

# Eliciting patients' preferences for adjuvant chemotherapy in breast cancer: development and validation of a bedside decision-making instrument in a French Regional Cancer Centre

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## Abstract

**Introduction** In developed countries, the physician-patient relationship is moving from a paternalistic model to new decision-making models that take patient preferences into account.

**Objectives** Our aim was to develop a Decision Board (DB) and to test its acceptability in a French Regional Cancer Centre regarding the decision on whether or not to use chemotherapy after surgery in postmenopausal women with breast cancer. This paper presents the development process for this instrument and reports the pretesting phase, as well as the corresponding results.

**Methods** A working group was created with oncologists, psychologists and economists. Following the first phase, i.e. the development process, a first version of the instrument was presented to health professionals. Their feedback led to important modifications of the instrument. The DB was then presented to experienced patients, which resulted in slight changes. The second phase consisted of pretesting the comprehension, internal and across-time consistency of the DB on healthy volunteers.

**Results** The DB was pretested in a group of 40 healthy volunteers. Eighteen respondents chose chemotherapy and 22 chose not to have chemotherapy. Comprehension rates were very high ( $\geq 87.5\%$ ). Internal consistency was assessed considering option attitudes based on outcomes and option attitudes based on process. Women shifted their choices in a predictable way. Across-time consistency was appraised using the test-retest method with Visual Analog Scales. The Intraclass Correlation Coefficient was 0.97.

**Discussion-conclusion** Due to cultural differences, the DB developed in our French Cancer Centre is quite different from the DBs previously developed elsewhere. Our instrument showed good comprehension and consistency properties, which are corroborated

by the DB literature. Whether our DB is acceptable for patients with breast cancer must still be tested. Patients' reactions will tell us which type of decision-making model is at work. Further research is needed in order to explore the shared decision-making process and clarify the concept.

## Introduction

Broad social changes have occurred in North America since the 1960s, (though a little later in Europe), in relation to two linked notions: individual autonomy and consumer rights.<sup>1,2</sup> Applied to general medical practices, these two notions have stimulated active patient participation in terms of establishing goals and making clinical decisions. Indeed, patients indicate a desire for more information concerning their disease and the need to be more involved in their health care decisions.<sup>3,4</sup> In the past, physicians tended to make treatment decisions for their patients, thus endorsing a paternalistic behaviour<sup>1,5</sup> and placing patients in a passive and dependent role.<sup>5-7</sup> But now, particularly in North America, physicians often see the process of clinical decision-making as a joint venture between the patients and themselves.<sup>8</sup>

In France, important changes have also taken place in clinical decision-making since the early eighties, inspired by AIDS patient associations.<sup>9,10</sup> Physicians are now required by law to ask for patients' consent before performing any medical investigation or intervention, on the basis of clear, comprehensive and honest information.<sup>11-14</sup> More than 50% of the lawsuits brought against physicians are due to a lack of information given to the patients. The Supreme Court of Appeal recently stated that physicians must prove that good information has been provided to their patients.<sup>15</sup> Moreover, in a report to the Minister of Health, the National Advisory Committee of Ethics claimed that 'shared decision-making is the best way to proceed'.<sup>16</sup> In this report, shared decision-making is defined as the 'full association of the physician's expertise and responsibility with the patient's complete understanding of the different options'. However, the report outlines a gap

between legal obligation and real practice because shared decision-making, as defined in the report, is far from being implemented consistently.

The concept of shared decision-making seems to be well-suited to different clinical contexts, but especially in situations where, as Coulter<sup>17</sup> underlined, 'there are several treatment options with different possible outcomes, and particularly those that are likely to have differential effects on the patient's quality of life'. This is the case, for example, in cardiology,<sup>18</sup> gynaecology,<sup>19</sup> neonatology,<sup>20</sup> genetics<sup>21</sup> and oncology. In oncology, decisions often involve a trade-off between the toxicity of the treatment (i.e. the quality of the patient's life) and potential survival (i.e. quantity of life). Moreover, the uncertainty of the outcome at the individual level further complicates the problem. According to Sebban *et al.*,<sup>22</sup> the process of shared decision-making can be restated as follows: in order to make clinical decisions which involve trade-offs and uncertainty, two components are required: knowledge of the risks and the benefits of each course of action (i.e. the knowledge component), and individual preferences regarding potential outcomes (i.e. the preference component). Yet as knowledge exists in one body, the physician, and preferences in another, the patient, shared-decision making may take on a variety of different forms.

In their typology of treatment decision-making models, Charles *et al.*<sup>23</sup> point out three criteria related to: (1) information exchange, (2) the deliberation process and (3) treatment decision. The 'shared decision-making' model is defined according to these three criteria, as follows. Firstly, the information exchange is two-way; the physician transfers knowledge to the patient and the patient provides information concerning his/her preferences to the physician.

The second stage is deliberation. This refers to the process of expressing and discussing treatment options and is characterized by its interactional nature. As Charles *et al.*<sup>23</sup> state 'both parties through the deliberation process work towards reaching an agreement.' Thirdly, as a result, the treatment decision involves at least two decision-makers: the physician and the patient.

Thus defined, the shared decision-making model can be viewed as an intermediary between two other models, namely what can be referred to as the 'patient as decision-maker' model and the 'physician as decision-maker' model. In the former, which is similar to the 'informed treatment decision-making' model described by Gafni *et al.*,<sup>24</sup> 'information exchange is one-way, from physician to patient'.<sup>23</sup> There is therefore no deliberation process between patient and physician, as the decision is made by the patient according to his/her preferences, on the basis of the information provided by the physician. The patient is thus the sole decision-maker and the physician is seen as a technical adviser whose preferences, *per se*, have no place.<sup>25,26</sup>

Conversely, in the latter, the decision is made by the physician. But this encompasses two very different situations, namely 'the paternalistic model'<sup>23</sup> and the 'physician as a perfect agent for the patient' model.<sup>24</sup> As Charles *et al.*<sup>23</sup> report, 'in the paternalistic model, the information exchange is largely one-way and the direction is from physician to patient. At a minimum, the physician must provide the patient with legally required information on treatment options and obtain informed consent on the treatment recommended... In general, this model assumes that the physician knows best, and will make the best treatment decision for the patient'. Therefore, there is no deliberation between patient and physician, and the latter is the sole decision-maker.

In the 'physician as a perfect agent for the patient' model, the physician uses their 'extensive knowledge to make the treatment decision for the patient, taking the patient's point of view'.<sup>24</sup> Here the information flow of patient

preferences is one-way (from patient to physician), because the physician 'needs to know each patient's utility function' in order to make a decision.<sup>19</sup> In this case, there is no deliberation between patient and physician, as the latter is the sole decision-maker. Interestingly, as Gafni *et al.*<sup>24</sup> argue, in theory the 'physician as a perfect agent' model and the 'informed treatment decision-making' model result in the same outcomes.

Of course, these decision-making models relate to theoretical paradigms, whereas situations in the real world most often conform to in-between approaches. All of the models, except the paternalistic one, include patient preferences, and eliciting them is becoming a major issue. In France, it is now time to develop and test strategies aimed at eliciting patient preferences at the physician-patient level. We are not aware of any systematic attempts at this except by Sebban *et al.*,<sup>22</sup> who developed a Decision Board for allogenic bone-marrow transplant which was pretested on healthy volunteers in the Lyon area, but never tested with patients at the decision point. Thus, the acceptability of this new kind of decision-making process in the French sociological and cultural context still needs to be tested.<sup>27</sup>

As stated before, such a decision-making process seems to be well suited to different clinical contexts, particularly in oncology. Up until now, the use of postoperative adjuvant chemotherapy for postmenopausal women with node-positive breast cancer ( $N < 8$ ) and positive hormonal receptors ( $ER \geq 10$ ) has been controversial. According to randomized clinical trials on adjuvant therapy for postmenopausal breast cancer patients,<sup>28,29</sup> chemotherapy decreases relapse rates with no significant impact on overall survival. Therefore, in clinical practice guidelines developed by the French Federation of Cancer Centre, chemotherapy is not considered as a therapeutic standard but only as an option, as opposed to hormone-therapy and radiotherapy, which are both part of standard treatment in this situation.<sup>30</sup> In such cases, the patient and the oncologist are both faced with the question of whether the

short-term reduction in the patient's quality of life due to chemotherapy is worth the long-term reduction in the risk of recurrence.

Various strategies taking patient preferences into account could have been explored in this therapeutic situation, such as video techniques,<sup>31,32</sup> booklets and audio cassette tapes, leaflets,<sup>18,19,33</sup> and the Decision Board (DB) method which uses visual aid and written material.<sup>22,34–37</sup> We chose the latter because it comes closest to everyday interactions between patients and physicians in France. To the best of our knowledge, this approach was first used in the Hamilton Regional Cancer Centre (Ontario, Canada), for women with node-negative breast cancer.<sup>34</sup> They were faced with the decision of whether or not to receive adjuvant chemotherapy. Because the DB was found acceptable and helpful for both patients and physicians, it is now used routinely in this Canadian Cancer Centre.

## Objectives

Our general objective was to develop and test a DB that would allow doctors to transfer clear and comprehensive information to patients, so that the patient could then make a decision or discuss it with another doctor. Accordingly, our approach is consistent with two of the decision-making models defined above, the 'patient as decision-maker' model and the 'shared decision-making' model. This paper presents the instrument development process in our Regional Cancer Centre located in Lyon, France, and reports the pretesting phase in terms of comprehension, internal consistency and across-time consistency, as well as the corresponding outcomes.

## Methods

As mentioned above, we developed a decision-making instrument for postmenopausal women with node-positive breast cancer ( $N < 8$ ) and positive hormonal receptors ( $ER \geq 10$ ). The aim was to present the different postoperative treatments available to these women, thus allowing

them to elicit a preference for one of the two options (one which included chemotherapy and the other which did not). A working group was created with five oncologists, one psychologist and two economists, who met once a month from the beginning of 1997. Two phases can be clearly identified: the instrument development phase and the pretest phase.

### Instrument development phase

An initial version of the DB was first elaborated by the working group, then presented for testing with health professionals and experienced patients.

#### *DB – initial version*

The two treatment options are described with their risks and benefits in an unbiased manner by means of written material and visual aids. The written material includes all the information to be transferred and can be seen as the physician's guide for using the visual aids. The visual aid is empty at the beginning of the interview and, each time a piece of information is orally provided to the patient, a corresponding card with written information is attached to the board with Velcro. By the end of the interview, all the information cards are on the board and all the information included in the written material has been transferred.

As regards the type and amount of information to be conveyed, the first version of the instrument was close to the one developed by Levine *et al.* 1992.<sup>34</sup> Information concerning relapse, free survival and overall survival was based on available results from randomized trials.<sup>28,29</sup>

Psychologists and economists have shown that the preferences elicited may depend on the way information is presented to respondents.<sup>38,39</sup> Even if other authors did not observe this phenomenon in the field of shared health care decision-making,<sup>40</sup> we attempted to minimize these potential presentation effects when designing the visual aids. Firstly, the order of presentation of the two therapeutic options could cause sequencing effects. We therefore

decided to present the two options simultaneously in eight successive points: (1) results of cancer surgery, (2) presentation of mandatory treatments (tamoxifen and radiation treatment), (3) formulation of therapeutic choice, (4) description of chemotherapy treatment, (5) presentation of the risks of relapse induced by the two options, (6) information about overall survival, (7) presentation of chemotherapy side-effects, and (8) treatment schedules. Secondly, in order to avoid format effects, the two treatment options were both presented in the visual aid by colours that would have as little influence as possible on the patient's choice: pale yellow for chemotherapy and pale orange for no chemotherapy. For the same reason, information concerning relapse rates was provided using bar charts instead of pie charts. This choice is rather unusual, but it was guided by the results of a survey conducted by Siminoff *et al.*,<sup>41</sup> where respondents found bar charts easier to understand, although less pleasant, than pie charts.

#### *Test with health professionals*

In order to test the content and presentation of the information conveyed, the first version of the instrument was presented to two groups of health professionals (one group of four nurses and one group of eight physicians), from the staff of the Cancer Centre. In both groups, the information was presented in the same way as it would to a patient. Reactions were approximately the same in the two groups and can be summarized as follows: (1) giving detailed information to the patient about the effects of chemotherapy and metastatic relapse may be viewed as too violent, (2) speaking of overall survival may be very frightening for the patient and can generate strong adverse reactions, (3) telling her that overall survival is not affected by chemotherapy, whereas the relapse rate is, can be difficult to understand and misleading, and (4) asking the patient to decide can result in an opinion that the physician may not know what the best option is, and therefore may decrease her confidence in her doctor. This last point throws into question the very principle of using DBs for health care decision-making.

However, the working group decided to continue, knowing that it would always be possible for a patient to refuse either to be informed and/or to decide. Such patient reactions, if they occurred, would provide very useful information concerning the acceptability of the instrument. Regarding the second and third points on overall survival, the choice was between giving the corresponding information to the patient or not. While recognizing that the points made by the health professionals were relevant, the working group decided to maintain the information. It was considered that this information was essential, and omitting it would be paradoxical since it would not allow the patient to make an 'informed-decision'.<sup>5,34,36,42</sup> Taking into account the first point regarding the amount of information provided, the working group decided to modify the initial version. Certain developments were shortened, especially those concerning metastatic relapse. Moreover, as many authors recommended, the language was simplified and made as unspecialized as possible.<sup>43-45</sup>

#### *Test with experienced patients*

After the written material and visual aid had been tested with health professionals and modified accordingly, another test was conducted with women who had already completed chemotherapy. The aim was to assess the clarity of language and presentation of the instrument, and to determine whether it reflected their experience. Women were selected according to two criteria: (1) they had received both chemotherapy and radiotherapy and (2) they had been operated on for breast cancer more than five years ago. The reason for the second point was that we did not want them to feel concerned retrospectively by the information provided on the five-year relapse rates. The psychologist for the working group presented the instrument to six women. All six women found that the instrument was clear, comprehensible and reflected their experience, except for tiredness induced by chemotherapy which was not specifically mentioned. Consequently, we added the possibility of feeling tired after

each course as one of the side-effects of chemotherapy.

In the final version of the instrument, the two major consequences of chemotherapy as compared to no chemotherapy (decrease in relapse risk and side-effects), were depicted as follows: the five-year relapse rates were estimated at 30% with chemotherapy vs. 40% without chemotherapy.<sup>28,29</sup> Four major potential side-effects were finally presented: hair loss, nausea and vomiting, tiredness and infection requiring hospitalization.

#### Pre-test phase

Comprehension, internal consistency and across-time consistency of the instrument were tested on a group of healthy volunteers. We felt that it would be unethical to manipulate information concerning therapies and outcomes with patients at the decision point without first having tested these properties on healthy volunteers.

#### *Pre-test subjects*

The instrument was tested on a group of healthy volunteers who were more than 50 years old and who had never experienced cancer. The sample was chosen as close as possible to the patient population in terms of the characteristics which, according to the literature, could influence patients' attitudes towards oncology treatments.<sup>46-49</sup> We selected four criteria: (1) age, (2) family situation, (3) parenthood and (4) professional situation. Healthy volunteers were recruited so that distribution in these four categories was the same as the distribution observed in the patient population. Once again, the same skilled interviewer used the instrument to interview all the volunteers, followed by a two-week retest on their decision to accept or reject chemotherapy treatment.

#### *Intervention materials*

Based on the outcomes of the development phase, we created a visual aid made of light cardboard, 35 cm wide and 50 cm high – large enough for the respondent to be able to read the cards without effort, but small enough to be carried

around easily. In line with the DB approach, a paper take-home version was created as well and given to the patient at the end of the interview (Fig.1). This would allow her to have further discussions with different people, such as relatives and family doctor, before making a decision.\*

#### *Comprehension*

We decided to test comprehension in the same way as Whelan *et al.* when they developed a DB for breast irradiation postlumpectomy.<sup>35</sup> During the first test with the DB, the interviewer provides the healthy volunteer with information, then asks her to answer 13 true or false statements regarding basic information items, which included: three statements related to general postoperative information, five regarding chemotherapy treatment and five concerning chemotherapy side-effects (Table 1). The items selected were those considered as key information to be understood by patients. It seemed important to assess comprehension rather than mere recall, because information must be fully understood by patients in order to justify claims to informed consent.

#### *Internal consistency*

As there is no gold standard to determine whether the expressed choice is the patient's true preference, only the internal consistency of the preference structure surrounding the treatment options can be evaluated.<sup>50</sup> In order to assess whether the choice of treatment changed in a predictable way according to changes in relapse rates and chemotherapy characteristics, two different approaches were used. One related to option attitudes based on outcomes, and the other to option attitudes based on process. Corresponding questions were asked after the comprehension questionnaire had been administered.

#### (1) Option attitudes based on outcomes

The hypothesis was that systematic manipulation of the five-year relapse rates would lead to predictable shifts in expressed choice<sup>51,52</sup>

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\*Written material and information cards can be obtained by writing to the authors.

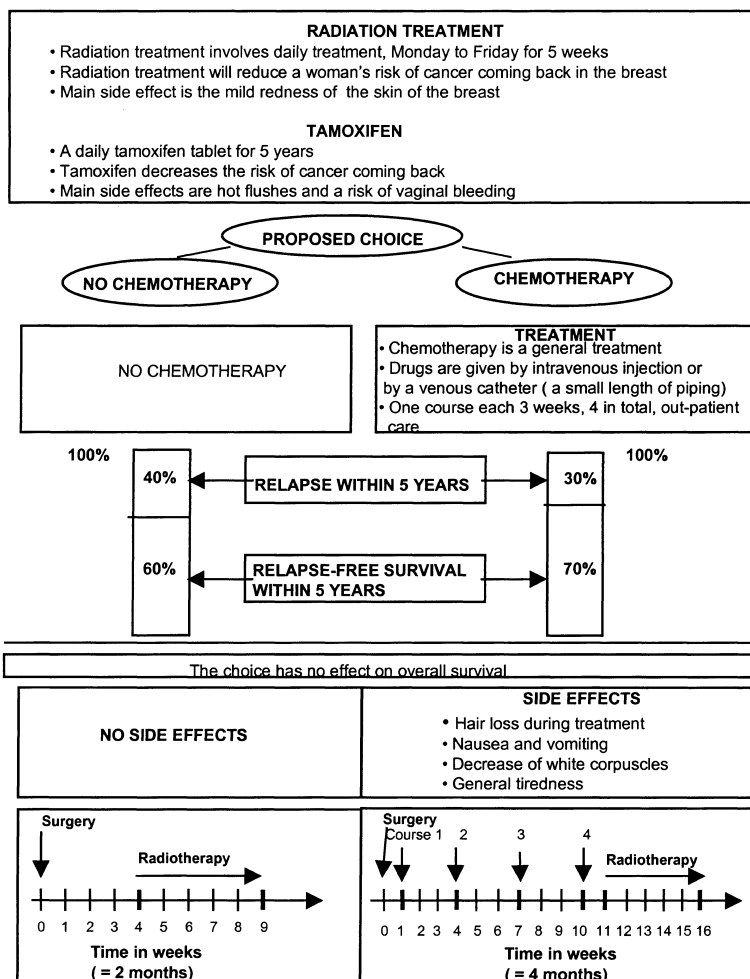


Figure 1 The decision board (take-home version).

(Table 2). For women who chose chemotherapy, the relapse rate without chemotherapy was held constant, while the relapse rate with chemotherapy was progressively increased. It was predicted that for a small or no gain in relapse rate, a woman would choose not to receive chemotherapy. For women who chose no chemotherapy, the relapse rate with chemotherapy was held constant and the relapse rate without chemotherapy was systematically increased until relapse was certain within 5 years. The prediction here was that a high enough increase in the relapse rate without chemotherapy would lead a woman to choose to receive chemotherapy.

(2) Option attitudes based on process

The hypothesis tested here was that modifying certain characteristics of the chemotherapy

treatment (conditions of administration and side-effects) would lead to predictable shifts in expressed choices (Table 3). The characteristics of the chemotherapy treatment were changed one by one, the others being held constant. Because we wanted them to be realistic, only slight changes were made. For a woman who chose chemotherapy, side-effects such as hair loss and risk of infection were increased. Conditions of administration were worsened: the catheter became mandatory, eight courses of chemotherapy instead of four were required, or hospitalization was implied. It was predicted that these changes would lead the woman to give up chemotherapy. Conversely, for a woman who chose no chemotherapy, the side-effects previously mentioned were suppressed, and

**Table 1** Comprehension questionnaire

Below are some statements on breast cancer and chemotherapy. Some of them are true and some are false. Please take your time and show whether you think they are true or false by circling the corresponding word beside each statement.

<b>CIRCLE ONE WORD ONLY</b>		
<b>TREATMENTS</b>		
1. Surgery fully protects against relapse	TRUE	FALSE
2. Tamoxifen is given by intravenous injection	TRUE	FALSE
3. Radiation treatment involves daily treatment Monday to Friday for 5 weeks	TRUE	FALSE
<b>CHEMOTHERAPY TREATMENT</b>		
4. Chemotherapy is a mandatory extra treatment	TRUE	FALSE
5. Chemotherapy is given by injection	TRUE	FALSE
6. Chemotherapy requires 8 courses at the Regional Cancer Centre	TRUE	FALSE
7. Chemotherapy requires spending nights at the Regional Cancer Centre	TRUE	FALSE
8. With chemotherapy all treatments are completed 2 months after surgery	TRUE	FALSE
<b>EFFECTS OF CHEMOTHERAPY</b>		
9. Chemotherapy decreases the risk of relapse Some side-effects of chemotherapy are:	TRUE	FALSE
10. Permanent hair loss	TRUE	FALSE
11. Nausea, vomiting	TRUE	FALSE
12. General tiredness	TRUE	FALSE
13. Having chemotherapy or not does not alter overall survival	TRUE	FALSE

conditions of administration improved: chemotherapy could be received at home, or could be orally administered. The prediction here was that these changes would lead the woman to choose chemotherapy.

It was not possible to use a parallel structure for the two subgroups. In fact, side-effects, such as tiredness, could be clearly suppressed in the no chemotherapy group. Conversely, worsening them in the chemotherapy group was not easy to express in a precise way. Moreover, some changes in the conditions of chemotherapy administration only pertained to one subgroup. This was the case for home chemotherapy, which was considered as an improvement for the no chemotherapy group.

#### *Across-time consistency*

The across-time consistency of the preference structure elicited by the DB intervention was assessed using the test-retest method, which means that the instrument was used on the same

respondent on two separate occasions. We chose a two-week time interval, which is appropriate in this sort of situation.<sup>50</sup> At the end of the first test with the instrument, each healthy volunteer was asked not only to choose whether or not to be treated, but also to indicate her strength of preference on a Visual Analog Scale (VAS) by moving a cursor along the scale. It was graduated from 0, representing indifference between the two options, to 10, corresponding to an absolute preference for the chosen option. The gradation was only visible to the interviewer, who could score the stated preference between 0 and 10.

Two weeks later, the instrument was administered again to the same respondent by the same skilled interviewer. Each woman was asked again to state her decision and specify a strength of preference on a VAS. Reliability was assessed using the Intraclass Correlation Coefficient based on variance analysis (ANOVA) for repeated measures.<sup>53</sup>



**Table 2** Internal consistency: option attitudes based on outcomes (5-year relapse rates)**Questionnaire for healthy volunteers having chosen chemotherapy**

Remember that the risk of relapse within 5 years is 30% with chemotherapy and 40% without chemotherapy, which represents a difference of 10%.

I am going to suppose that chemotherapy is less effective. So I am going to increase the risk of relapse with chemotherapy and you will have to tell me if you change your choice.

The risk of relapse without chemotherapy is still equal to 40%.

- (1) If the risk of relapse with chemotherapy is 32%, which means that the difference is 8%, do you choose chemotherapy?  
 Yes  No
- (2) If the risk of relapse with chemotherapy is 34%, which means that the difference is 6%, do you choose chemotherapy?  
 Yes  No
- (3) If the risk of relapse with chemotherapy is 36%, which means that the difference is 4%, do you choose chemotherapy?  
 Yes  No
- (4) If the risk of relapse with chemotherapy is 38%, which means that the difference is 2%, do you choose chemotherapy?  
 Yes  No
- (5) If there is no difference between the two options, do you choose chemotherapy?  
 Yes  No

**Questionnaire for healthy volunteers not having chosen chemotherapy**

Remember that the risk of relapse within 5 years is 30% with chemotherapy and 40% without chemotherapy, which represents a difference of 10%.

I am going to suppose that the risk of relapse without chemotherapy is higher and you will have to tell me if you change your choice. The risk of relapse with chemotherapy is still equal to 30%.

- (1) If the risk of relapse without chemotherapy is 45%, which means that the difference is 15%, do you choose no chemotherapy?  
 Yes  No
- (2) If the risk of relapse without chemotherapy is 50%, which means that the difference is 20%, do you choose no chemotherapy?  
 Yes  No
- (3) If the risk of relapse without chemotherapy is 55%, which means that the difference is 25%, do you choose no chemotherapy?  
 Yes  No
- (4) If the risk of relapse without chemotherapy is 60%, which means that the difference is 30%, do you choose no chemotherapy?  
 Yes  No
- (5) If the risk of relapse without chemotherapy is 70%, which means that the difference is 40%, do you choose no chemotherapy?  
 Yes  No
- (6) If the risk of relapse without chemotherapy is 80%, which means that the difference is 50%, do you choose no chemotherapy?  
 Yes  No
- (7) If the risk of relapse without chemotherapy is 90%, which means that the difference is 60%, do you choose no chemotherapy?  
 Yes  No
- (8) If the risk of relapse without chemotherapy is 100%, which means that the difference is 70%, do you choose no chemotherapy?  
 Yes  No

**Results***Characteristics of pretest participants*

Comprehension, internal consistency and across-time consistency of the instrument were tested on a group of 40 healthy volunteers. In

the published literature on DBs, sample sizes range from 25 to 42.<sup>22,34,36,37</sup> Healthy volunteers were selected so that the distribution of the sample in terms of the four selected criteria (see Methods) would be the same as the distribution of the patient population. This distribution was

**Table 3** Internal consistency: option attitudes based on process (characteristics of chemotherapy)**Questionnaire for healthy volunteers having chosen chemotherapy**

I am now going to increase chemotherapy side-effects and you will have to tell me if you still choose chemotherapy.  
For each question only one effect will be modified, others will be the same as presented before.

- (1) If chemotherapy involves total hair loss for one year, do you choose chemotherapy?  
 Yes  No
- (2) If chemotherapy systematically involves a decrease in white corpuscles requiring hospitalisation, do you choose chemotherapy?  
 Yes  No
- (3) If chemotherapy administration requires a catheter, do you choose chemotherapy?  
 Yes  No
- (4) If chemotherapy requires 8 courses instead of 4, which increases the treatment duration by 2 and a half months, do you choose chemotherapy?  
 Yes  No
- (5) If each course of chemotherapy requires two days' hospitalization, do you choose chemotherapy?  
 Yes  No

**Questionnaire for healthy volunteers not having chosen chemotherapy**

I am now going to decrease chemotherapy side-effects and you will have to tell me if you change your choice.  
For each question only one effect will be modified, others will be the same as presented before.

- (1) If chemotherapy does not involve hair loss, do you choose chemotherapy?  
 Yes  No
- (2) If chemotherapy involves neither nausea nor vomiting, do you choose chemotherapy?  
 Yes  No
- (3) If chemotherapy is given at your home, do you choose chemotherapy?  
 Yes  No
- (4) If chemotherapy is given orally, do you choose chemotherapy?  
 Yes  No
- (5) If chemotherapy does not increase tiredness, do you choose chemotherapy?  
 Yes  No

obtained from the patient database at the Cancer Centre concerning 348 postmenopausal breast cancer women admitted in 1996 and 1997. Mean age was 61 years: 16 women between 50 and 59, 14 between 60 and 69, and 8 over 70. Seventeen (42%) lived alone, and 7 (17%) had no children. Fifteen were retired, 15 were employed, and 10 were unemployed.

The first interview lasted 1 hour on average, and the second one 30 min.

*Initial choice, strength of preference and comprehension*

Eighteen respondents chose chemotherapy (45%), nine of whom definitely preferred this

option with a VAS score of 10 (Table 4, initial test). Twenty-two respondents chose not to have chemotherapy (55%), 10 of whom definitely preferred this option. Scores presented mean values of 7.8 ( $\sigma = 2.64$ ) and 8.3 ( $\sigma = 2.1$ ), respectively, in the two subgroups. A moderate preference being defined by a score less than 5 on the VAS (graduated from 0 to 10), there were 5 moderate preferences out of 40, none of them being less than 3.

Comprehension rates, defined as the proportion of right answers for each of the 13 questions, were never lower than 87.5% (Table 5). Therefore, none of the questions were randomly answered ( $P < 5 \cdot 10^{-6}$ , one-tailed  $\chi^2$  test).



Statement regarding	Number	Percentage
<b>TREATMENTS</b>		
1. Surgery fully protects against relapse	38	95
2. Tamoxifen is given by intravenous injection	36	90
3. Radiation treatment involves daily treatments Monday to Friday for 5 weeks	39	97.5
<b>CHEMOTHERAPY TREATMENT</b>		
4. Chemotherapy is a mandatory extra treatment	39	97.5
5. Chemotherapy is given by injection	39	97.5
6. Chemotherapy requires 8 courses at the Regional Cancer Center	35	87.5
7. Chemotherapy requires spending nights at the Regional Cancer Center	40	100
8. With chemotherapy all treatments are completed two months after surgery	39	97.5
<b>EFFECTS OF CHEMOTHERAPY</b>		
9. Chemotherapy decreases the risk of relapse Some side-effects of chemotherapy are:	38	95
10. Permanent hair loss	40	100
11. Nausea, vomiting	40	100
12. General tiredness	40	100
13. Having chemotherapy or not does not alter overall survival	37	92.5

**Table 5** Healthy volunteers comprehension: Correct responses by statement ( $n = 40$ )

As regards across-time consistency, none of the women shifted their choice between the two interviews (Table 4), and the Intraclass Correlation Coefficient was 0.97.

### Discussion and conclusion

The development of a Decision Board in our French Cancer Centre showed that this instrument is highly influenced by sociological and cultural contexts. For this reason, and not surprisingly, our DB is rather different from the one developed by Levine *et al.* in Ontario, Canada.<sup>34</sup> The latter addressed the role of adjuvant chemotherapy postoperatively in women with axillary node-negative breast cancer, which is close to our situation. But, to make the instrument acceptable for the health professionals in our Cancer Centre, we had to omit certain information essentially related to metastatic relapse. This most likely reflects fundamental differences between the two sociological and cultural contexts. After the DB had been tested with health professionals, another test was conducted with experienced patients,

where its clarity of language and presentation were confirmed. Comprehension and internal and across-time consistency of the instrument were then tested on a group of 40 healthy volunteers, who chose either chemotherapy (45%) or no chemotherapy (55%). These two percentages are close to those reported by Levine *et al.*<sup>34</sup> in a group of 30 healthy women (57% and 43%, respectively). Comprehension rates were very high, none being less than 87.5% in each of the 13 true or false statements. This finding is close to the result obtained by Elit *et al.* in advanced epithelial ovarian cancer.<sup>36</sup> According to the authors, 'the comprehension questionnaire was correctly answered by 96% of healthy volunteers'.

With regard to internal consistency, we first tested whether choice changed in a predictable way according to changes in relapse rates. In the two subgroups of women who chose either chemotherapy or no chemotherapy, they shifted their choice in the predicted way. This finding is consistent with Levine *et al.*,<sup>34</sup> Sebban *et al.*,<sup>22</sup> Elit *et al.*,<sup>36</sup> and Whelan *et al.*<sup>37</sup> It must be emphasised that four out of 40 women chose the

**Table 6** Preference shifts associated to changes in five-year relapse rates**Table 6.1** Shifts in the subgroup of healthy volunteers having chosen chemotherapy ( $n = 18$ )

Five year relapse rate with chemotherapy	Number	Percentage
30%	0	0
32%	0	0
34%	1	5
36%	8	44
38%	11	61
40%	17	94

**Table 6.2** Shifts in the subgroup of healthy volunteers not having chosen chemotherapy ( $n = 22$ )

Five year relapse rate without chemotherapy	Number	Percentage
40%	0	0
45%	1	4
50%	14	64
55%	15	68
60%	16	73
70%	17	77
80%	18	82
90%	18	82
100%	18	82

no chemotherapy option even when the five-year relapse was assumed to be certain, which reflects a strong aversion to chemotherapy.

**Table 7** Preferences shifts associated to changes in the characteristics of chemotherapy**Table 7.1** Shifts in the subgroup of healthy volunteers having chosen chemotherapy ( $n = 18$ )

Chemotherapy characteristics	Number	Percentage
1. If chemotherapy involves total hair loss for one year	2	11
2. If chemotherapy systematically involves a decrease in white corpuscles requiring hospitalization	5	28
3. If chemotherapy administration requires a catheter	3	17
4. If chemotherapy requires 8 courses instead of 4, which increases the treatment duration by 2 and a half months	1	5
5. If each course of chemotherapy requires a two days hospitalization	1	5

**Table 7.2** Shifts in the subgroup of healthy volunteers not having chosen chemotherapy ( $n = 22$ )

Chemotherapy characteristics	Number	Percentage
2. If chemotherapy involves neither nausea nor vomiting	8	36
3. If chemotherapy is given at your home	4	18
4. If chemotherapy is given orally	6	27
5. If chemotherapy does not increase tiredness	7	32

Secondly, we tested whether choice changed in a predictable way according to changes in chemotherapy characteristics. For the women who chose chemotherapy, their decision was not very sensitive to increasing side-effects or worsening conditions of treatment administration. Our results are not as affirmative as those reported by Levine *et al.*, which is that: 94% of the women 'switched their choice when the toxicity of treatment was increased such that the chance of a fatal side-effect was 50%'.<sup>34</sup> But this change is much more extreme than those we tested. With regard to the no chemotherapy choice, it was rather sensitive to changes in the conditions of administration and side-effects of chemotherapy, especially hair loss: 50% shifted to chemotherapy when hair loss was eliminated, all other characteristics being held constant. Our findings are supported by what Levine *et al.* reported: '100% shifted when toxicity was eliminated'.<sup>34</sup> However, it is important to remember that all these results are highly dependent on presumed changes in chemotherapy characteristics (nature and magnitude).

Across-time consistency assessed using the test-retest method was excellent. None of the women shifted their choice between the two

interviews, and the ICC was as high as 0.97. This result is consistent with the findings of other authors, although they did not score preferences using a VAS, but rather a Likert scale, either with six points<sup>34</sup> or seven points.<sup>22</sup> In addition to good comprehension and consistency properties, another advantage of the DB instrument is its flexibility. It can be easily and inexpensively modified as new relevant data are reported. This is now the case for our therapeutic situation, since new data report a slight significant increase in overall survival with chemotherapy,<sup>54</sup> whereas previous scientific literature did not.<sup>28,29</sup>

This feature emphasises another important point. Since the DB method involves giving the patient a take-home version at the end of the interview, developers of such instruments must use the highest quality information available. This ensures that the patient benefits from the best research evidence available related to the treatment options.<sup>55</sup>

As previously stated, up until now, several methods have been used to transfer information from physician to patient. The DB approach is one of them and was chosen here because it is well adapted to every day interactions between patients and physicians in our country. All of these methods raise many unresolved questions,<sup>17,56</sup> and further empirical research is needed to assess their effects.<sup>57,58</sup> Questions to be addressed include which presentation options people find most useful, and how they affect people's understanding and decisions. With regard to the general application of the DB method, the different stages (tests with health professionals, people who have experienced the options under consideration, and healthy volunteers) could be used to validate any physician-to-patient information transfer. It could be applied to any health care decision situation which involves patient trade-offs, in an oncology context or in another. And, interestingly enough, it could also be used in informed consent decision situations, where the information transferred is not systematically validated today.

Health care decision situations which involve patient trade-offs require a decision-making

process in which the physician and patient are both involved.<sup>24,59</sup> According to the two reference models, namely the "shared decision-making" model and the 'patient as decision-maker' model, the physician acknowledges the importance of the patient's preferences and provides him/her with current information related to the different options. Available literature shows that most patients have a high preference for information concerning their disease. However, their preference for participation in decision-making is not so clear.<sup>3,4,60-64</sup> Therefore, the decision-making process must take into account the patient's desire to be informed on the one hand, and willingness to participate in decision-making on the other.<sup>45,65</sup>

In our setting, the DB approach is now being tested with real patients. Their reactions will tell us which type of decision-making model is at work. It might be the 'patient as decision-maker' model, the 'shared decision-making' model, or even the 'physician as decision-maker' model if the patient does ask the physician to make the decision for her.

More generally, further research is needed to explore the process of shared decision-making and to clarify what the concept means.<sup>23,25</sup> It is important as well that we study the determinant characteristics that influence the degree of patient involvement in treatment choices in different sociological and cultural contexts. For this purpose, international comparisons could be quite appropriate.

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