


# Effect of a multilevel implementation programme on shared decision-making in breast cancer care

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## Abstract

**Background:** Women with newly diagnosed breast cancer face multiple treatment options. Involving them in a shared decision-making (SDM) process is essential. The aim of this study was to evaluate whether a multilevel implementation programme enhanced the level of SDM behaviour of clinicians observed in consultations.

**Methods:** This before–after study was conducted in six Dutch hospitals. Patients with breast cancer who were facing a decision on surgery or neoadjuvant systemic treatment between April 2016 and September 2017 were included, and provided informed consent. Audio recordings of consultations made before and after implementation were analysed using the five-item Observing Patient Involvement in Decision-Making (OPTION-5) instrument to assess whether clinicians adopted new behaviour needed for applying SDM. Patients scored their perceived level of SDM, using the nine-item Shared Decision-Making Questionnaire (SDM-Q-9). Hospital, duration of the consultation(s), age, and number of consultations per patient that might influence OPTION-5 scores were investigated using linear regression analysis.

**Results:** Consultations of 139 patients were audiotaped, including 80 before and 59 after implementation. Mean (s.d.) OPTION-5 scores, expressed on a 0–100 scale, increased from 38.3 (15.0) at baseline to 53.2 (14.8) 1 year after implementation (mean difference (MD) 14.9, 95 per cent c.i. 9.9 to 19.9). SDM-Q-9 scores of 105 patients (75.5 per cent) (72 before and 33 after implementation) were high and showed no significant changes (91.3 versus 87.6; MD  $-3.7$ ,  $-9.3$  to  $1.9$ ). The implementation programme had an association with OPTION-5 scores ( $\beta = 14.2$ ,  $P < 0.001$ ), hospital ( $\beta = 2.2$ ,  $P = 0.002$ ), and consultation time ( $\beta = 0.2$ ,  $P < 0.001$ ).

**Conclusion:** A multilevel implementation programme supporting SDM in breast cancer care increased the adoption of SDM behaviour of clinicians in consultations.

## Introduction

Approximately 14 000 Dutch women are diagnosed with breast cancer every year<sup>1</sup>. The emotional stress following a diagnosis of breast cancer has been shown to affect both patient information recall and the decision-making process<sup>2,3</sup>. Ideally, clinicians should help patients to achieve an informed decision that best fits their personal preferences, circumstances, and concerns by involving these patients in a shared decision-making (SDM) process<sup>4,5</sup>. SDM has been promoted in cancer care for many years<sup>5</sup>. Despite the need for SDM, its implementation in clinical practice remains a challenge<sup>6,7</sup>. In general, clinicians either find it difficult to apply SDM<sup>8</sup>, think that they already involve patients in decisions, or do not consider SDM key to their clinical role<sup>6</sup>. Practical problems, such as lack of time, perceived lack of applicability due to patient characteristics or the clinical situation<sup>9,10</sup>, and a poor fit into workflow can all negatively influence implementation of SDM<sup>6,11,12</sup>.

Particularly in breast cancer care, implementing SDM is even more challenging, given the many treatment options available<sup>13–16</sup>.

Clinicians must explain the risks associated with various treatments and help patients to value the different options available<sup>13,15,17</sup>. Multiple decisions must be made over an extended period of time and involve different clinicians working within a team<sup>14,17</sup>. Observed levels of SDM behaviour during breast cancer consultations show considerable room for improvement<sup>13,17–19</sup>. Clinicians often fail to communicate to the patient that a decision needs to be made<sup>18,20,21</sup>. A focus on ‘fighting’ the cancer may inhibit the process of valuing different treatment options, and also in considering long-term consequences<sup>20–22</sup>.

Interventions that have been proposed to promote SDM involve training clinicians (including the participation of patients) and using decision aids<sup>14,23–27</sup>, providing feedback on performance in consultations<sup>12,28</sup>, incorporating time-outs in care pathways<sup>12,29</sup>, and use of incentives<sup>6,11,12</sup>. In the oncology setting, suggested interventions include implementing decision aids<sup>27,30</sup>, acknowledging uncertainty, incorporating the patient’s values and preferences into SDM, involving caregivers, and making allowances for the additional time required for SDM<sup>14</sup>.

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The aim of this study was to evaluate whether a multilevel SDM implementation programme would actually help clinicians to adopt new behaviour needed for applying SDM in daily breast cancer care, and to investigate whether a potential change in clinical behaviour was noticed by patients.

## Methods

An unpaired before–after implementation study was used to evaluate whether a multilevel implementation programme would enhance the level of SDM of clinicians observed in consultations in a clinical outpatient setting, using the Standards for Reporting Implementation Studies (StaRI)<sup>31</sup> as a guideline.

### Study population and selection

Seven breast cancer outpatient clinics of hospitals in the Utrecht region of the Netherlands were asked to participate in the study. Six hospitals were included (1 university hospital, 2 teaching hospitals, and 3 general hospitals). One hospital declined to participate, as doctors were not convinced the implementation would further improve their level of SDM. All clinicians involved in the decision process with the patient regarding surgical or neoadjuvant treatments were invited to participate in the study.

The recruitment of all consecutive patients with newly diagnosed breast cancer, and who faced a treatment decision, took place between July 2016 and October 2016 (preimplementation), and between April 2017 and August 2017 (postimplementation). Each patient was informed about the study and completed an informed consent form. Each patient was included only once. Patients who did not speak Dutch were excluded, unless they were accompanied by a person who spoke Dutch fluently. Approval for the study was obtained from the medical research ethics committee (W16.019).

### Implementation programme

A theoretical framework for implementation was used for the design of the programme<sup>32</sup>. Responding to barriers to and facilitators of implementation at each of four implementation levels supports the design of an effective implementation. Four levels were used, and key factors for effective SDM implementation were incorporated into the programme<sup>6,7,9,10,14,24–26,33–35</sup> (*Table S1, supplementary material*).

#### *Innovation: the concept of SDM*

To help clinicians grasp what SDM entails for their behaviour during consultations, clinicians were asked repeatedly to reflect, using a practical four-step model for applying SDM, on their communication behaviour during feedback sessions, training, and in daily practice<sup>36,37</sup>.

#### *Users of the innovation*

Personal and team feedback on SDM behaviour was provided, followed by interdisciplinary team training<sup>26</sup>.

#### *Organizational context*

Teams looked at the allocation of time (time-outs) for SDM in clinical care pathways. Rapid cycle learning was included by explaining the plan–do–study–act cycle, and by encouraging teams to experiment with new ways of working and sharing their experiences at collaborative meetings and via the researchers<sup>38,39</sup>. The programme was tailored to the local context: each breast cancer team defined their goals within the scope of the

programme and selected tools to support the implementation of SDM.

### Sociopolitical context

Concurrent activities that might influence the level of SDM were monitored via a logbook. A clinician from each team, together with one of the researchers, kept this logbook. Patients were involved during all phases of the programme.

### Data collection

All consultations relevant to the decision-making process — meaning one or more consultations conducted by one or more clinicians from the team to make one decision about breast cancer treatment — were audiotaped. Physicians and patients were aware of this and were instructed to proceed with their consultation as normal (preintervention) or to apply what they had learnt during the intervention (postintervention).

As the primary outcome measure, the OPTION-5 was used to rate clinicians' performance in terms of involving patients in the decision-making process during real-life consultations<sup>40</sup>.

The OPTION-5 instrument is deemed suitable for use in oncology practice and scores five key decision-making behaviours<sup>19</sup>. Each of the five items were rated on a scale ranging from 0 (no effort made) to 4 (exemplary effort made), and the overall mean score was expressed on a scale of 0–100. This score reflects the extent to which the clinician showed the communicative behaviour needed to involve patients in the decision-making process. Higher scores indicate better SDM behaviour during the consultation; a minimum improvement of 10 points was considered clinically meaningful.

The secondary outcome measure was the patients' perceived level of SDM during the medical consultation(s), as measured with the SDM-Q-9<sup>29,41,42</sup>. The nine statements were rated on a six-point Likert-type scale ranging from 'completely disagree' (0) to 'completely agree' (5). These questions were completed at the end of the final consultation when a decision about breast cancer treatment was made. The scores of the 9 items per patient were added up and multiplied with 20/9 to provide a percentage of the maximum score, ranging from 0 (no SDM) to 100 (maximum level of SDM). A maximum of two missing items were imputed from the mean of items that were scored. Questionnaires were excluded when the patient left three or more items unanswered<sup>41</sup>.

### Sample size calculation

A preintervention mean score of 39 was assumed, which is high compared with that in other studies<sup>43</sup>. A relatively high score was anticipated because of the considerable variation in means across breast cancer studies, and because two-way communication in (breast) cancer care is already considered important<sup>13,18,19,24</sup>. A total sample size of 120 patients was calculated, based on an increase in OPTION-5 score from 39 before implementation to 49 after implementation, with a standard deviation of 13, an intracluster correlation  $\rho$  of 0.01 (to correct for interhospital differences), an  $\alpha$  of 0.05, a power of 80 per cent, and an effect size of 0.77. The aim was to include a total of 180 patients to account for possibly failed recordings or dropout of teams.

### Data analysis

Three raters applied the OPTION-5 coding scheme (<http://www.glynelwyn.com/observer-option-5-2014.html>), refined for vascular surgery and oncology<sup>44</sup>. The manual was adjusted to be relevant for breast cancer surgery in order to decrease raters' uncertainty in scoring the audio recordings (*Table 1*). The first

**Table 1 Refined scoring definitions for the OPTION-5 manual**

Item	Description	Specification
1	The provider draws attention to, or reaffirms, a problem for which alternative treatment or management options exist, and that requires the initiation of a decision-making process. If the patient draws attention to the availability of options, and the provider responds by agreeing that the options need consideration, the item can also be scored positively	0—not observed 1—definition of the problem 2—listing the options 3—equality of the options 4—is it clear/any questions
2	The provider reassures the patient, or reaffirms, that they will support the patient in becoming better informed. The provider will support or explain the need to deliberate about the different options	0—not observed 1—decide together 2—mention is it a difficult choice 3—will support irrespective of the choice of the patient 4—both options are OK; depends on the preferences of the patient; provider has a supportive role
3	The provider gives information, or reaffirms or checks understanding, about options that are considered reasonable (including taking no action), and supports the patient in understanding or comparing the pros and cons	0—no information 1—listing the options 2—explaining pros and cons 3—is it clear/any questions 4—ask the patient to repeat the information
4	The provider supports the patient to examine, voice, and explore their personal preference in response to the options that have been described	0—not observed 1—exploring preferences 2—exploring concerns 3—exploring expectations 4—integrates preferences, concerns, and expectations for recommendation
5	The provider makes an effort to integrate the patient's preferences in terms of decisions that are either made by the patient or arrived at by a process of collaboration and discussion	0—not observed 1—indicates need for decision 2—additional information to review the decision at home 3—appointment for evaluating the decision 4—provider indicates that the patient can abandon earlier choice Total score 0–20 Rescale 0–100

10 audio recordings were coded by all three raters, and resulting scores and coding rules were discussed. Next, all audio recordings were scored independently by two raters. These scores were compared, and agreement over the final score was reached.

Unweighted Cohen's  $\kappa$  values were used to determine the inter-rater agreement<sup>45</sup>.

## Statistical analysis

Descriptive statistics are presented as percentages or mean (s.d.) values. Differences are expressed as mean differences (MDs) with their 95 per cent confidence intervals. Pearson's  $\chi^2$  statistic was used to analyse differences between categorical variables. The implementation programme, duration of the consultation(s), hospital/team (number of recordings, starting level, composition), age, and number of consultations per patient before and after implementation were included in the regression model for the OPTION-5 score. Statistical analysis was carried out using SPSS Statistics® v. 17.0 (IBM, Armonk, NY, USA).  $P < 0.050$  (two-sided) was considered statistically significant.

## Results

Six of the seven hospitals approached participated in the study. One hospital declined to take part. One of the six participating hospital teams did not perform the postintervention measurement because they thought that feedback from a new series of consultations would not improve their practice further.

Twenty-two clinicians (surgeons, nurses, nurse specialists) participated in both measurements, and six clinicians (four nurse specialists, two nurses) participated only in the postimplementation measurement. The participating clinicians before and after the implementation were similar with regard to background and

education. The logbook showed that hospital teams did not participate in any concurrent activities unrelated to the programme that may have influenced the level of SDM. Four hospital teams adjusted their clinical pathway and/or appointment scheduling to allow for the implementation of SDM and to incorporate the time needed for patients to reflect on their decisions.

Patients' ages ranged from 32 to 91 (mean 62.3) years. The options discussed were mastectomy, lumpectomy, radiotherapy, neoadjuvant chemotherapy, and conservative treatment. Other options related to these decisions, such as breast reconstruction, the use of cooling caps during chemotherapy and extradiagnostic procedures, were not scored with the OPTION-5, but clinicians did receive feedback if considered relevant for applying SDM.

## Characteristics of consultations

A total of 139 consultations of patients with newly diagnosed breast cancer were recorded, including 80 consultations before and 59 after implementation. The mean number of recorded consultations was 1.8 (range 1–7) consultations per patient, with a mean (s.d.) duration of 47.7 (30.5) (range 6–91) min per patient, and no difference between before (mean (s.d.) 46.0 (29.5) min) and after (50.1 (31.8) min) implementation (MD 2.3 (95 per cent c.i. –4.1 to 8.8) min). The SDM-Q-9 was completed by 105 patients: 72 questionnaires before and 33 after implementation (response rate 75.5 per cent). Seven questionnaires were excluded because patients left three or more items unanswered.

## OPTION-5 scores

The three raters reached acceptable levels of inter-rater agreement ( $\kappa = 0.57$ ,  $\kappa = 0.54$  and  $\kappa = 0.61$ ). Mean (s.d.) OPTION-5 scores increased from 38.3 (15.0) at baseline (80 patients) to 53.2 (14.8) (59 patients) after implementation (MD 14.9, 95 per cent c.i. 9.9 to

**Table 2** Observed patient involvement ratings of breast cancer consultations per team, using OPTION-5

	Mean (s.d.) OPTION-5 score*	No. of patients
Hospital 1		
Preimplementation	44.1 (18.3)	17
Postimplementation	54.1 (14.6)	11
Hospital 2		
Preimplementation	46.7 (14.2)	12
Postimplementation	56.9 (12.5)	8
Hospital 3		
Preimplementation	35.0 (10.0)	16
Postimplementation	65.0 (7.5)	9
Hospital 4		
Preimplementation	28.1 (11.1)	13
Postimplementation	38.2 (11.2)	14
Hospital 5		
Preimplementation	35.6 (12.9)	16
Postimplementation	57.1 (12.6)	17
Hospital 6		
Preimplementation	43.3 (17.5)	6
Overall		
Preimplementation	38.3 (15.0)	80
Postimplementation	53.2 (14.8)	59

\*Observing Patient Involvement in Decision-Making (OPTION-5) score 0–100. Mean difference 14.9, 95 per cent c.i. 12.2 to 17.7  $P=0.003$ .

19.9). All five teams showed higher total OPTION-5 scores after the implementation for all items (Table 2).

### Perception of patients

For all 105 respondents, the mean (s.d.) score for the perceived involvement in decision-making was 89.9 (12.5). The mean (s.d.) score was 91.3 (11.5) at baseline (72 of 80 respondents; response rate 90 per cent) versus 87.6 (14.4) after implementation (33 of 59; response rate 56 per cent). No significant differences were observed between SDM-Q-9 scores before and after implementation (MD  $-3.7$ , 95 per cent c.i. 1.9 to  $-9.3$ ).

### Regression analysis

Linear regression analysis showed a significant correlation between the implementation programme ( $\beta = 14.2$ , 95 per cent c.i. 9.7 to 18.6;  $P < 0.001$ ) and the OPTION-5 score. Other significant factors were hospital ( $\beta = 2.2$ , 0.8 to 3.6;  $P = 0.002$ ) and duration of the consultation(s) ( $\beta = 0.2$ , 0.0 to 0.4;  $P < 0.001$ ). The  $\beta$  coefficient indicates the change in OPTION-5 score for a 1-unit change in the predictor variable. Consequently, the implementation programme resulted in a 14.2-point rise in OPTION-5 scores, whereas every minute of consultation time led to a 0.2 rise in OPTION-5 scores. No significant correlation was found for age or number of consultations per patient.

### Discussion

In this study, a multilevel implementation programme appeared to improve the adoption of SDM behaviour of clinicians, as observed during breast cancer consultations over time. This programme appears useful in the context of daily care, as five of the six hospital teams involved were able to participate fully in the programme while continuing their regular clinical care. Patients varied and different hospital teams (academic, teaching, and rural hospitals) comprising of team members from different clinical backgrounds (surgeons, nurses, nurse specialists) were included. Hence, the authors consider these results generalizable to any breast cancer treatment team.

This implementation programme was developed by using a four-level framework for designing an effective implementation strategy<sup>32</sup>. It was grounded in relevant theoretical literature, to include promising elements that support the adoption of SDM by clinicians in daily practice. These elements are not a predetermined set of implementation activities, but were tailored to teams and clinicians, to facilitate alignment to diverging needs of the teams and individual clinicians with regard to SDM and time-out. For example, SDM attitudes, skills, and clinical pathways differ per clinician and team<sup>12</sup>.

Baseline scores were relatively high, reflecting the present-day focus on communication with patients with breast cancer, compared with patients with other conditions<sup>24</sup>, and a clinical condition for which multiple options are feasible<sup>46</sup>. This was no barrier to further improvement, given the 15-point increase in OPTION-5 scores found after implementation. This increase is relatively high compared with that found in other studies<sup>43</sup>, although a more intense implementation approach in palliative cancer care showed a larger increase in standardized patients<sup>24</sup>.

Hospital team was associated with OPTION-5 scores. In most previous studies, researchers rated one consultation carried out by one clinician, whereas here the team performance per patient was rated. The implementation design responded to the needs of individual clinicians within the team and the local context. Each team defined its own goals and decided which tools to use to support SDM. Tailoring a programme to the team's needs may evoke social support within the team to improve one another's behaviour, as well as the intrinsic encouragement needed for sustainable behavioural change<sup>6,7,12</sup>.

Providing time-out for patients in the decision-making process was an explicit element of the implementation programme. This was based on patient feedback during the implementation process and the findings of previous research indicating that application of SDM might require lengthier or additional consultations<sup>29,43</sup>. This did not lead to an increase in either consultation time or mean number of consultations.

Patients did not perceive a higher level of SDM, a finding consistent with previous research<sup>47–49</sup>. Patient satisfaction was found already to be high before implementation, in agreement with previous findings<sup>48,50</sup>.

Future research should focus on how SDM can be incorporated effectively into clinical practice by improving implementation designs, aligning implementation efforts better to the local context, and finding better ways to evaluate any influence on patients' perceptions. To gain insight into which elements of the implementation programme are most helpful to support the change of clinicians, a logical next step is to investigate the relative contribution of each part of the implementation programme by a qualitative evaluation among study participants, and by monitoring the actual participation of each team and its team members. Patients often do not know what SDM entails and any communication of uncertainty might lead to dissatisfaction among women facing cancer decisions<sup>13</sup>. It is therefore suggested that objective measurement of SDM, such as the OPTION-5 instrument, be included in future research.

Limitations of this study included the design without a control group. It was difficult to identify any other factors (unrelated to the implementation programme) that may have influenced SDM over time<sup>51</sup>. Cluster randomization by hospital was considered, but found to be too expensive. Patients, clinicians, and investigators were not blinded to the intervention and the recordings, as the investigators had to provide relevant feedback as part of the



implementation. Clinicians may have attempted to provide optimal consultations, even though they were instructed to perform as usual. Previous studies, however, have indicated that audio recordings of the consultations have no significant effect on clinician behaviour<sup>52,53</sup>. In addition, investigators may have been biased in their scoring of the OPTION-5, as they knew whether they were listening to preimplementation or postimplementation recordings.

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## Supplementary material

Supplementary material is available at *BJS Open* online.

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