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Supporting women with breast cancer in making an informed decision about immediate breast reconstruction: the development and evaluation of a patient decision aid

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Citation

Stege, J. A. ter. (2024, May 28). *Supporting women with breast cancer in making an informed decision about immediate breast reconstruction: the development and evaluation of a patient decision aid*. Retrieved from <https://hdl.handle.net/1887/3754781>

Version: Publisher's Version

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Note: To cite this publication please use the final published version (if applicable).



Chapter 6

Patients' and plastic surgeons' experiences with an online patient decision aid for breast reconstruction: considerations for nationwide implementation

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Submitted

ABSTRACT

BACKGROUND

Women diagnosed with breast cancer undergoing a mastectomy often have the option to undergo breast reconstruction (BR). BR decisions are complex and have considerable impact. We developed a patient decision aid (pDA) to support patients' BR decision making. Here, we assess patients' and physicians' use of the BR pDA and their views on the barriers and facilitators for widespread implementation.

METHODS

Participants completed a questionnaire, and back-end data of the pDA was analyzed.

RESULTS

Of 116 eligible patients, 113 patients accessed the BR pDA (median age: 50 years and 50% were highly educated). Most patients (72%) were satisfied with the pDA and 74% would recommend the BR pDA to other women facing the same choice. Patients' preferences regarding how much, what kind and how to present information varied. Plastic surgeons (N=22; 71% response) were satisfied with the pDA. Their key factors for implementation included the perceived match between information and clinical practice, costs, impact on patients, and support from peers and management for the tool.

CONCLUSIONS

As the BR pDA was highly valued by its end users, the identified factors for implementation should be taken into account.

BACKGROUND

Women considering a mastectomy for breast cancer or ductal carcinoma in situ (DCIS) often have the option to undergo a breast reconstruction (BR). Decision making about whether to undergo BR is a preference-sensitive decision that needs to be driven by patients' informed preferences. BR can improve the quality of life of women undergoing a mastectomy, but women can also experience complications from treatment (e.g., bleeding, infection and wound healing problems) and need more time to recover (1-3). In addition to deciding whether to undergo a BR, women need to make decisions about the type (e.g., autologous vs. implant reconstruction) and timing (e.g., immediate with the mastectomy, vs. delayed) of the reconstructive procedure. These are often complex decisions that can significantly impact women's lives.

Studies have reported suboptimal BR knowledge and low decisional preparedness among women making BR decisions (4, 5). A study investigating women's expectations regarding their wellbeing immediately after BR found that often expectations were unmet and that women with unmet expectations were more likely to experience decisional regret (6). Knowledge and decisional preparedness can be improved with a patient decision aid (pDA) providing evidence-based information, patient experiences, and values clarification tasks. pDAs have been shown to reduce decisional conflict and increase knowledge in many different clinical contexts (7). We developed an online pDA for Dutch women with pre-malignant or invasive breast lesions considering immediate BR (8). The effectiveness of the pDA was evaluated in a randomized controlled trial (RCT). We did not find a significant improvement in terms of decision quality or health outcomes when comparing the BR pDA to a standard information leaflet (9). However, women who used the BR pDA felt better prepared for their consultation with the plastic surgeon and for decision making compared to those who did not use the pDA.

With the ongoing efforts to implement shared decision making in clinical practice, the number of pDAs is growing (7). However, implementation of pDAs remains a challenge (10). Here, we report on patients' and plastic surgeons' usage of and satisfaction with our BR pDA and their suggestions for improvements. The lessons learned from our experiences can help other pDA developers.

METHODS

PARTICIPANTS

Patients participating in the Dutch BR pDA RCT

The RCT and study population is described in detail elsewhere (9, 11). In brief, participants were women diagnosed with invasive breast cancer and/or DCIS who had the intent to undergo a mastectomy, were eligible for immediate BR, and had been referred to a plastic surgeon. A total of 116 out of the 126 (92%) women allocated to the pDA arm (i.e., intervention arm) of the RCT were included in this process evaluation. We excluded women (n=6) who did not complete the first follow-up questionnaire (T1; one week after consultation with a plastic surgeon) and

we excluded four women who no longer met the inclusion criteria as they had already planned to have breast conserving surgery at the time of completing the first follow-up questionnaire.

Plastic surgeons

Plastic surgeons who were working in one of the eight hospitals participating in the RCT and who had consultations with breast cancer or DCIS patients during the trial's recruitment period were invited to complete an anonymous online questionnaire. The questionnaire was sent to them in the final month of recruitment for the trial (April 2019).

BR PDA

For a detailed description of the BR pDA consult the protocol and the paper describing the development of the pDA (8, 11). Briefly, the pDA consists of three parts (Figure 1 provides an overview); first, a consultation sheet on which surgical oncologists indicate the patients' options and provide a personalized link to the pDA. Second, the online tool (available at <https://br.keuzehulp.nl> (in Dutch)) in which patients receive an overview of reconstructive options, pros and cons of each option, information on consequences of each option for patients' daily life, exercises to clarify personal values, and stories depicting the experiences of patients who had previously decided about BR. The pDA also includes illustrations of the different types of BR. Patients can select the information that they want to read. Third, upon completion of the online tool, a summary sheet is generated with patients' considerations, preferences and questions to help inform and guide the discussion between the patient and her plastic surgeon.

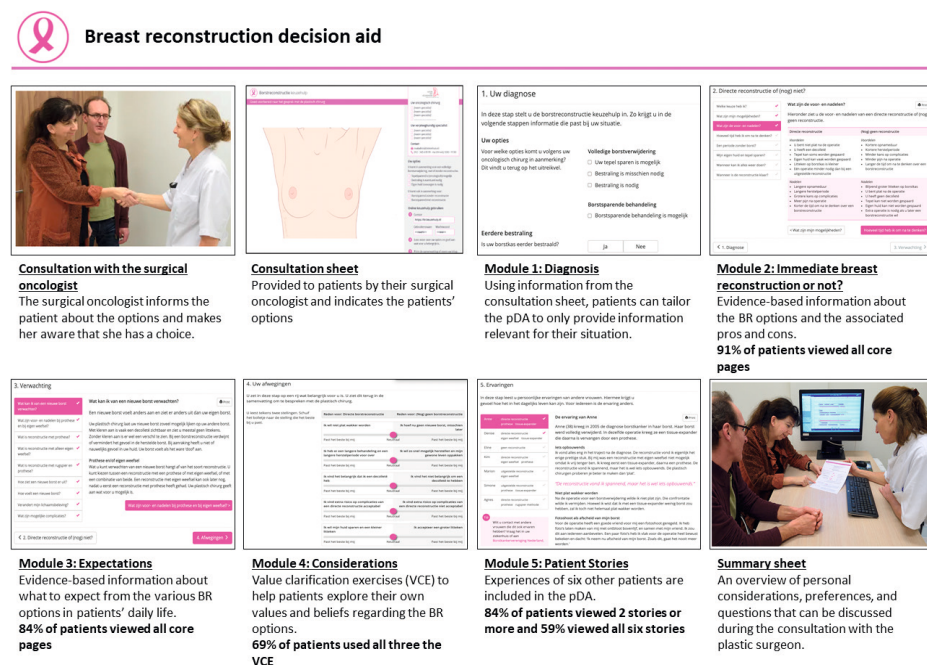


Figure 1. Overview of the BR pDA components and usage

MEASURES

Patients

Three sources of patient data were used for the purposes of this process evaluation, namely: 1. Patient questionnaires: data were collected in the baseline and the first follow-up questionnaire (T1; one week after consultation with a plastic surgeon) that patients completed as part of the RCT evaluating the effectiveness of the BR pDA. With the baseline questionnaire socio-demographic and clinical characteristics were obtained, specifically age, country of birth, education level, marital status, employment status, perceived skills in internet usage, diagnosis, history of breast cancer. In the first follow-up questionnaire (T1), information was obtained regarding patients' use of, satisfaction with and perceived usefulness of the pDA. Also, patients' feedback on the pDA was obtained via a non-compulsory open-ended question (i.e., 'If you have any additional remarks regarding the Breast Reconstruction Decision Aid, you can insert them here').

2. Data from the backend of the BR pDA: individual-level data on pDA use by patients participating in the trial were recorded in the pDA, specifically: how much time they spent viewing the pDA, and which components they viewed. Furthermore, patients' feedback on the pDA was collected directly after using it via a non-compulsory open-ended question (i.e., 'What did you like and what could be improved?').

Plastic surgeons

A study-specific questionnaire among plastic surgeons measured: (1) socio-demographic characteristics (i.e., age, gender, number of years of clinical experience, and type of hospital they work at), (2) their use of the pDA, (3) their satisfaction with the pDA, and (4) their perception of the impact of the pDA on the consultation and the patient. Additionally, via non-compulsory open-ended questions, plastic surgeons were asked for: (5) their reasons to continue or discontinue usage of the pDA after the RCT, (6) the conditions under which they would continue using the pDA after the RCT, and (7) their suggestions for improvement for the pDA (see supplement for study questionnaire).

ANALYSES

Descriptive analyses were performed to describe socio-demographic characteristics of patients and plastic surgeons. Answers to open-ended questions from patients and plastic surgeons were categorized into topics by one researcher (EGE) and a second researcher (JtS) reviewed the categorization with discrepancies being resolved through consensus. Then two researchers (EGE, JtS) independently organized these topics into barriers, facilitators, and suggestions for improvements according to the Consolidated Framework for Implementation Research (CFIR) (12). The CFIR is a framework of constructs that have been associated with effective implementation. We used the CFIR to systematically organize the potential barriers and facilitators of successful long-term implementation of the BR pDA described by patients and physicians according to validated constructs associated with effective implementation. Discrepancies were resolved through consensus.

RESULTS

PATIENTS' PERSPECTIVE

The median age of patients was 50 years (SD 11), 71% had been diagnosed with invasive breast cancer and 29% with DCIS only (Table 1). Most patients were born in the Netherlands (93%) and had an intermediate (47%) or high (50%) educational level.

Table 1. Patient characteristics (N= 116)

	N (%)
Age (mean (SD))	50 (11)
Born in the Netherlands (yes)	108 (93)
Education level	
Low (i.e., primary school, lower vocational education)	4 (4)
Intermediate (i.e., secondary school, intermediate vocational education)	53 (47)
High (i.e., higher vocational education, university)	57 (50)
Missing	2
Marital status (married/in a relationship)	105 (91)
Employment status	
Full or part-time work (yes)	58 (50)
Self-employed (yes)	17 (15)
Self-rated internet skills	
(Very) good	84 (72)
Average	32 (28)
(Very) bad	0 (0)
Diagnosis	
DCIS	34 (29)
Invasive breast cancer	61 (53)
Invasive breast cancer and DCIS	21 (18)
Radiotherapy indicated (yes/maybe)	65 (56)
Prior breast cancer or DCIS diagnosis (yes)	17 (15)
Type of hospital patients were treated at	
Oncology hospital	69 (60)
Academic medical center	13 (11)
General hospital	34 (29)

Abbreviations: **SD** standard deviation; **DCIS** ductal carcinoma in situ

Patients' use of the pDA

In total, 113 out of 116 (97%) patients included in this study logged into the pDA. Half of the patients (52%) visited the pDA once, while the other half (46%) visited the pDA multiple times (median number of sessions: 1 (range: 1-6 sessions)). Overall, 79% of patients spent 30 minutes or more viewing the pDA (median of 51 minutes (range: 9-351 minutes)). The pages with information regarding BR options, pros and cons, and what to expect from BR were viewed by more than 85% of the patients (Figure 1). The values clarification exercises aimed at helping patients to weigh their options were viewed by more than 90% of patients. The items to indicate treatment preference were used by: 88% to indicate preference BR yes vs. no, and 72% to indicate preference for BR with own tissue vs. implant. The patient stories were viewed by on average 76% (range: 66-95%) of the patients who logged into the pDA. Ninety-one patients (81%) viewed all main components of the pDA, defined as having viewed all pages with information (i.e., module 2 and module 3), the value clarification exercises and one or more patient stories. In the questionnaire, 111 (98%) patients indicated that they had reviewed the pDA prior to their consultation with their plastic surgeon. Seventy-seven (68%) respondents indicated that they had taken a printout of the summary sheet to the consultation with the plastic surgeon; 59 (56%) indicated that the pDA summary had been discussed during the consultation.

Patient satisfaction with the pDA

Table 2 provides an overview of patients' satisfaction with and perception of the usefulness of the pDA. Eighty-one patients (72%) indicated that they were satisfied with the pDA in general. When asked about their satisfaction with the amount of information, 68 (61%) patients thought it was just right, 9 (8%) patients thought it was too much, and 35 (31%) thought it was not enough. All main components of the pDA were considered useful by most patients in helping them to decide. Overall, 98 (88%) patients indicated that the pDA was easy to use and 83 (74%) women indicated that they would recommend the pDA to other women facing the same choice.

Table 2. Overview of patients' use and satisfaction with the BR pDA (N=113)

	N (%)
Usage of pDA	
Time spent on pDA (minutes), median (IQR, range)	51 (61, 9-351)
<15 minutes	5 (4)
16-30 minutes	19 (17)
31-90 minutes	60 (53)
>90 minutes	29 (26)
When did you look at the BR pDA?	
Prior to the consultation with my plastic surgeon	99 (88)
After the consultation with my plastic surgeon	1 (1)
Both prior to and after the consultation with my plastic surgeon	12 (11)
Missing	1
Did you take the pDA summary to the consultation with your plastic surgeon?	
Yes	77 (69)
No	35 (31)
Missing	1
Did you discuss the pDA summary during the consultation with your plastic surgeon?	
Yes	59 (56)
No	47 (44)
Missing	7
How satisfied are you in general with the BR pDA?	
Unsatisfied	7 (6)
Neither satisfied nor unsatisfied	24 (21)
Satisfied	81 (72)
What did you think of the amount of information in the BR pDA?	
Too much	9 (8)
Just right	68 (61)
Not enough	35 (31)
Missing	1
To what extent did components of the BR pDA help you with making a decision about BR? (Not at all / somewhat / very useful)	
Tables with pros and cons of each option	11 (10) / 44 (39) / 57 (51)
Value clarification exercises	23 (21) / 54 (48) / 35 (31)
Patient stories	20 (18) / 40 (36) / 52 (46)
Summary sheet	18 (16) / 51 (46) / 43 (38)
The BR pDA was easy to use	
Disagree	4 (4)

Neutral	10 (9)
Agree	98 (88)
Missing	1
Would you advice others facing the same treatment decision to use the BR pDA?	
No	5 (5)
I don't know	24 (21)
Yes	83 (74)
Missing	1

Abbreviations: **BR** breast reconstruction; **pDA** patient decision aid. Percentages do not always add up to 100% due to rounding off.

PLASTIC SURGEONS' PERSPECTIVE

Twenty-two of 31 (71%) participating plastic surgeons (partly) completed the questionnaire (Table 3). At least one plastic surgeon of each participating hospital completed the questionnaire. The median age of participating plastic surgeons was 44 years (range: 29-61), and 73% was female.

Table 3. Characteristics of plastic surgeons (N=22)

	N (%)
Age (Md. (range))	43.5 (29-61)
Gender (female)	16 (73)
Clinical experience (Md. (range))	7.5 (1-27)
5 years or less	8 (44)
6-10 years	4 (22)
More than 10 years	6 (33)
Missing	4
Type of hospital*	
Oncology hospital	6 (26)
General (teaching) hospital	11 (48)
Academic hospital	6 (26)
Frequency of discussing the pDA with a patient	
Never	8 (36)
1-3 times	8 (36)
4-10 times	4 (18)
More than 10 times	2 (9)

*Numbers do not always add up to 22, because one plastic surgeon worked in two participating hospitals.

Use of the pDA during consultations

Fourteen plastic surgeons indicated that they had discussed the pDA during the consultation with at least one patient. Most of them discussed the summary sheet (n=9) or asked whether the patient had used the pDA (n=11), and some viewed the pDA together with the patient (n=2). Eight respondents never discussed the pDA with a patient and the reasons provided were: not having had consultations with patients who had been randomized to the pDA arm (n=4), not knowing the pDA well (n=2), having sufficiently involved patients in treatment decision making without the pDA (n=2), and patients not having brought up the pDA (n=2).

Plastic surgeons' satisfaction with the pDA

Of the 14 plastic surgeons who discussed the pDA nine were (very) satisfied, four were neither satisfied or dissatisfied and 1 was dissatisfied. Eleven out of 14 respondents thought that the use of the pDA was of added value, specifically: patients are better prepared for the consultation (n=11), the consultation is more effective (n=7), patients get reliable information (n=6) and the pDA helps increase patient participation in the decision making process (n=4). The 14 plastic surgeons who had discussed the pDA with their patients, indicated that using the pDA impacted the following aspects of the consultation: content of the consultation (n=10), level of patient participation in decision making (n=10), patients' treatment preference (n=7), duration of the consultation is longer (n=6) and the number of questions that patients asked (n=6). Nine plastic surgeons would recommend using the pDA to other plastic surgeons. Ten respondents wished to continue using the BR pDA after closure of the trial.

VIEWS OF PATIENTS AND PLASTIC SURGEONS ON BARRIERS AND FACILITATORS FOR IMPLEMENTATION OF THE PDA AND SUGGESTIONS FOR IMPROVEMENTS

In total, 79 patients (68%) and 21 plastic surgeons provided feedback on barriers and facilitators for implementing the pDA and/or suggestions for improvements of the pDA by answering at least one of the open-ended questions. Table 4 shows an overview of the barriers and facilitators and the suggested improvements. The CFIR construct most often touched upon by patients was Design Quality & Packaging. The facilitators for implementation of the pDA recurrently listed by patients were: availability of clear and extensive information, availability of patient stories, the pDA being perceived as an effective tool to prepare for consultation and it helps to reflect. The barriers for implementing the pDA recurrently listed by patients were: information on specific topic(s) is missing, more illustrations/photos and experiences of other patients need to be added, and the values clarification exercise was perceived by some patients not to be helpful (e.g. not all considerations were included). Patients' suggestions for improvements related mainly to missing or desiring more information on specific topics such as: specific types of BR (e.g., a combination of implant-based and autologous BR), bilateral mastectomy, advice on which hospital is best for specific types of reconstruction, and DCIS-specific considerations.

Plastic surgeons' feedback regarding the pDA related mostly to the CFIR constructs Implementation Climate, Compatibility, Relative Priority, Available Resources, Relative Advantage, and Adaptability of the intervention. Across the constructs of the CFIR, facilitators were: being involved in the development of the tool, the intervention fitting into the clinical workflow, perception that the tool provides good quality information to patients and can reduce consultation time as patients are better prepared. Barriers across the CFIR constructs were: the perception that information in the tool does not match current practice at their hospital, costs, the perception that the tool has a negative impact on patients (e.g., information not (fully) understood or causing confusion) and the potential lack of enthusiasm from peers and/or management to adopt the pDA after the trial. Suggestions for improvement related to allowing modules in the pDA to be personalized to match BR options provided at specific hospitals and embedding the pDA in the patient electronic record system.

Table 4. Patients' and plastic surgeons' statements regarding barriers, facilitators and suggestions for improvement organized according to the Consolidated Framework for Implementation Research Constructs

Patients			Plastic surgeons		
Construct	Barrier	Facilitator	Suggestion for improvement	Facilitator	Suggestion for improvement
I. INTERVENTION CHARACTERISTICS					
Intervention Source					
Evidence Strength & Quality					
Participation in development pDA					
Depends on findings trial regarding effectiveness					
• Depends on findings trial regarding effectiveness • Proof that pDA improves patient outcomes and/or reduces duration of consultations					
Relative Advantage					
• Good information is essential for patients • Patients are better prepared for consultation after pDA use • Provides information to patients • Can reduce consultation time • Improves communication with patient					
No perceived added value					
• Does not reduce number of questions from patients • The perception of patients not being satisfied with pDA • Information was not completely understood by patients • pDA causes information overload in patients					
Effective tool to prepare for consultation and helps to reflect					
• Gives clarity					
Little perceived added value to support decision making					
Information does not match hospital's clinical practice					
Information does not match hospital's clinical practice					
Information does not match hospital's clinical practice					
Modules should be adapted to hospital-specific practices					
Depends on tailoring pDA to match hospital practice. For example, with modules that can be adapted to hospital-specific practices					

Table 4. Continued

Construct	Patients			Plastic surgeons	
	Barrier	Facilitator	Suggestion for improvement	Barrier	Facilitator
Design Quality & Packaging	• Information missing on specific topic(s) • Values clarification exercise is not perceived as helpful • Specific information is not clear • Information is not new • Summary sheet has no added value • Experiences of other patients are not perceived as helpful • Information does not match diagnosis DCIS	• Availability of clear and extensive information • Availability of personal stories • Digital format • Availability of summary sheet • Easy to relate to own circumstances • Step-by-step guidance through the options	• More illustrations/add photos • Add more experiences of other patients • Place experiences of other patients prior to values clarification exercises • Add place to make notes or write down questions on summary sheet • Content can be made more concise • Only show experiences of other women by clicking on a link		
Cost				Depends on costs	• Depends on costs • Period of no/reduced costs for usage of pDA until results of trial
III. INNER SETTING					
Implementation Climate.				Depends on colleagues and breast cancer team	• Depends on colleagues and breast cancer team • Motivated nurse specialists and/or surgeons to provide pDA to patients

Table 4. Continued

Patients					
Construct	Barrier	Facilitator	Suggestion for improvement	Barrier	Plastic surgeons Facilitator
Compatibility			• Adjust timing of pDA handout so that surgical options are clear • pDA is more suited for further reading after consultation with plastic surgeon		pDA should be given well in advance of consultation with plastic surgeon for patients to have sufficient time to use it Incorporation of results in electronic patient record system
Relative Priority				Depends on policy in hospital	Depends on policy in hospital
Available Resources					Digital link via breast cancer nurse
Access to Knowledge & Information	Not clear how to fill in the treatment options used to tailor the pDA if these are not provided by surgeon		Desire for more information about what to expect from pDA		• Instruction • Clarity about which patient used the pDA
IV. CHARACTERISTICS OF INDIVIDUALS					
Knowledge & Beliefs about the Intervention	It is an impersonal method of information provision				
Other Personal Attributes					Motivation
V. PROCESS					
Engaging					Active involvement and instruction

DISCUSSION AND CONCLUSION

DISCUSSION

As part of a trial investigating the effectiveness of a new Dutch BR pDA, we assessed patients' and plastic surgeons' use of and satisfaction with the pDA. The uptake of the BR pDA was high among patients. Most patients and plastic surgeons were satisfied with the tool and found it to be of added value in the decision-making process. Most plastic surgeons who had used the pDA in clinical practice would recommend it to colleagues and wished to continue using it after the end of trial. Furthermore, our study identified key facilitators and barriers for implementation of the pDA and suggestions for improvement of the pDA from both patients' and plastic surgeons' perspective.

What stands out most from our results is the extent to which preferences and information needs regarding the pDA differ among patients. For example, while most patients highly valued the availability of patient stories, other patients considered them distressing, and again other patients thought that more stories should be added to represent a wider variety of patients. Also, patients varied in their valuation of the values clarification exercises. Some patients found them too brief and wanted more statements to be included to reflect the complexity of the choice better, whilst others found them to be useful as they were. The variation in patients' information needs regarding the pDA was further reflected by the variation in the perceived usefulness of the main components of the pDA. These findings emphasize the need for pDAs to be flexible and allow users to tailor the amount of information and the type of information they access on the various topics contained within the tool.

Overall, our results regarding patients' and plastic surgeons' barriers, facilitators and suggestions for improvements that could help the successful widespread implementation of our pDA beyond the trial are in line with the findings recently reported by Joseph-Williams and colleagues from the International Patient Decision Aid Standards Collaboration (10). Plastic surgeons' main points deemed important for implementation align with their key recommended pDA implementation strategies, specifically: (1) feeling involved in the production of the pDA, (2) making sure the whole breast care team involved in implementation of the pDA are aware of what they need to do and underscore the relevance, (3) support from management/senior colleagues for the use of the pDA, and (4) quantifying the impact of the pDA to show its added value in terms of patient outcomes (10).

An important potential barrier to widespread implementation of the pDA reported by plastic surgeons was a perceived mismatch between the BR options described in the tool and the options available at their hospital. From conversations with plastic surgeons whilst developing the pDA and about their experiences with the pDA during the trial, there were two specific patient groups in which they perceived this mismatch. The first group of patients were patients with an indication for adjuvant radiotherapy. In line with the national BR guideline (13), in our BR pDA it was stated that: *"If it is already clear before the operation that you need radiation,*

delayed breast reconstruction is often advised". However, in some of the participating hospitals, immediate BR is also offered to patients with an indication for adjuvant radiotherapy. Some of these patients were surprised to hear from their plastic surgeon that immediate BR was an option for them, and plastic surgeons commented that they had to reassure these patients that immediate BR was a valid option for them. The second group of patients that led to this perceived mismatch were patients with a preference for immediate autologous BR. While some Dutch hospitals offer immediate autologous BR to patients, most hospitals that can perform autologous BR only offer this as an immediate procedure to patients having a salvage or a prophylactic mastectomy, or as a two-stage or delayed procedure. Some plastic surgeons commented that they had difficulties to explain patients with a preference for immediate autologous BR after having used the pDA that this option was not available to them (at least not in their hospital). To improve the pDA, plastic surgeons suggested to make some of the pDA's information modules optional, thereby allowing them to 'turn off' modules for options that are not available at their hospitals. This could certainly help the tool integrate better into their existing practice and thereby facilitate widespread implementation. However, in the development of the pDA, we made the conscious choice to provide information on all the BR options presented in the national clinical guidelines. Moreover, besides the practical difficulties of such an adjustment, making information optional depending on hospital practice goes against a key principle of shared decision making, namely that patients should be informed of all options that are medically viable in their situation (14). It raises the question whether it is ethical not to provide patients with information about a treatment option not offered at their hospital, but that would be a medically viable option for them if they were treated at another hospital. This can be a point of tension between pDA developers and healthcare providers as incorporating options that a specific hospital does not offer, not only leads to disappointment if a certain option cannot be provided in a particular hospital, but can also have financial implications if a patient chooses to go to another hospital. For our pDA, we added information (for these two specific situations) to emphasize options may vary among hospitals. In general, more attention should be given to ways in which pDAs can fully and transparently inform patients about the available options, without them getting false expectations. This to prevent potential dissatisfaction with pDA usage among patients and healthcare professionals, and hindering implementation.

While the uptake of the pDA was good amongst patients, only half of patients reported that they had discussed the summary sheet of the pDA during the consultation with their plastic surgeon. From our data, it remains unclear why half of the patients did not discuss the pDA during the consultation, and how patients valued this. For shared decision making to take place, patients' considerations and preferences should be discussed and considered in the decision (14). Although it is possible that patients who reported that they had not discussed the summary sheet may have discussed their considerations and preferences without explicitly referring to the summary sheet, an exploratory analysis in our population (data not shown) suggests that patients who discussed the summary sheet of the pDA during the consultation perceived significantly higher levels of shared decision making (as measured by the SDM-Q-9

(15, 16)) than patients who had not discussed the summary sheet. It seems that to achieve optimal impact of the pDA, discussing the summary sheet during the consultation should be encouraged. The recommended strategy for implementing pDAs, as described by Joseph-Williams (10), is for the healthcare professional to be the one to invite patients to discuss the pDA and thereby making it clear to patients that their contribution in the decision-making process is valued and important. Interestingly, plastic surgeons indicated that patients bringing up the pDA during the consultation would prompt them to discuss it. This suggests that it is important to clarify roles.

This study has some limitations. First, it is an evaluation carried out during a trial and may not fully reflect implementation in routine clinical practice. The three main differences in implementation of pDA during the trial as compared to routine clinical practice were: (1) the link to the pDA was provided to patients by the research team via email instead of by the surgical oncologist during a consultation, (2) patients received a reminder by email on the possibility to use the pDA from the research team two days before their consultation with their plastic surgeon, and (3) the research team made notes of patients' allocation in their electronic medical record to incite plastic surgeons to discuss the pDA with patients. As these logistic adjustments might have influenced usage of the pDA among patients and plastic surgeons (both positively and negatively), it is important to keep monitoring usage after closure of the trial. Second, participating patients might not fully reflect the total patient population. For example, because specific patient subgroups did not meet the inclusion criteria (e.g., women with a language barrier) or due to selection (e.g., women who wanted to participate in the decision-making process were overrepresented). Further, not all plastic surgeons at participating centers completed the questionnaire and physicians' answers on the open-ended questions intended to clarify their views and preferences were often very concise. However, at least one plastic surgeon from each hospital participating in the trial did complete the questionnaire. Using interviews instead of a questionnaire, particularly to get insights into plastic surgeons' views could have yielded more information. However, the themes we have identified in our data generally match those identified in a previous interview study evaluating an Australian BR pDA (17), suggesting that although physicians' answers were concise, they were informative, and we were able to identify relevant topics. Important strengths of this evaluation study are that we assessed experiences with the pDA from both patients and plastic surgeons, and we had access to backend data to see the actual use of the pDA.

CONCLUSION

This evaluation study suggests that our Dutch BR pDA is a well-used resource valued by its end users. The great variation in patients' information needs means that pDAs should allow patients to tailor the amount and presentation of information for these tools to be of even more benefit to a wider range of patients.

PRACTICE IMPLICATIONS

This evaluation study embedded within an effectiveness RCT provides important insights into the end users' experiences with the pDA, and helps to understand user, intervention and organizational factors that can influence implementation of the pDA into clinical routine practice. The results of this evaluation study were used to further optimize the tool by for example adding (more) information on topics patients were missing or felt should be expanded upon. As the number of pDAs is rapidly increasing, but the implementation into clinical routine practice is still lagging behind [10], process evaluation studies like ours are of great added value to help speed up the implementation.

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SUPPLEMENTAL INFORMATION

SURVEY ON HEALTHCARE PROFESSIONALS' EXPERIENCES WITH THE PDA

Demographics

1. What is your age? [open text field]
2. What is your gender? (Male / Female)
3. What is your position? (Plastic surgeon / Physician in training to be a plastic surgeon / Other, namely: [open text field])
4. How many years have you been working in the above position? [open text field].
5. In which hospital are/were you employed during the TANGO study?

Use of the decision aid

1. Have you reviewed the content of the decision aid? (Yes / No / Don't know (anymore))
2. How often have you discussed the decision aid with a patient? (Never / 1 to 3 times / 4 to 10 times / More than 10 times)
3. **If Q2 = never:** What is the reason you have never discussed the decision aid with a patient? Multiple answers possible. (I have not spoken to any patients who had used the decision aid / I do not know the decision aid well / I do not support the content of the decision aid / I expect it to cost me extra time / With my current working method, I involve patients sufficiently in the choice of treatment / I do not expect that discussing the decision aid will add anything / The patient did not bring it up / Other, namely: [open text field])
4. **If Q2 = never:** When would you discuss the decision aid with your patient? [open field]

If Q2 = never: skip questions 1 and 2 in section 'Experience with the decision aid', and continue with question 3.

Experience with the decision aid

1. How satisfied are you with using the decision aid? (Very satisfied / Satisfied / Not satisfied, not dissatisfied / Dissatisfied / Very dissatisfied)
2. Would you recommend other (plastic) surgeons to use the decision aid? (Yes / No / Don't know)
3. Do you experience added value from the decision aid? (Yes / No)
4. **If Q2 = Yes:** What do you experience as added value? Multiple answers possible (I can involve the patient more in the choice / The patient is better prepared for the conversation / The conversation is more effective / The conversation is more enjoyable / The patient receives reliable information / The patient is more satisfied / Other, namely: [open field])
5. Do you experience barriers in using the decision aid? (Yes / No)
6. **If Q5 = Yes:** What do you experience as barriers? Multiple options can be selected (I have to change my working method / It costs me extra time / The patient asks more or more difficult questions / The information in the decision aid does not fit well with the practice of my hospital / Other, namely: [open field])
7. Does discussing the decision aid with a patient affect the length of the consultation? (Yes, the consultation is shorter / Yes, the consultation is longer / No / Don't know)

8. Has the use of the decision aid influenced: the number of questions the patient asked during the consultation/the patient's involvement in the treatment choice/the patient's preference regarding breast reconstruction/the content of the consultation? (Yes / No / Don't know)
9. Do you have any suggestions for improvement of the decision aid? [open text field].
10. Would you like to continue using the decision aid after completion of the TANGO study? (Yes / No / Don't know)
11. What is your reason for wanting to continue using the decision aid or not? [open text field]
12. **If Q9 = yes or don't know:** What do you need to continue using the decision aid? [open text field]