. Many of these screen-detected "pseudo-cancers" would even have disappeared spontaneously, if they had been left alone, without treatment.

Since it is not possible to tell the difference between the dangerous and the harmless cell changes and cancers, all of them are treated. Therefore, screening results in treatment of many women for a cancer disease they do not have, and that they will not get. Based on the randomised trials, it appears that:

> *If 2000 women are screened regularly for 10 years, 10 healthy women will be turned into cancer patients and will be treated unnecessarily. These women will have either a part of their breast or the whole breast removed, and they will often receive radiotherapy, and sometimes chemotherapy. Treatment of these healthy women increases their risk of dying, e.g. from heart disease and cancer.*
>
> *Unfortunately, some of the early cell changes (carcinoma in situ) are often found in several places in the breast. Therefore, the whole breast is removed in one out of four of these cases, although only a minority of the cell changes would have developed into cancer.*

More extensive surgery and aftertreatment - For women diagnosed at screening with a small “true” cancer, the operation and aftertreatment may be less extensive than if the cancer had been detected at a later time. However, as screening also leads to overdiagnosis and subsequent overtreatment of healthy women,

more women in total will have a breast removed when there is screening than if there had not been screening. Also, more women will receive radiotherapy unnecessarily.

False alarm - If the X-ray shows something that might be cancer, the woman is recalled for additional investigations. In some cases it turns out that what was seen on the X-ray was benign, and that it was therefore a false alarm.

> *If 2000 women are screened regularly for 10 years, about 200 healthy women will experience a false alarm. The psychological strain until it is known whether or not there is a cancer can be severe. Many women experience anxiety, worry, despondency, sleeping problems, changes in the relationships with family, friends and acquaintances, and a change in sex drive. This can go on for months, and in the long term some women will feel more vulnerable about disease and will see a doctor more often.*

Pain at the examination - The breast is squeezed flat between two plates while an X-ray is taken. It only takes a moment, but about half of the women find it painful.

False reassurance - Mammography screening cannot detect all cancers. It is important, therefore, that the woman sees a doctor if she finds a lump in her breast, even if she has had a mammogram recently.

Gøtzsche PC, Hartling OJ, Nielsen M, et al. Mammography screening leaflet. Copenhagen: Nordic Cochrane Centre 2012. https://www.cochrane.dk/mammography-screening-leaflet (accessed Janv 2022)

Tool 2

Should I be screened with mammography for breast cancer?

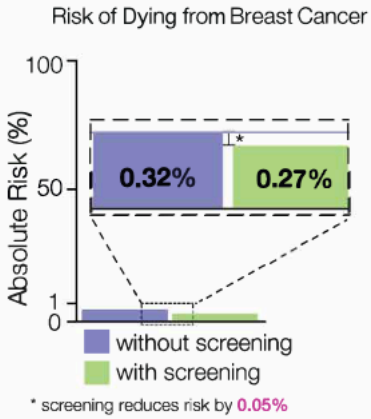
For women between 40 and 49 years of age:

Among women who do not screen, the risk of dying from breast cancer is:	**1 in 313**
With regular screening your risk of dying of breast cancer is:	**1 in 370**
However, with regular screening:	
... your risk of having a false positive mammogram requiring further screening is:	**1 in 3**
... your risk of having a biopsy is:	**1 in 28**
... your risk of having part or all of a breast removed unnecessarily is:	**1 in 200**

Be informed!

You may hear the risks or benefits of breast cancer screening described as either **absolute** or **relative**. But what does all this mean and how does it apply to you?

The main difference is that absolute risk takes into consideration the fact that whether or not you get screened or treated, you still have a baseline risk of dying of breast cancer: **1 in 313** or **0.32%**. With regular screening that risk changes to: **1 in 370** or about **0.27%**. Relative risk does not consider baseline risk in the same way and may lead to confusion about how regular screening reduces risk.



The absolute risk is simply the difference in risk between regular screening (0.27%) and no screening (0.32%).
0.32% - 0.27% = 0.05%
Therefore screening in women aged 40-49 reduces your ***absolute risk*** of dying of breast cancer by **0.05%**.
So the ***absolute benefit*** of screening is **0.05%**.

Relative risk only looks at the reduction in risk as a proportion of the total risk (so it doesn't consider that you are already at risk of cancer, this can lead to larger values than absolute risk).
0.05%/0.32% = 15%
Thus, screening in women aged 40-49 reduces your ***relative risk*** of dying of breast cancer by **15%**. So the ***relative benefit*** of screening is **15%**.

So how does this translate into actual numbers? Among 100 000 women aged 40 to 49 who are:

Screened **EVERY** 2 years for 11 years:
- **270** would die of breast cancer
- **32 700** would experience a false alarm
- **3600** would have a biopsy
- **500** would have part or all of a breast removed without having cancer
- **50** would escape a breast cancer death

NOT screened for 11 years:
- **320** would die of breast cancer
- **99 680** would not

For more info visit:
http://www.canadiantaskforce.ca

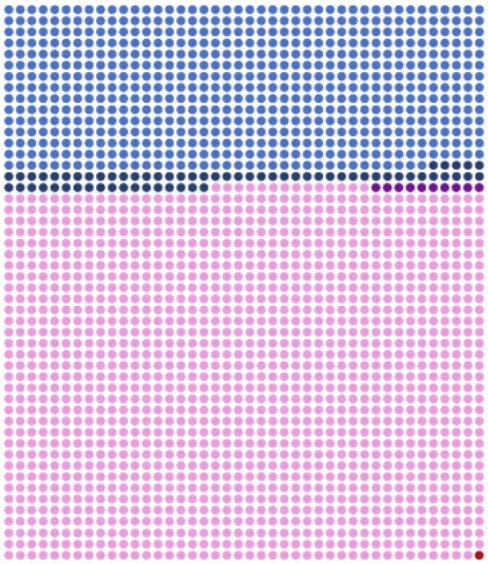
Should I be screened with mammography for breast cancer?

Absolute Benefit of Screening with Mammography

If we wanted to describe the previous information in regards to the effect on an individual woman then we can look at what would occur in a base of 2100 women instead of 100 000.

In the graphic below, each dot represents 1 woman (● = 1 woman)

If we screened **2100** women, aged 40-49 years, at average risk of breast cancer every two years for 11 years...



...about **700** women would experience a false positive mamogram requiring further imaging...

...**75** of these women would have a biopsy, all to confirm that they do not have breast cancer

...at least **10** women would have part or all of a breast unnecessarily removed and bear the burden of over- diagnosis

...**1** woman would escape a breast cancer death

For more information visit: **http://www.canadiantaskforce.ca**

Should I be screened with mammography for breast cancer?

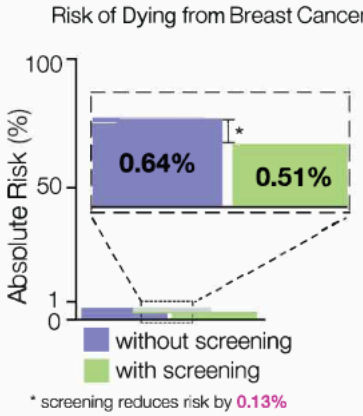
For women between 50 and 69 years of age:

Among women who do not screen, the risk of dying from breast cancer is:	**1 in 155**
With regular screening your risk of dying of breast cancer is:	**1 in 196**
However, with regular screening:	
... your risk of having a false positive mammogram requiring further screening is:	**1 in 4**
... your risk of having a biopsy is:	**1 in 28**
... your risk of having part or all of a breast removed unnecessarily is:	**1 in 200**

Be informed!

You may hear the risks or benefits of breast cancer screening described as either **absolute** or **relative**. But what does all this mean and how does it apply to you?

The main difference is that absolute risk takes into consideration the fact that whether or not you get screened or treated, you still have a baseline risk of dying of breast cancer: **1 in 155** or **0.64%**. With regular screening that risk changes to: **1 in 196** or about **0.51%**. Relative risk does not consider baseline risk in the same way and may lead to confusion about how regular screening reduces risk.



The absolute risk is simply the difference in risk between regular screening (0.47%) and no screening (0.64%).
0.64% - 0.51% = 0.13%
Therefore screening in women aged 50-69 reduces your ***absolute risk*** of dying of breast cancer by **0.13%**.
So the ***absolute benefit*** of screening is **0.13%**.

Relative risk only looks at the reduction in risk as a proportion of the total risk (so it doesn't consider that you are already at risk of cancer, this can lead to larger values than absolute risk).
0.13%/0.64% = 21%
Thus, screening in women aged 50-69 reduces your ***relative risk*** of dying of breast cancer by **21%**. So the ***relative benefit*** of screening is **21%**.

So how does this translate into actual numbers? Among 100 000 women aged 50 to 69 who are:

Screened **EVERY** 2 years for 11 years:
- **510** would die of breast cancer
- **28 200** would experience a false alarm
- **3700** would have a biopsy
- **500** would have part or all of a breast removed without having cancer
- **138** would escape a breast cancer death

NOT screened for 11 years:
- **640** would die of breast cancer
- **99 360** would not

For more info visit:
http://www.canadiantaskforce.ca

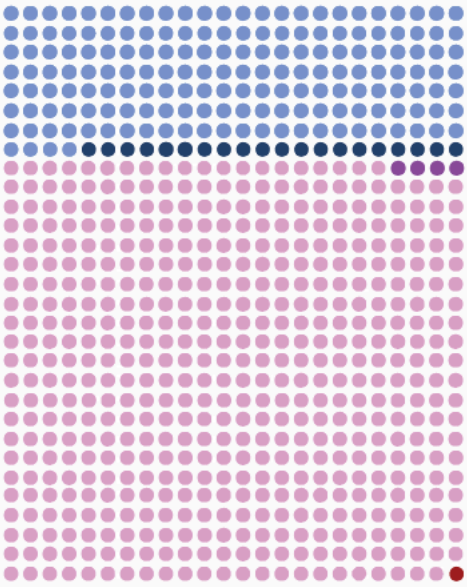
Should I be screened with mammography for breast cancer?

Absolute Benefit of Screening with Mammography

If we wanted to describe the previous information in regards to the effect on an individual woman then we can look at what would occur in a base of 720 women instead of 100 000.

In the graphic below, each dot represents 1 woman (● = 1 woman)

If we screened **720** women, aged 50-69 years, at average risk of breast cancer every two years for 11 years...



...about **204** women would experience a false positive mammogram requiring further imaging...

...**26** of these women would have a biopsy, all to confirm that they do not have breast cancer

...at least **4** women would have part or all of a breast unnecessarily removed and bear the burden of over- diagnosis

...**1** woman would escape a breast cancer death

For more information visit: **http://www.canadiantaskforce.ca**

Should I be screened with mammography for breast cancer?

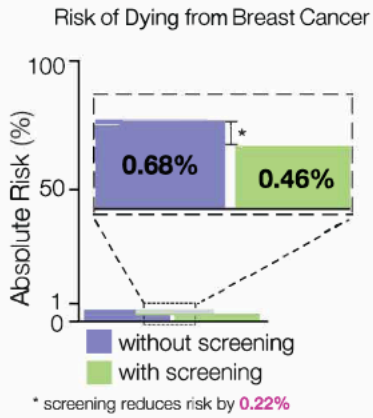
For women between 70 and 74 years of age:

Among women who do not screen, the risk of dying from breast cancer is:	**1 in 146**
With regular screening your risk of dying of breast cancer is:	**1 in 217**
However, with regular screening:	
... your risk of having a false positive mammogram requiring further screening is:	**1 in 5**
... your risk of having a biopsy is:	**1 in 38**
... your risk of having part or all of a breast unnecessarily removed is:	**1 in 200**

Be informed!

You may hear the risks or benefits of breast cancer screening described as either **absolute** or **relative**. But what does all this mean and how does it apply to you?

The main difference is that absolute risk takes into consideration the fact that whether or not you get screened or treated, you still have a baseline risk of dying of breast cancer: **1 in 146** or **0.68%**. With regular screening that risk changes to: **1 in 217** or **0.46%**. Relative risk does not consider baseline risk in the same way and may lead to confusion about how regular screening reduces risk.



The absolute risk is simply the difference in risk between regular screening (0.46%) and no screening (0.68%).
0.68% - 0.46% = 0.22%
Therefore screening in women aged 70-74 reduces your ***absolute risk*** of dying of breast cancer by **0.22%**.
So the ***absolute benefit*** of screening is **0.22%**.

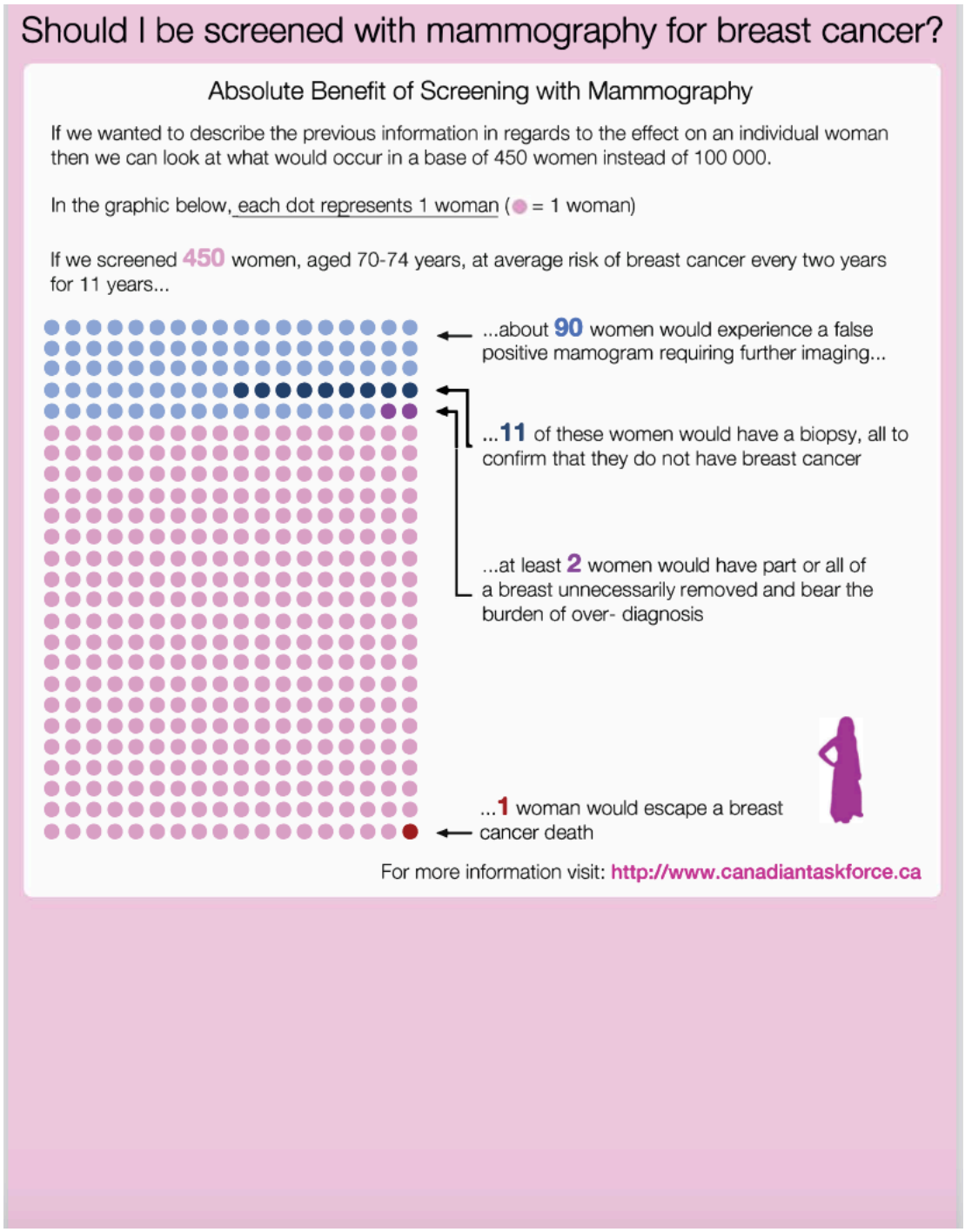
Relative risk only looks at the reduction in risk as a proportion of the total risk (so it doesn't consider that you are already at risk of cancer, this can lead to larger values than absolute risk).
0.22%/0.68% = 32%
Thus, screening in women aged 70-74 reduces your ***relative risk*** of dying of breast cancer by **32%**. So the ***relative benefit*** of screening is **32%**.

So how does this translate into actual numbers? Among 100 000 women aged 70 to 74 who are:

Screened **EVERY** 2 years for 11 years:
- **460** would die of breast cancer
- **21 200** would experience a false alarm
- **2600** would have a biopsy
- **500** would have part or all of a breast removed without having cancer
- **222** would escape a breast cancer death

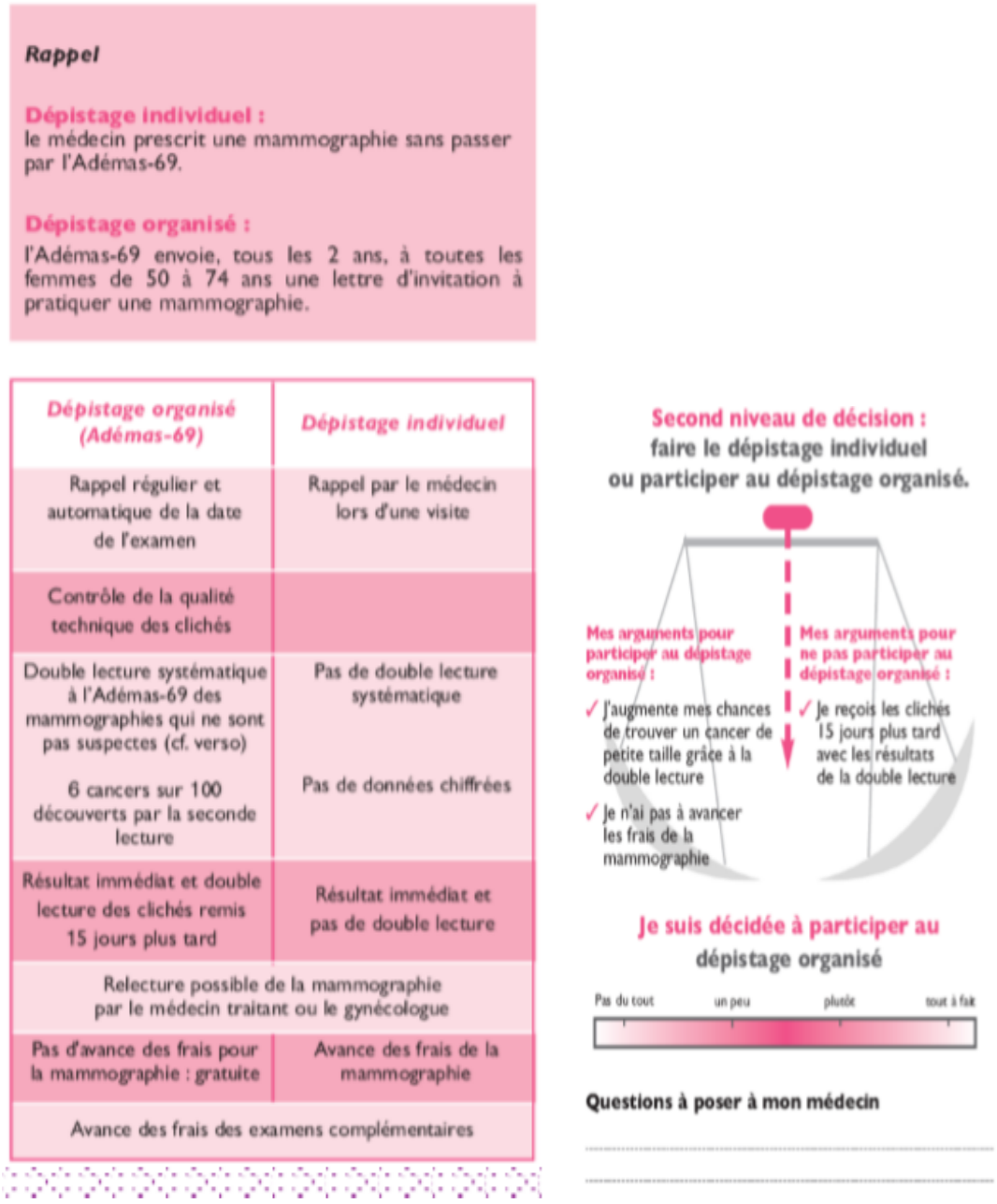
NOT screened for 11 years:
- **680** would die of breast cancer
- **99 320** would not

For more info visit:
http://www.canadiantaskforce.ca



Canadian Task Force on Preventive Health Care. Breast Cancer (2011). Montreal: CTFPHC 2011. https://canadiantaskforce.ca/tools-resources/breast-cancer-2/ (accesses Janv 2022)

Tool 3



Rappel

Dépistage individuel :
le médecin prescrit une mammographie sans passer par l'Adémas-69.

Dépistage organisé :
l'Adémas-69 envoie, tous les 2 ans, à toutes les femmes de 50 à 74 ans une lettre d'invitation à pratiquer une mammographie.

Dépistage organisé (Adémas-69)	*Dépistage individuel*
Rappel régulier et automatique de la date de l'examen	Rappel par le médecin lors d'une visite
Contrôle de la qualité technique des clichés	
Double lecture systématique à l'Adémas-69 des mammographies qui ne sont pas suspectes (cf. verso)	Pas de double lecture systématique
6 cancers sur 100 découverts par la seconde lecture	Pas de données chiffrées
Résultat immédiat et double lecture des clichés remis 15 jours plus tard	Résultat immédiat et pas de double lecture
Relecture possible de la mammographie par le médecin traitant ou le gynécologue	
Pas d'avance des frais pour la mammographie : gratuite	Avance des frais de la mammographie
Avance des frais des examens complémentaires	

Second niveau de décision :
faire le dépistage individuel ou participer au dépistage organisé.

Mes arguments pour participer au dépistage organisé :
- ✓ J'augmente mes chances de trouver un cancer de petite taille grâce à la double lecture
- ✓ Je n'ai pas à avancer les frais de la mammographie

Mes arguments pour ne pas participer au dépistage organisé :
- ✓ Je reçois les clichés 15 jours plus tard avec les résultats de la double lecture

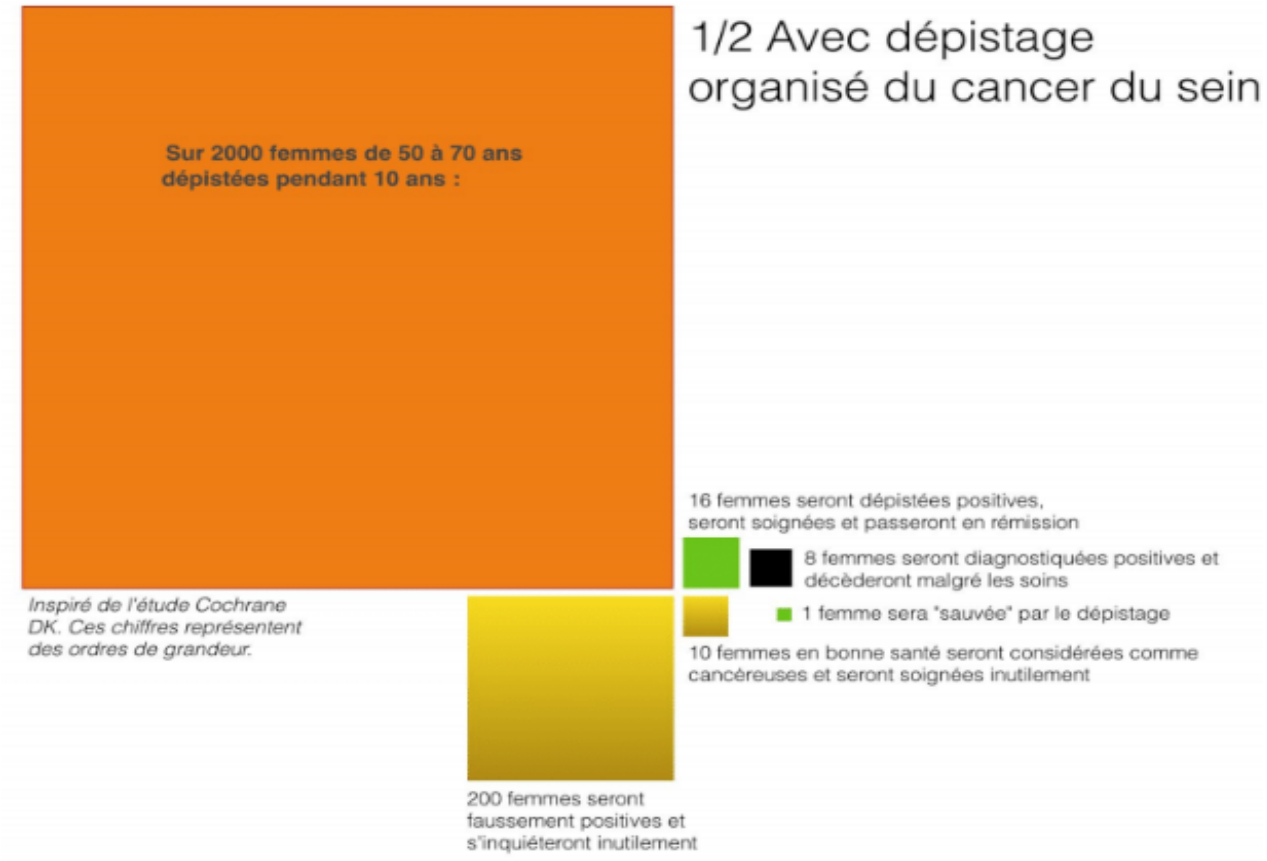
Je suis décidée à participer au dépistage organisé

Pas du tout | un peu | plutôt | tout à fait

Questions à poser à mon médecin

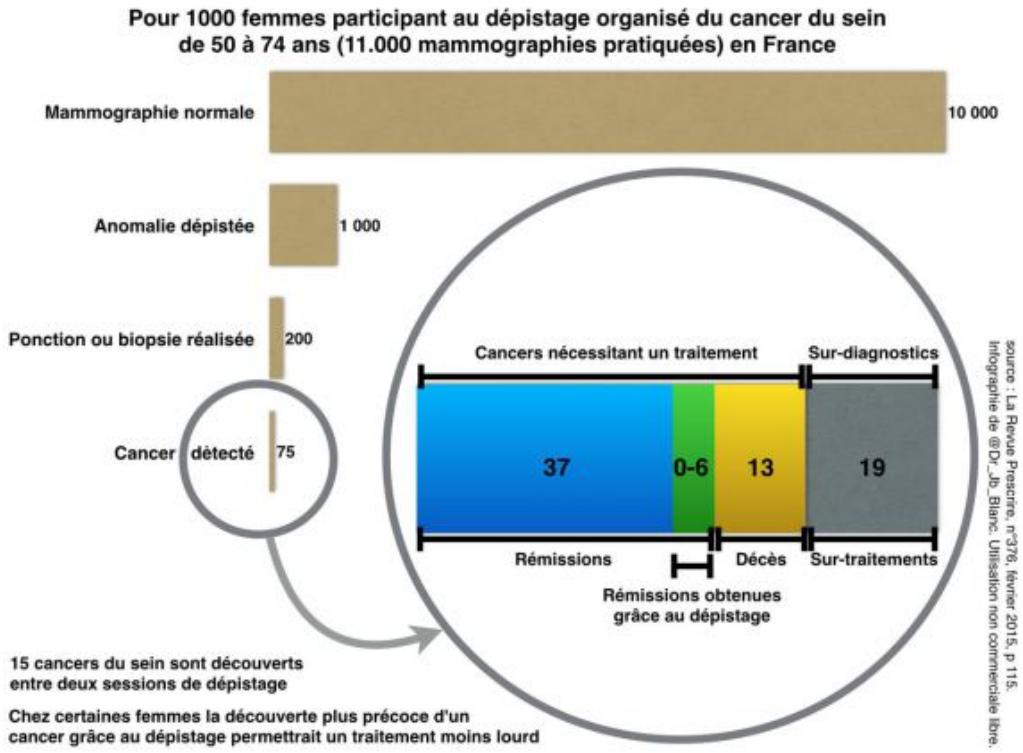
Bourmaud A, Soler-Michel P, Oriol M, et al. Decision aid on breast cancer screening reduces attendance rate: results of a large-scale, randomized, controlled study by the DECIDEO group. Oncotarget 201615;7(11):12885-92.

Tool 4



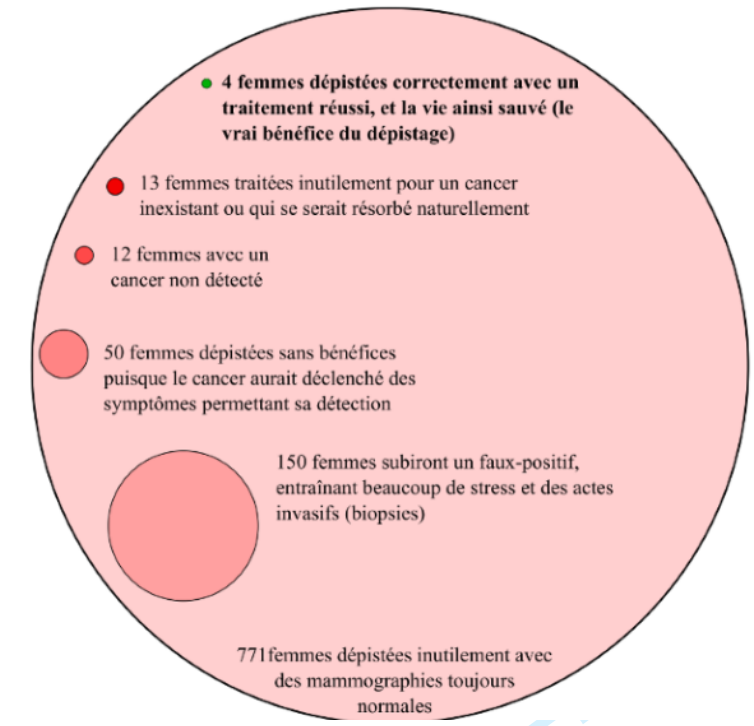
Blanc JB. Comment pratiquer la prise de décision partagée en médecine générale? [Mémoire en vue du diplôme inter universitaire de requalification à la pratique de la médecine générale]. Université de Rennes1 2015. https://sites.google.com/site/ladecisionpartagee/home (accesses Janv 2022)

Tool 5



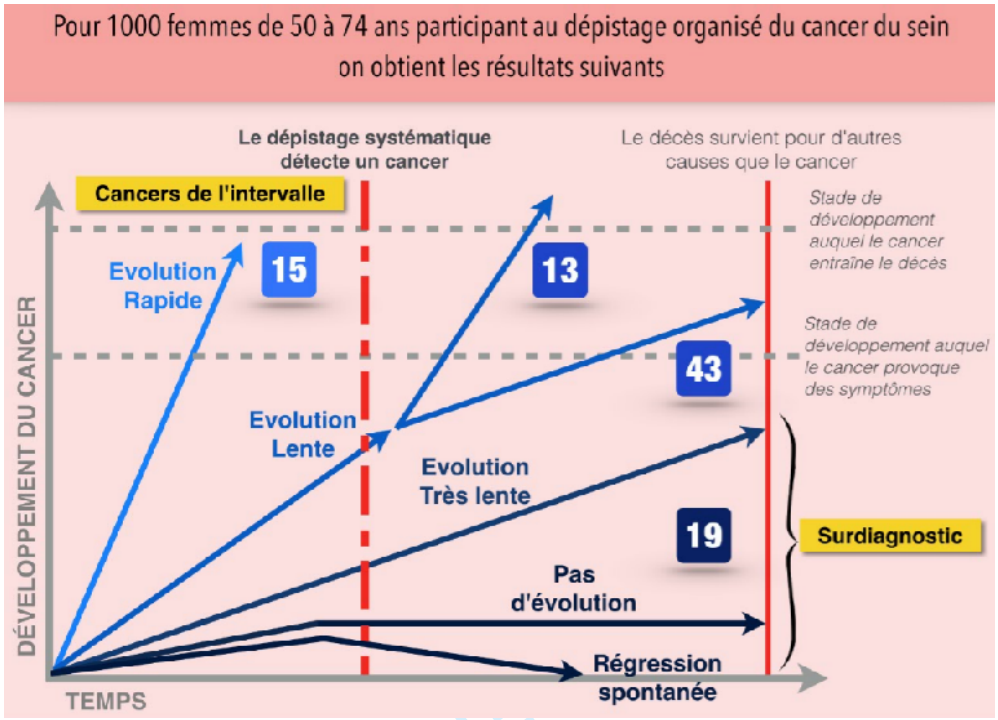
Prescrire. Partager avec les femmes les informations utiles pour décider de participer ou non au dépistage des cancers du sein. Rev Prescrire 2015;35(376):115.

Tool 6



Dur à avaler. La mammographie de dépistage pour le cancer du sein : inutile et dangereuse ? Noumea: Dur à avaler 2016. https://www.dur-a-avaler.com/la-mammographie-de-depistage-pour-le-cancer-du-sein-inutile-et-dangereuse/ (accessed Janv 2022)

Tool 7



PDQ® Screening and Prevention Editorial Board. PDQ Breast Cancer Screening. Bethesda, MD: National Cancer Institute 2021. https://www.cancer.gov/types/breast/patient/breast-screening-pdq (accessed Janv 2022)

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

No	Item	Guide questions/description
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Ok p7	Interviewer/facilitator	Which author/s conducted the interview or focus group?
2. Ok p7	Credentials	What were the researcher's credentials? *E.g. PhD, MD*
3. Ok p7-p21	Occupation	What was their occupation at the time of the study?
4. Ok p7	Gender	Was the researcher male or female?
5. Ok p7	Experience and training	What experience or training did the researcher have?
Relationship with participants		
6. Ok p8	Relationship established	Was a relationship established prior to study commencement?
7. Ok p8	Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. *personal goals, reasons for doing the research*
8. Ok p7	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic*
Domain 2: study design		
Theoretical framework		
9. Ok p7	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis*
Participant selection		
10. Ok p7	Sampling	How were participants selected? *e.g. purposive, convenience, consecutive, snowball*
11. Ok p7	Method of approach	How were participants approached? e.g. *face-to-face, telephone, mail, email*
12. Ok p9	Sample size	How many participants were in the study?
13. Ok p7	Non-participation	How many people refused to participate or dropped out? Reasons?
Setting		
14. Ok p7	Setting of data collection	Where was the data collected? e.g. *home, clinic, workplace*
15. Ok p7	Presence of non-	Was anyone else present besides the

No	Item	Guide questions/description
	participants	participants and researchers?
16. Ok p9	Description of sample	What are the important characteristics of the sample? *e.g. demographic data, date*
Data collection		
17. Ok p8-Suppelmentary tables	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?
18. Ok p8	Repeat interviews	Were repeat interviews carried out? If yes, how many?
19. Ok p7	Audio/visual recording	Did the research use audio or visual recording to collect the data?
20. Ok p8	Field notes	Were field notes made during and/or after the interview or focus group?
21. Ok p9-10	Duration	What was the duration of the interviews or focus group?
22. Ok p8	Data saturation	Was data saturation discussed?
23. Ok p8	Transcripts returned	Were transcripts returned to participants for comment and/or correction?
Domain 3: analysis and findings		
Data analysis		
24. Ok p8	Number of data coders	How many data coders coded the data?
25. Ok p8	Description of the coding tree	Did authors provide a description of the coding tree?
26. Ok p8	Derivation of themes	Were themes identified in advance or derived from the data?
27. Ok p8	Software	What software, if applicable, was used to manage the data?
28. Ok p8	Participant checking	Did participants provide feedback on the findings?
Reporting		
29. Ok p10-16	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. *participant number*
30. Ok p17-20	Data and findings consistent	Was there consistency between the data presented and the findings?
31. Ok p10-16	Clarity of major themes	Were major themes clearly presented in the findings?
32. Ok p10-16	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes