

## ORIGINAL ARTICLE

# Implementing a breast cancer patient decision aid: Process evaluation using medical files and the patients' perspective

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## Abstract

**Objective:** Although patient decision aids (PtDAs) have been shown to improve shared decision-making, integration into clinical care pathways remains limited. This study investigated, among other outcomes, the uptake of the PtDA by professionals and the uptake as perceived by patients.

**Methods:** We performed a process evaluation among four breast cancer care teams that had been exposed to a multifaceted implementation strategy. Data were gathered by auditing patient files using a standardised data extraction sheet and conducting telephone interviews with patients using a structured interview guide. We analysed the data by using descriptive statistics.

**Results:** We found that the implementation strategies, including advice on how and when to present the PtDA to the patient, were followed for 14% of the included patients ( $N = 84$ ); 92% of the patients reported to have received a login code for the web-based PtDA, while 67% logged in and used the PtDA at home. An important factor influencing the use was the clinician promoting it when delivering the PtDA (OR 9.95 95% CI 3.03–37.72).

**Discussion:** The implementation strategies were followed in 14% of the patients, and a high delivery of the PtDA was achieved. Redesigning the care pathway and providing personal instruction on using PtDAs seem crucial.

## KEYWORDS

breast cancer, implementation, patient decision aid, patient involvement, preference-sensitive decision, shared decision-making

## 1 | INTRODUCTION

For most women diagnosed with early-stage breast cancer (stage I or II), breast-conserving therapy (BCT) and mastectomy are equally effective in terms of survival (Fisher et al., 2002; Litiere et al., 2012;

van Maaren et al., 2019; McGuire et al., 2009), which indicates that the patient's preference should probably dominate the decision. Preferences that are often mentioned by patients are related to the level of fear and anxiety, perceived survival odds, body image values, attitudes towards radiotherapy, the preference or perceived

Wilma contributed equally to this work.

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preference of the surgeon, the communication between patient and professional, and the patient's involvement in the decision-making process (Caldon et al., 2011; Hershman et al., 2009).

Several studies have shown that involving patients in the decision-making process improves their knowledge of treatment risks and benefits and increases their satisfaction with the final decision (Barry & Edgman-Levitan, 2012). Patient decision aids (PtDAs) increase patient involvement in the decision-making process and also result in more accurate risk perceptions among patients and decisions that are more consistent with the patients' values (Stacey et al., 2014).

Although support for the large-scale adoption of shared decision-making (SDM) is growing, actual implementation is slow and faces many challenges (Elwyn, Scholl, et al., 2013). Implementation of SDM is suffering from a lack of knowledge and self-efficacy among clinicians, who may have negative attitudes towards SDM in general or towards the content of PtDAs (Gravel et al., 2006; Legare et al., 2014). Although the majority of patients prefer the SDM model, a minority of patients may not be prepared to be involved in the decision-making process, due to feeling they have insufficient capacity or knowledge to be involved in the decision-making process. Patients' emotional needs and lack of time can also prevent them from participating in the SDM process (Moreau et al., 2012; O'Brien et al., 2014). Assuming that PtDAs are an essential tool in supporting the SDM process, we developed a PtDA based on the IPDAS criteria between 2013 and 2015, as part of the implementation of SDM in breast cancer care (Savelberg et al., 2017; see Appendix S1).

During the development period, we encountered various challenges such as embedding the PtDA in the clinical pathway, enabling its timely presentation to patients without delaying the start of treatment, motivating professionals to actually deliver the PtDA, and dividing the decision-making process over more than one consultation. Not all patients used the PtDA, either due to lack of motivation, not being clearly instructed, being distracted by intense emotions, or otherwise showing resistant. We learned that to implement the PtDA, we need a combination of implementation strategies focussing not only on the clinician but also on the process and organisation of breast cancer care. The local problems we found are in line with comparable studies from the UK, France and Canada (Joseph-Williams et al., 2017; Nguyen et al., 2014; O'Brien et al., 2014; Sivell et al., 2012).

To overcome the barriers we encountered in our development study and in the literature on breast cancer care, we developed the implementation strategies described in the method section, some

of which were customised for each hospital. We subsequently used these strategies to implement the PtDA in breast cancer care. This study is part of a larger study on the development of a PtDA and implementation strategies to integrate the PtDA into daily clinical practice (Savelberg et al., 2019; Savelberg et al., 2017). The main aim of the current implementation study was to investigate the implementation process of the PtDA and thereby improve the process of SDM. We did so by assessing the uptake of the implementation strategies in breast cancer care by professionals and the uptake of the PtDA as perceived by patients. Next to this primary outcome, we were able to assess patients' perceptions of being involved in decision-making. Lastly, we assessed concordance between the patients' stated preferences and the actual decisions made about treatment.

## 2 | METHOD

### 2.1 | General design

We designed an observational study, which was a prospective process evaluation of the below-described strategies to implement the PtDA in regional hospitals. Although our study was prospectively planned, the data for the process evaluation were collected during the implementation process, and not afterwards by asking the participants about their perceptions of or experiences with PtDA uptake and SDM performance in hindsight. Quantitative data were collected by auditing patient files and by interviewing patients by telephone. In the interviews, we used a structured questionnaire and asked the patients to explain their answers with concrete examples. To describe our findings, we used SQUIRE 2.0 guidelines for reporting quality improvement study (Ogrinc et al., 2016).

The study took place from May 2016 to June 2017, with four hospitals being included on starting dates at their own convenience and a maximum duration of intervention and data collection of eight months per hospital.

### 2.2 | Participants

The breast cancer team of MUMC+ is part of a regional oncology network (OncoZON) consisting of nine breast cancer teams in the south of the Netherlands. Four of these teams agreed to participate

TABLE 1 Hospitals, member of the regional consortium OncoZON participating in the study

Hosp. 1 <sup>a</sup>	Hosp. 2 <sup>b</sup>	Hosp. 3 <sup>a</sup>	Hosp. 4 <sup>c</sup>	Hosp. 5 <sup>b</sup>	Hosp. 6 <sup>a</sup>	Hosp. 7 <sup>c</sup>	Hosp. 8 <sup>b</sup>	Hosp. 9 <sup>a</sup>
Implementing SDM		Implementing SDM	Implementing SDM		Implementing SDM	Implementing SDM		Implementing SDM
Participated in study		Participated in study			Participated in study			Participated in study

<sup>a</sup>Hospitals willing to implement the PtDA and participating in the study.

<sup>b</sup>Hospitals not willing to implement the PtDA.

<sup>c</sup>Hospitals willing to implement the study, without participating in the study.

in the process evaluation. Table 1 gives an overview of the regional network and the participating hospitals. To gain access to the PtDA, the teams had to consent to pay a fixed fee of € 2500 to the company hosting the PtDA. Each hospital was asked to consecutively include 30 patients with newly diagnosed breast cancer, stage I or II, who were eligible for breast-conserving therapy or mastectomy and who had been offered the PtDA, according to the professionals. Eligible patients should be able to speak and understand Dutch and were identified at the tumour board meetings. The clinician provided written information about the aim and procedure of the study. If the patient gave permission to be approached, the researcher (W.S.) phoned the patient within two weeks after the consultation but before the treatment started.

## 2.3 | Ethical considerations

The MUMC+ ethics committee (No. 16-4-083) declared that this study does not fall under the scope of the Medical Research Involving Human Subjects Act. Handling of personal data was in accordance with the Dutch Personal Data Protection Act and Medical Research (Human Subjects) Act.

## 2.4 | Implementation strategies

We planned to perform a pre- and post-implementation pilot study, to collect outcome and process data from patients and objective outcomes with regard to professional performance on involving patients in four breast cancer teams from three hospitals and one specialised breast cancer clinic. During the pre-implementation period, 1 hospital withdrew, and the specialised breast cancer clinic was not able to include patients, due to lack of time and motivation, while inclusion in the other two hospitals was not easy as well. We included 14 patients instead of the 40 patients we aimed for. Before we started the post-implementation period, two breast cancer teams from other hospitals signed up to participate in the study. This resulted in more, but scattered data, not equally divided among hospitals and with quite a few missing data. This meant we could not use the data as planned and had to deviate from the original protocol. Based on these experiences in the pilot study, we concluded that we would not be able to conduct a multicentre cluster RCT to test the implementation of SDM and a PtDA. Nevertheless, the gathered data did provide useful insights in the clinical practice of breast cancer care and contributed to compile the multifaceted implementation strategy we developed in this study. The implementation strategies were based on implementation theories and were co-created with the end users.

Based on the lessons from the development period, we designed the following implementation strategies: (a) a procedure aimed at clinicians and patients for presenting and using the PtDA and (b) advice aimed at the clinicians, teams and designers of the pathway to enhance the performance of SDM in clinical practice. The strategies are flexible and can be tailored to the specific needs and workflow

of each hospital. At the start of the study, we invited each team to a specific hospital meeting in which we explained all the implementation strategies, we gave advice with regard to procedures, and we monitored them during the process. Hereafter, we had regular contact with the nurse practitioners per team to answer questions and explain the procedures.

### 2.4.1 | The PtDA

The web-based PtDA presents comprehensive information about all the possible options. The information includes numerical information about survival and recurrence rates, pros and cons of treatments and side effects. The numerical information is presented in graphical population diagrams. For each treatment option, patient values are elicited by inviting the patient to indicate the importance of certain issues on visual analogue scales. The patient can illustrate values and issues with open-text wordings or narratives. To conclude, the patient can print a one-page sheet summarising her personal value scores and open-text wordings, so she can bring these to the next consultation.

The PtDA includes a four-minute video, aimed at both patients and professionals, in which a clinician and a patient talk about the importance of SDM and how the PtDA can be used to support this process. The purpose of the video is to raise awareness of the collaborator nature of the SDM process and the positive impact of SDM.

### 2.4.2 | The strategies to implement the PtDA

Our advice regarding implementation was aimed at the clinicians and teams to enhance the performance of SDM in clinical practice. This advice consisted of the following components:

- A standardised procedure that could be adapted to specific hospital needs to discuss the treatment options and decide whether there is an indication for using the PtDA in the multidisciplinary tumour board meetings and to systematically record the treatment options and the indication for using the PtDA in the patient's file.
- Tailored advice for the breast cancer team about the timing of the delivery of the PtDA to the patient. Ideally it should be offered by the surgeon to the patient at the end of the consultation in which the diagnosis is discussed and explained. After the prescription of the PtDA by the surgeon, the breast cancer nurse further explains how and why to use the PtDA. The nurse mentions the completeness of the risk information that may summarise the information given during the consultation. The nurse also mentions the value elicitation part of the PtDA, which can help the patient reflect on what is important in her life.
- A recommendation to record the treatment options discussed with the patient and the actual delivery of the PtDA, or the reason for not discussing this in the patient file.

- An invitation for the teams to attend a meeting in which the application of the SDM process is explained and ways to motivate patients to use the PtDA are discussed.

### 2.4.3 | Strategy to be used during patient-physician encounter

The patient can log in and read the PtDA at home. After first reading the general information, the patient is invited to tick the options that had been marked on the prescription pad sheet, so only the treatment options that are available to the individual patient are shown on the screen. Thus, each patient can personalise the PtDA to prevent overload of information.

The personal login code is printed on a paper prescription pad, which is available on the clinician's desk in the consultation room. Besides a unique personal login code, each sheet contains a drawing of the breasts, so that the clinician can indicate the size and location of the tumour, as well as the various treatment choices to remind the professional about presenting the PtDA.

The clinician hands the patient the prescription pad sheet with the personal login code to 'prescribe' the PtDA. The clinician personalises the sheet by ticking the treatment options that are relevant for the patient in addition to breast-conserving treatment or mastectomy, that is adjuvant or neo-adjuvant chemotherapy, and/or reconstructive surgery during or after the curative surgery (Appendix S1).

In close consultation with each participating hospital, the implementation strategy was tailored to the hospital. For instance, each breast cancer team chose when to offer the PtDA. In some hospitals, the PtDA was offered by the surgeon, while in others, it was offered by the nurse in a second consultation. In some hospitals, the follow-up consultation which included decision talk was conducted by telephone, while in other hospitals, this was done face-to-face. The company hosting the PtDA and the first author both acted as the change agents.

## 2.5 | Endpoints and data collection

To assess the uptake of the set of implementation strategies by professionals, we collected data from the tumour board reports as well as from the patient files using a standardised data extraction sheet (Appendix S2). We did not collect data from the server of the company that hosted the PtDA. The reports of the multidisciplinary tumour board were systematically audited for the suggested treatment plan or options and whether an indication for the PtDA had been recorded. The patient files were further audited for records of the presentation of the PtDA and the final treatment decision.

To assess the uptake of the PtDA as perceived by patients, concordance between preferred and actual treatment, and the patients' perception of the SDM process, patients were interviewed

by telephone using a structured questionnaire. This questionnaire consisted of four sections (Appendix S3).

1. A section consisting of three items assessing co-variables including age in years and educational level (lower level education; intermediate level education; higher education).
2. A section consisting of 13 items assessing the patient's perceptions of the process of presentation, promotion and actual uptake of the PtDA (with answer options 'yes', 'no', 'I don't know'), and the patient's satisfaction with the use of the PtDA, on a 10-point Likert scale.
3. A section assessing the patient's preference for the type of surgical treatment, on a 7-point scale (anchors: I definitely do/do not intend to choose to have a BCT/ mastectomy) (Winn et al., 2015).
4. A section assessing the patient's experience of SDM, measured by the Dutch version of the CollaboRATE instrument (Barr et al., 2014; Elwyn, Barr, et al., 2013; Stubenrouch et al., 2016), including three questions with a 10-point anchored scale (0 = no effort was made, 9 = every effort was made).

To assess concordance between preferred and actual treatment, we also collected data on actual treatment from the patient files.

## 2.6 | Data analysis

The data were analysed using descriptive statistics in the Statistical Package for Social Sciences, version 11 (Appendix S4). For each variable, we calculated proportions, means and standard deviations for the total sample and for each individual hospital. In case of skewed data, we calculated medians and interquartile ranges. With regard to the CollaboRATE instrument, we calculated the average and top score (Barr et al., 2014). To calculate the top score, we coded each encounter as '1' if the response to all three items was 9 or '0' if the response to any of the three items was <9. We then calculated the percentage of all encounters that were coded as '1'. This is the CollaboRATE top score.

We hypothesised that a higher adherence by professionals to the implementation strategies—for example systematically recording the delivery of the PtDA to the patient (by whom, how) in the patient file as well as giving personalised instructions on the importance and use of the PtDA—would result in a better uptake of the PtDA by patients. To test this hypothesis, we built a multivariate backward logistic regression model for the uptake of the PtDA (logged in yes or no) as a dependent variable and the following independent variables: age, educational level, recording of the delivery of the PtDA in the patient file and whether the patient clearly remembered that the clinician who delivered the PtDA had promoted its use.

We also hypothesised that stating whether the PtDA was indicated by the multidisciplinary tumour board and recording the delivery of the PtDA would result in a higher score on the CollaboRATE instrument. To test this hypothesis, we built a

multivariate backward logistic regression model of the perceived process of SDM (i.e. top score or no top score for all three questions of CollaboRATE) as the dependent variable and the following independent variables: age, educational level, setting the indication for the PtDA by the multidisciplinary tumour board and recording the delivery of the PtDA.

### 3 | RESULTS

#### 3.1 | Study population

A total of 86 patients were initially eligible, 84 of whom consented to participate. One patient reconsidered and did not want to participate and another patient could not be reached in time. The teams did not manage to include the preferred number of 30 patients per hospital due to lack of time, perceived overload of research tasks in breast cancer care and organisational issues. Table 2 summarises

the demographic and clinical characteristics of the included patients. The average age of the participants was 61 years, and one-third of them (30%) reported a low educational level.

#### 3.1.1 | Topic 1: Uptake of the strategies to implement the PtDA in breast cancer care by the professionals

For 14% (12) of the patients, the recommended implementation strategy (i.e. the five steps mentioned below) was followed completely. Based on our audit of the patient files, the most frequently missed step was setting the indication for the PtDA by the tumour board (see Table 3).

1. For 49 (58%) patients, the tumour board report recommended two treatment options. The indication for the PtDA was reported in 30 (34%) of the tumour board reports.

TABLE 2 Patient demographic and clinical characteristics

Demographic characteristics	Total N = 84	Hosp. 1 N = 31	Hosp. 2 N = 25	Hosp. 3 N = 18	Hosp. 4 N = 10
Age (years) mean, standard deviation (SD)	61.1 (9.9)	60.2 (10.8)	61.8 (9.9)	61.6 (10)	61.2 (6.6)
Education level					
Low level of education	25 (29%)	8 (25%)	8 (32%)	7 (37%)	2 (20%)
Intermediate to higher level of education	59 (69%)	23 (72%)	16 (64%)	12 (63%)	8 (80%)
Missing	2 (2%)	1 (2%)	1 (4%)	0	0
Treatment plan					
No. of patients with one option	35 (42%)	5 (16%)	6 (24%)	14 (78%)	10 (100%)
No. of patients with > one option	49 (58%)	26 (84%)	19 (76%)	19 (76%)	0

TABLE 3 Uptake of the SDM implementation strategies by professionals, according to the tumour board report or patient files

	Total (N = 84)	Hosp. 1 (N = 31)	Hosp. 2 (N = 25)	Hosp. 3 (N = 18)	Hosp. 4 (N = 10)
Indication for PtDA recorded in the tumour board report	30 (34%)	18 (58%)	10 (42%)	2 (11%)	0
Recording of treatment options in the patient file	51 (59%)	24 (77%)	21 (88%)	6 (33%)	0
Records of discussions on treatment options between clinicians and patients	33 (39%)	20 (65%)	7 (29%)	1 (6%)	5 (50%)
Recording the delivery of the PtDA in the patient file	68 (79%)	29 (94%)	21 (88%)	12 (67%)	6 (60%)
Final surgical treatment					
BCT	63 (75%)	18 (58%)	19 (79%)	16 (89%)	9 (90%)
Mastectomy	20 (24%)	13 (42%)	5 (17%)	2 (11%)	1 (10%)
Missing	1 (1%)		1 (4%)		

TABLE 4 Results of the structured telephone interviews

Variable	Total N = 84	Hosp. 1 N = 31	Hosp. 2 N = 25	Hosp. 3 N = 18	Hosp. 4 N = 10
The doctor explained there were different options for treating your breast cancer					
Yes	77 (93%)	29 (94%)	23 (96%)	15 (83%)	10(100%)
No	4 (5%)	2 (6%)	1 (4%)	1 (6%)	
? <sup>a</sup>	2 (2%)			2 (11%)	
The doctor made it clear that a decision needed to be made					
Yes	73 (88%)	28 (90%)	20(83%)	15(83%)	10(100%)
No	5 (6%)	3 (10%)	1 (4%)	1 (6%)	
?	5 (6%)		3 (13%)	2 (11%)	
Patient received a prescription pad sheet					
Yes	77 (93%)	27 (87%)	21(88%)	18(100%)	10(100%)
No	2 (2%)		2 (8%)		
?	5 (6%)	4 (13%)	1 (4%)		
The clinician personalised the PtDA					
Yes	67(80%)	21 (66%)	18(76%)	17 (94%)	10(100%)
No	3 (4%)		2 (8%)	1 (6%)	
?	14 (16%)	10 (34%)	4 (16%)		
The clinician explained the importance and/or gave instructions on using the PtDA					
Yes	59 (69%)	20 (64%)	15(58%)	13 (72%)	10(100%)
No	4 (5%)	2 (6%)	1 (4%)	1 (6%)	
?	21 (26%)	9 (30%)	9 (38%)	4 (22%)	
Patient logged in to PtDA					
Yes	56 (67%)	14 (45%)	17(71%)	15 (83%)	9 (90%)
No	28 (33%)	17 (55%)	7 (29%)	3 (17%)	1 (10%)
Treatment preference					
BST	56 (67%)	19 (61%)	15(63%)	15 (83%)	6 (60%)
Mast.	20 (24%)	9 (30%)	7 (29%)	1 (6%)	3 (30%)
?	8 (9%)	3 (9%)	2 (8%)	2(11%)	1 (10%)
	<b>Total N = 56</b>	<b>Hosp. 1 N = 14</b>	<b>Hosp. 2 N = 17</b>	<b>Hosp. 3 N = 15</b>	<b>Hosp. 4 N = 9</b>
Patient personalised the PtDA					
Yes	49 (88%)	13 (92%)	14(82%)	12 (80%)	9 (100%)
No	3 (5%)	1 (8%)	1 (6%)	1 (7%)	
?	4 (7%)		2 (12%)	2 (13%)	
Patient read the value elicitation statements					
Yes	50 (90%)	13 (92%)	15(88%)	13 (87%)	8 (89%)
No	5 (9%)	1 (8%)	1 (6%)	2 (13%)	1 (11%)
?	1 (1%)		1 (6%)		
Patient found the value elicitation statements useful					
Yes	42 (77%)	10 (71%)	13(76%)	13 (87%)	6 (67%)
No	4 (7%)	1 (8%)	2 (6%)		1 (11%)
?	9 (16%)	3 (21%)	2 (6%)	2 (13%)	2 (22%)
Patient took a printed summary to the next consultation					
Yes	25 (45%)	9 (64%)	8 (47%)	3 (20%)	4 (45%)
No	28 (50%)	5 (36%)	8 (47%)	12 (80%)	3 (33%)
?	3 (5%)		1 (6%)		2 (22%)

(Continues)

TABLE 4 (Continued)

	Total N = 56	Hosp. 1 N = 14	Hosp. 2 N = 17	Hosp. 3 N = 15	Hosp. 4 N = 9
The clinician discussed the summary with the patient					
Yes	13 (24%)	2 (14%)	5 (29%)	4 (27%)	1(11%)
No	42 (75%)	12 (86%)	11(65%)	11 (73%)	8 (89%)
?	1(1%)		1 (6%)		
Score for satisfaction With PtDA Mean and standard deviation (SD)	7.9 (1)	8.2 (9,9)	7.9 (1)	7.9 (1)	7.6 (0.7)
Score for recommending PtDA to other patients Mean (SD)	8.1 (0.9)	8.3 (0.8)	8 (1.2)	8.3 (0.7)	7.8 (0.4)
<b>CollaboRATE</b>	<b>N = 80</b>	<b>N = 29</b>	<b>N = 23</b>	<b>N = 18</b>	<b>N = 10</b>
How much effort was made to help you understand your health issues? Mean, (SD)	8.3 (0.8)	8 (1.1)	8.5 (0.6)	8.4 (0.6)	8.2 (0.4)
How much effort was made to listen to the things that matter most to you about your health issues? Mean, (SD)	8.2 (0.9)	7.9 (1.1)	8.3 (0.7)	8.3 (0.7)	8.2 (0.4)
How much effort was made to include what matters most to you in choosing what to do next? Mean, (SD)	7.9 (1)	7.5 (1.8)	7.7 (1.3)	8.2 (0.7)	8.1 (0.3)
CollaboRATE total. Mean (SD)	8.1 (0.8)	7.9 (1)	8.3 (0.7)	8.3 (0.6)	8.2 (0.3)
CollaboRATE top score	24.4%				

°? = patient did not know or could not answer the question.

2. With regard to the reports in the patient files, we found more than one treatment option recorded in 51 (59%) patient files, while delivery of the PtDA was recorded in 68 (79%) patient files.

Based on the interviews, most patients remember the clinician explaining that there is more than one option and receiving a prescription pad for the PtDA (see Table 3).

- The majority of patients (93%) clearly remembered that the clinician had explained to them that there was more than one treatment option available, while 88% of the patients remembered that the clinician had made it clear that a choice between the options had to be made.
- Most patients (93%) remembered that they had received a prescription pad sheet with a login code, while 67 (80%) patients reported that the clinician had personalised the PtDA by ticking the boxes of the applicable treatment options on the prescription pad.
- Two-thirds of the patients ( $n = 58$ , 69%) clearly remembered the clinician explaining the importance of using the PtDA and/or receiving instructions on how to use it.

### 3.1.2 | Topic 2: The uptake of the PtDA as perceived by patients

The average duration of the telephone interview was 8.4 (SD 2.6) minutes. Duration ranged from 4 minutes with patients who had not

used the PtDA to about 16 minutes for patients who had. Two-thirds ( $n = 56$ , 67%) of the patients had actually logged in to the PtDA (see Table 4). Various reasons for not logging in were mentioned: nine patients indicated they had received too much information, six patients indicated they had no computer or computer skills, four patients had forgotten about the PtDA, three patients had already decided on their treatment and consequently felt no need to use the PtDA, and six patients gave other individual reasons.

Fifty-six patients logged in to the PtDA, of whom 80% ( $n = 45$ ) personalised it. Ninety per cent ( $n = 50$ ) of those patients read the value clarification statements; 77% ( $n = 43$ ) used them and found them helpful. In addition, 45% of these patients ( $n = 35$ ) printed out the summary of the value clarification tool and took it along to the next consultation. Thirteen (24%) patients reported having discussed the summary with their clinician. Patients who used the PtDA gave a score of 7.9 (SD 1.0) on a scale of 0–10 for satisfaction.

The multivariate backward logistic regression model showed that clearly remembering the clinician promoting the use of the PtDA was positively related to using the PtDA (OR 9.95; 95% CI 3.03–37.72) (see Table 5), whereas older age was negatively related to using the PtDA (OR 0.91 95% CI 0.85–0.97).

We took a close look at the subgroup of patients for whom the professionals fully adhered to the recommended implementation strategy. There is no statistically significant difference regarding the uptake of the PtDA in this subgroup compared to the other patients.



**TABLE 5** Influence of demographic characteristics and the implementation strategies on the odds that patients use the PtDA and the patients' experience with the process of shared decision-making

Login in to the PtDA			Score on CollaboRATE		
Dependent: 1= patient logged in to the PtDA 0= patient did not log in to the PtDA			Dependent: 1 = top score 0 = no top score		
Independent variables that remain in the analysis: Age in years Remembering the clinician explaining the importance and/or use of the PtDA (yes=1, no =0)			Independent variables that remain in the analysis: Recording of delivery of the PtDA Logging in to the PtDA		
Independent	Beta (SE)	Adjusted OR (95% CI)	Independent	Beta (SE)	Adjusted OR (95% CI)
Intercept	5.446 (2.17)		Intercept	-1.53 (0.81)	
Age in years	-0.100 (0.34)	0.91 (0.85 - 0.97)/0.004	Recording of delivery	1.2 (0.82)	3.3 (0.67-16.33)/0.108
Recalling instructions	2.298 (0.61)	9.95 (3.03-32.72)/0.001	Logging in	-0.86 (0.55)	0.42 (0.15-1.25)/0.077
R <sup>2</sup> = 29.98 (significant)			R <sup>2</sup> = 10 (not significant)		

Adjusted odds ratio (OR) and 95% confidence intervals (CIs) N = 84 patients.

**TABLE 6** Concordance between preference and final treatment.

	Hosp. 1 N = 84	Hosp. 2 N = 31	Hosp. 3 N = 18	Hosp. 4 N = 25	Hosp. 5 N = 10
Non-concordance	15 (17%)	6 (19%)	2 (11%)	3 (12%)	4 (40%)
Preference for breast-conserving therapy Eventual mastectomy treatment	8				
Preference for mastectomy Eventual breast-conserving therapy	7				
Concordance	59 (72%)	22 (71%)	14 (78%)	19 (76%)	5 (50%)
No preference	8 (10%)	3 (10%)	2 (11%)	2 (8%)	1 (10%)
Missing	1 (1%)			1 (4%)	

### 3.1.3 | Topic 3: Patients' perceptions of the SDM process

The mean patient-reported outcome of the SDM process as measured by the CollaboRATE was 8.1 (SD 0.8) on a scale of 0–9. One-quarter of the patients (24.4%) gave a top score (a score of 9 on all three topics).

The multivariate backward logistic regression model of the perceived process of SDM showed that neither whether the delivery of the PtDA had been recorded (OR 1.2; 95% CI 0.67–16.33) nor whether the patient had logged in to the PtDA (OR -0.86; 95% CI 0.15–1.3) was significantly related to the patient's perception of the process of SDM, as measured by CollaboRATE.

### 3.1.4 | Topic 4: The proportion of patients for whom there was concordance between their stated preference and the actual decision about their treatment during the intervention period

The stated preference corresponded with the actual decision made for 59 (72%) patients, while 8 (10%) patients had no preference. For 15 (17%) patients, the actual decisions made about their treatment

differed from the previously stated preferences during the interview (see Table 6). Eight patients had preferred a BCT, whereas an audit of the patient files revealed that the actual surgical treatment was a mastectomy. For three of these patients, no clear reason for this difference was found. Two patients had some additional diagnostic tests that showed there was another tumour present. Thus, BCT became impossible. Three patients underwent neo-adjuvant therapy, hoping the tumour would decrease enough to undergo BCT, but still the tumour remained too large for BCT.

Seven patients with a preference for a mastectomy underwent BCT. For one patient, there was no clear reason for the non-concordance. Three of them first underwent neo-adjuvant chemotherapy with positive results and thus they chose BCT after all. Three patients thought the complexity of the choices made it hard to make a decision and they all felt insecure about the impact of radiotherapy. Two of them were offered another consultation with the radiotherapist and one patient sought reassurance by talking to the nurse again. After this, they all decided to undergo BCT.

The audit of the patient files also showed that five of the patients should not have received the PtDA because breast-conserving therapy was not indicated or because the patient had been diagnosed with ductal carcinoma in situ, for which the PtDA is not suitable.



## 4 | DISCUSSION

In our motivated teams of breast cancer clinicians, who were aware they were being observed, the adherence to specific implementation strategies was fairly modest. Although there is still a long road ahead, glimpses of actual SDM behaviour were present.

Almost all the patients (93%) reported having been informed about two treatment options and that a decision therefore had to be made (88%). However, even in cases of clear equipoise, which we were able to assess from the patient files and tumour board reports, the tumour boards indicated only one option for nearly half (41%) of the patients. In two-thirds of the cases (66%), they failed to set an indication for the PtDA. Nevertheless, almost all patients (93%) reported having received the prescription pad sheet for the PtDA, and this was recorded in the patient file for nearly all patients (89%). Above all, a substantial proportion of patients (67%) actually logged in to the PtDA. Explaining the importance of using the PtDA and giving instructions on how to use it seem to be predictors of its actual use.

The average item score on the CollaboRATE instrument was high, although only one in four patients gave a top score (24.4%). This is rather low if we compare it to other studies in which CollaboRATE top scores of 68%–86% were found (Forcino et al., 2018; Hurley et al., 2019). However, we should be cautious comparing these results. The nature and populations of both studies are quite different from our study. Recording the delivery of the PtDA seems to enhance a patient's experience of SDM, although this finding did not reach statistical significance. Another non-significant finding is that the proportion of patients logging in to the PtDA seems to be negatively related to their rating of top scores for the SDM experience. This might suggest that patients who actually use the PtDA not only gain information but also develop rather high expectations of the SDM process in the subsequent consultation. This may also illustrate an underlying pitfall of the tumour board 'simply' indicating a preference-sensitive decision and assuming that offering a PtDA in itself guarantees SDM. This is in line with findings in other studies (Légaré, & Thompson-Leduc, 2014; Savelberg et al., 2020; Steffensen, 2019).

Interestingly, overuse of the PtDA did occur, as five patients were inappropriately informed about the treatment choices they had. Although the tumour board reported mastectomy as the only treatment option for different reasons (tumour too large, metastases), the PtDA was offered. In two of these patients, the PtDA was handed over on explicit request of the patient, while in three patients, the nurse had erroneously offered the PtDA. This could raise false expectations for patients, and because their preference is not available to them, it could result in confusion, disappointment, decisional conflict and dissatisfaction. It is important for clinicians to be aware that using a PtDA is not an aim in itself, but only an instrument to support the process of SDM and to help patients think about the options, their preferences and the actual decision.

A process evaluation is used to monitor and document the implementation of new programmes and can help in understanding the relationship between the different implementation strategies

and results. An effective process evaluation helps researchers assess whether the implementation strategy has reached the intended target group and achieved the intended goals (Saunders et al., 2005). Although originally planned, we do not aim to test the implementation strategies on effect. The implementation strategies were based on implementation theories and were, more importantly, co-created with the end users. We investigated the feasibility of our co-created implementation strategies to learn what might be important determinants of successful implementation of SDM and uptake of PtDAs.

### 4.1 | Strengths and limitations

The breast cancer teams were willing to invest financially in using the PtDA, which implies an intrinsic motivation to implement SDM. A strength of this study was that the patient sample was representative of the Dutch breast cancer patient population with regard to educational level. The patients' age, educational level and perceived experience of SDM were comparable between the different hospitals, implying that this study did not suffer from large differences between hospitals with regard to patient selection and SDM performance. Nevertheless, we need to be cautious in interpreting the results because of the small study size ( $N = 84$ ).

The most important limitation is that we could not check the use of the PtDA by analysing the server data of the company that hosted the PtDA and instead had to rely on patients' self-reports. The subjective perceptions of the patients may suffer from recall bias to a certain extent, but we are confident that our findings are comparable with the server data because in the interview we asked the patients to substantiate their statements with concrete examples.

Another limitation is the possible selection bias: the hospitals may have included those patients to whom they thought they could successfully deliver the PtDA. It is also possible that these patients in particular were already intrinsically motivated to use the PtDA, as they remembered the clinician promoting its use. The relatively large number of low-educated patients may be evidence against this bias. We did not find other studies with which we could compare our findings. If this selection bias has occurred, it has probably resulted in overestimating the level of implementation success.

In this study, we used the CollaboRATE instrument in the telephone interviews to measure the patients' perception of SDM. Some of the patients perceived the questions, in particular the last question, as difficult to answer, so additional explanation was necessary. The explanations given to these patients could have differed from each other, which might have caused some ambiguity.

## 5 | CONCLUSION AND RECOMMENDATIONS

Despite the limitations, we can conclude that SDM seems to be improving among breast cancer teams that are reasonably motivated to

implement SDM. The teams adopted the complete implementation strategy in a small proportion of the patients. Some self-contained implementation strategies were indeed adopted in a large proportion of the patients. This study suggests that it is important for clinicians to personally encourage patients to use the PtDA. At the same time, this creates expectations among patients and obligations for clinicians. Although the uptake of the PtDA was 92% and the uptake of the different implementation strategies varied, with 14% of the clinicians following the full implementation strategy, patients scored high on the SDM process. Still, clinicians have to take the opportunity to discuss decisional attributes after the patient has used the PtDA. This implies that in order to systematically implement SDM, breast cancer teams may have to redesign the entire pathway.

We recommend a clear and systematic recording of the multiple options for each patient in the tumour board reports. This might prevent patients from erroneously receiving a PtDA. In addition, it seems wise to also systematically record the patient's considerations and decisional attributes. Together with the results from the value elicitation exercise in the PtDA, which the patients would ideally bring along to the next consultation, this could be a robust starting point for a dialogue in a subsequent consultation. Implementing SDM in the existing pathway is complex and involves many different aspects that need to be considered. Data from this study should be used to design a larger implementation study to validate our findings.

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#### CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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#### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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