Effect of a Decision Aid on Knowledge and Treatment Decision Making for Breast Cancer Surgery

A Randomized Trial

Timothy Whelan, BM, BCh
Mark Levine, MD
Andrew Willan, PhD
Amiram Gafni, PhD
Ken Sanders, MD
Doug Mirsky, MD
Shelley Chambers, MA
Mary Ann O'Brien, MSc
Susan Reid, MD
Sacha Dubois, BA

REAST CANCER IS COMMON AFfecting more than 200000 women per year in North America. It usually presents at an early stage with disease confined to the breast and axillary lymph nodes. Prior to 1980, the standard surgical treatment involved a modified radical mastectomy. In the early 1980s, 2 published randomized trials from Italy and the United States demonstrated that removal of the cancer and radiation to the remaining breast called breast conservation therapy (BCT), resulted in equivalent survival.^{1,2} Since then 4 other published randomized trials³⁻⁶ and a number of meta-analyses7,8 confirmed these findings. Randomized trials have also suggested improved quality of life and satisfaction for women treated with BCT.^{9,10}

The decision about the different surgical treatment options for early stage breast cancer is difficult. Information de-

See also pp 442 and 496.

Context The long-term results of randomized trials have demonstrated equivalent survival rates for mastectomy and breast-conserving therapy for the treatment of early stage breast cancer. Consequently, the choice of treatment should be based on a patient's preferences.

Objective To evaluate the impact of a decision aid regarding the different surgical treatment options on patient decision making.

Design and Setting A cluster randomized trial for which general surgeons in the communities of central-west, and eastern Ontario, Canada, were randomly assigned to use the decision aid or not in the surgical consultation. Patients received the decision aid or not based on the surgeon seen.

Participants Twenty surgeons participated in the study. Of the 208 eligible women with newly diagnosed clinical stage I or II breast cancer seen by study surgeons, 201 agreed to be evaluated: 94 were assigned to the decision board and 107 to usual practice. Patients were recruited from November 1999 to April 2002.

Intervention The decision board is a decision aid designed to help physicians inform their patients about different treatment options and to enable patients to express a preference for treatment.

Main Outcome Measures Patient knowledge about the surgical treatment of breast cancer; decisional conflict; satisfaction with decision making; and the treatment decision following the consultation.

Results Patients in the decision board group had higher knowledge scores about their treatment options (66.9 vs 58.7; P<.001), had less decisional conflict (1.40 vs 1.62, P=.02), and were more satisfied with decision making (4.50 vs 4.32, P=.05) following the consultation. Patients who used the decision board were more likely to choose BCT (94% vs 76%, P=.03).

Conclusions The decision board was helpful in improving communication and enabling women to make a choice regarding treatment. Such instruments should be considered by surgeons when communicating the different surgical options to women with breast cancer.

JAMA. 2004;292:435-441

www.iama.com

Author Affiliations: Department of Medicine (Drs Whelan and Levine and Mss Chambers and O'Brien), Department of Clinical Epidemiology and Biostatistics (Drs Whelan, Levine, Willian, and Gafni and Mr Dubois), and Department of Surgery, McMaster University (Dr Sanders); Juravinski Cancer Centre (Drs Whelan and Levine), Hamilton Health Sciences

(Drs Sanders and Reid and Ms O'Brien), Hamilton; and Queensway-Carleton Hospital (Dr Mirsky), Ottawa, Ontario, Canada.

Corresponding Author: Tim Whelan, BM, BCh, Juravinski Cancer Centre, 699 Concession St, Hamilton, Ontario, L8V 5C2, Canada (tim.whelan @hrcc.on.ca).

©2004 American Medical Association. All rights reserved.

(Reprinted) JAMA, July 28, 2004—Vol 292, No. 4 435

scribing the options is complex and the decision comes at an emotionally charged time when communication can be difficult. The decision board was developed as an aid to enhance communication between the physician and patient during the decision-making process and to help the informed patient decide which treatment she prefers.11 It consists of a visual aid and written material based on the best available evidence and is presented by the clinician to the patient during the medical consultation. The instrument enables patients to discuss different treatment options with their clinician and to express a preference for treatment. Previous decision boards were developed for patients and their oncologists working at comprehensive cancer centers. 12,13 The instruments were shown to improve patient knowledge and facilitate patient decision making. 12-14 Based on these promising results, we developed a decision board for community general surgeons and their patients considering the different surgical treatment options for breast cancer.15 We conducted a randomized trial to examine whether the decision board could improve communication and empower patients in the decision-making process.

METHODS

Patient Population

Women with clinical stage I or II breast cancer newly diagnosed either by cytology or histological examination who had not received definitive surgical treatment were eligible for study. Patients were excluded for the following reasons: serious nonmalignant disease, eg, cardiovascular, respiratory, renal, that would preclude definitive surgical treatment; breast of insufficient size to perform a lumpectomy (defined as the surgical excision of the tumor with a rim of normal tissue): diffusely abnormal mammogram that would preclude a lumpectomy; not a candidate for breast irradiation, eg, previous breast irradiation or pregnancy; inability to speak or read English fluently; mental incompetence including any psychiatric or addictive disorder that would preclude taking part in the process of shared decision making and adherence to the protocol; and unwilling to give informed consent to participate in the study. The institutional review boards at McMaster University and the University of Ottawa approved the study protocol, and patients gave oral informed consent.

Intervention

Details on the design, development, and preliminary evaluation of the decision board for the surgical treatment of breast cancer are described elsewhere.15 The decision board was based on a systematic review of randomized trials comparing mastectomy to BCT and qualitative interviews and focus groups with women with breast cancer and their surgeons regarding informational needs for decision making. The decision board is an aid that presents written and visual information from clinical trials to patients regarding their treatment options; the acute and long-term adverse effects associated with treatment; and the effects of treatment on a patient's breast. long-term survival, and quality of life. It is composed of foam core and measures 26×20 in $(64 \times 51$ cm). The board has 4 subtitles: "Treatment Choice," "Side Effects," "Results of Treatment Choice for the Breast," and "Results of Treatment Choice for Survival." Below each heading are 2 informational panels (1 for mastectomy and 1 for lumpectomy plus radiation) resulting in 8 separate panels. The instrument is presented by the surgeon. Initially, each panel is covered by a sliding door. The panels are opened to reveal information in a sequential fashion. Each panel contains written information in bullet points with a diagram (in some instances) describing the option, associated adverse effects, or outcomes. Each panel is read together by the patient and the surgeon. The patient is encouraged to ask questions during the presentation and afterward. In addition to the board, there are 3 separate informational cards, which provide background information about breast cancer and the purpose of the decision board, details about breast reconstruction, and questions for the patient to reflect on how the treatment will affect her as an individual. At the end of the presentation, the patient is faced with an overall visual representation of her 2 options and the possible outcomes associated with each choice. The patient is given a take-home version to review and discuss with others if she so desires. In a previous pilot study, the instrument was timed to take an average of 21 minutes to complete and did not increase the length of the consultation.

Study Design and Procedures

A paired cluster randomization process was used.16 General surgeons in the cities of Hamilton, Ottawa, and surrounding communities in Ontario who treated women with breast cancer were approached to participate in the study. Surgeons were pair-matched according to sex and age as surrogates for style of information giving. They were then randomly assigned in a concealed fashion either to use the decision board in their surgical consultation or to retain their routine consultation style. Eligible patients received the decision board or not depending on the surgeon they saw in consultation. Patients were recruited from November 1999 to April 2002.

Surgeons randomly assigned to the decision board group were trained to use the instrument. An instructional video was developed outlining how the instrument should be administered. The video was viewed by the surgeon with 1 of the investigators (T.W. and D.M.) and the research assistant and any questions were answered. The surgeon was asked to practice presenting the instrument on a volunteer, often the research assistant. The research assistant was available throughout the study to address any concerns of the surgeon.

After providing her medical history and undergoing a physical examination, eligibility for the study was confirmed and the patient was approached to participate in the study. In the experimental group, the surgeon explained the patient's surgical treat-

436 JAMA, July 28, 2004—Vol 292, No. 4 (Reprinted)

ment options using the decision board. In the control group, the surgeon discussed the treatment in his/her usual fashion without using the decision board. The research assistant contacted patients by telephone a few days following their consultation to collect information on the study outcomes.

Surgeons were randomly assigned after being paired in a sequential fashion. During the course of the study, 7 surgeons were withdrawn because they did not see any eligible patients in the first 3 months. These surgeons either worked part-time or were close to retirement. Four of them belonged to the same pairs respectively and 3 were part of different pairs. This left 3 unpaired surgeons who continued to recruit patients. Two of these surgeons who were similar in sex and age were paired. The remaining surgeon was grouped with another surgeon by randomly selecting a surgeon from a pool of 5 surgeons yet to be randomized. The remaining 4 surgeons were paired and randomized. Ultimately 20 surgeons contributed patients to the study. The study groups were balanced for surgeon characteristics and community size. Ninety percent of surgeons were men, the mean age was 47.7 years, the mean number of years since graduation from medical school was 22.4, and the mean community population was 230000.

Outcome Measures

The major outcome measures for the study were patient knowledge; decisional conflict; satisfaction with decision making; and the treatment decision following the consultation. Patient knowledge was assessed using a 44item questionnaire that covered various content areas including general information about breast cancer, details regarding mastectomy and BCT, and the associated adverse effects and benefits of the respective treatments. Thirtysix items consisted of a statement followed by a true, false, or unsure response and the 4 items inquiring about numerical risk had a multiple-choice format with 4 options each. The instrument was scored out of 100; each correct true or false statement received a score of 2 and each correct multiple-choice question received a score of 5. We have shown this approach to be valid and reliable. 12-15

Patient decisional conflict was assessed using the decisional conflict scale, which assesses how well-informed patients feel about their choices and the associated benefits and risks; the clarity of their values; the support they have in the decision-making process; and their level of uncertainty.¹⁷ It consists of 16 items followed by a Likert response of 1, strongly agree, to 5, strongly disagree. A mean score was obtained for each patient. Patient satisfaction with decision making was assessed using the effective decision-making subscale of the decisional conflict scale.17 The subscale consists of 4 items on satisfaction with decision making. Scores for patient satisfaction with decision making were reversed so that the higher scores reflected higher levels of satisfaction (ie, a reversed Likert scale in which 5 is the highest score). Patient knowledge and her treatment decision were assessed following the consultation. Patient decisional conflict and satisfaction with decision making were assessed following the consultation and at 6 and 12 months after surgery.

Other important outcomes assessed included whether patients perceived that they were offered a choice, how strongly they preferred their decision, and levels of anxiety and depression. Anxiety was assessed by the Spielberger State Anxiety Inventory, which consists of 20 items—each with a 4-point Likert scale from 1 to 4.18 The inventory yielded total scores of 20 to 80. Depression was assessed by the Centre for Epidemiologic Studies Depression scale, which consists of a 20-item scale—each with a 4-point Likert scale from 0 to 3 yielding total scores of 0 to 60.19 Levels of anxiety and depression were measured following the consultation and at 6 and 12 months after surgery.

Statistical Considerations

The study was designed to enrol 200 patients to detect an effect size of 0.3

in decisional conflict with a 2-sided α of .05 and a power of 90%.²⁰ For a conservative sample-size calculation, a within-physician correlation of 0.3 was assumed. Treatment-arm comparisons were performed using methods appropriate for a cluster randomized trial.21 Using a meta-analysis approach, usually used for summarizing data across several trials, each surgeonpair was considered a separate "trial." A treatment effect with corresponding variance was calculated for each pair, and a random effects model was used to summarize the data over pairs to arrive at an overall estimate of the treatment effect and corresponding variance. Weighted averages were used to estimate central tendency for the different scales by treatment group. It should be noted that due to the nonlinearity of the statistical methods used, the estimated difference between groups is not the straight arithmetic difference between the estimates for each group. All statistical tests were 2-sided. *P*<.05 was considered statistically significant. All analyses were performed using SAS statistical software Version 8.2 (Carey, NC).

RESULTS

Patient Population

The trial profile is shown in the FIGURE. Two hundred eight eligible patients were approached to participate: 98 patients by surgeons randomly assigned to the decision board and 110 patients by surgeons randomly assigned to the control group. Seven patients refused to provide consent to participate in the study: 4 in the decision board group and 3 in the control group. The analysis is based on 201 patients. Age, marital status, educational level, employment status, and preference for role in decision making were similar between the 2 treatment groups (TABLE 1).

Outcomes

Patients in the decision board group had higher knowledge scores than patients in the control group (66.9 vs 58.7; difference, 9.34; SE, 2.64, P<.001). One of the greatest improvements in

©2004 American Medical Association. All rights reserved.

(Reprinted) JAMA, July 28, 2004—Vol 292, No. 4 **437**

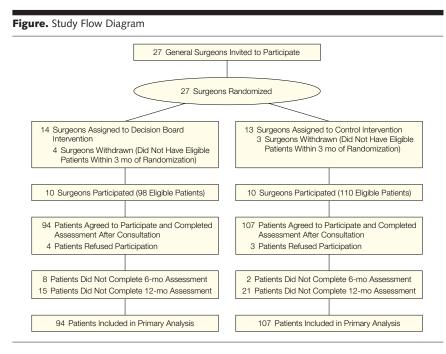


Table 1. Patient Characteristics*					
Characteristics	Decision Board (n = 94)	Control (n = 107)			
Age, median Married >High school education Employed Preference for decision making	58.2 59 (63) 47 (50) 43 (46)	58.1 73 (68) 50 (47) 53 (50)			
Independent Shared Dependent	36 (38) 41 (44) 17 (18)	49 (46) 44 (41) 14 (13)			

^{*}Data are presented as number (percentage) unless otherwise indicated.

knowledge was observed for understanding that survival was the same with mastectomy or BCT (73 [77.7%] of 94 correct in the decision board group vs 62 [57.9%] of 107 correct in the control group; P = .006]. Patients in the decision board group also had lower decisional conflict scores (1.40 vs 1.62; difference, -0.223; SE, 0.0958; P = .02) and higher satisfaction with decisionmaking scores (4.50 vs 4.32; difference, 0.215; SE, 0.110; P = .05) following the consultation. No differences were seen between groups in decisional conflict and patient satisfaction at 6 and 12 months after surgery (TABLE 2).

Patients in the decision board group were more likely to choose BCT than

patients in the control group (88 [94%] vs 81 [76%]; P=.03]). Patients in the decision board group were also more likely to perceive that they were offered a clear choice regarding treatment by their surgeons (82 [87%] vs 74 [69%]; P=.07) and to strongly prefer the treatment they choose (78 [83%] vs 76[72%]; P=.05).

Patient anxiety scores were high just after the consultation but decreased at 6 and 12 months after surgery (TABLE 3). No differences were observed between the decision board or control groups. Patient depression scores were not increased at any point and no differences between groups were observed (Table 3).

COMMENT

Results of randomized trials have demonstrated equivalent survival rates for BCT and mastectomy. Consequently the choice of treatment should be based on a patient's preferences. Previous studies have suggested that there are problems with communicating to patients the different surgical options and with offering women choice. In 1990, Fallowfield et al²² reported that a significant proportion of women with breast cancer were not offered a choice

in surgical treatment of their breast cancer by their surgeons. More recent reports continue to suggest that up to 17% to 29% of women in some areas of the United States do not receive adequate discussion of the different surgical treatment options for breast cancer. ^{23,24}

The decision board was developed to aid surgeons in communicating the different surgery options for breast cancer and to permit women to express a preference for treatment. The results of this randomized trial demonstrate that the decision board not only improved patient knowledge about breast cancer and its treatment but also decreased their decisional conflict and increased their satisfaction with decision making following the consultation. The instrument permitted women to make different treatment decisions consistent with their preferences: women who used the decision board were more likely to choose BCT and to more strongly prefer their treatment choice.

These findings are in keeping with the hypothesis that physician-patient communication and decision making can be improved with the use of decision aids. Studies have demonstrated that women with breast cancer ideally prefer to receive information about the disease and its treatment from their physician.²⁵ The surgical consultation about the diagnosis of breast cancer and its treatment is often understandably an upsetting time for women. This was evidenced by the level of anxiety observed in women around the time of consultation in our study. It has been suggested that increased anxiety may make it difficult to recall and understand complicated information regarding the treatment of the cancer.26 Presenting information in different forms—written, oral, and visual can help improve patient knowledge.²⁷ The judicious use of repetition and providing women with a take-home version of the decision aid to reflect on when they are less distressed may further improve understanding.²⁸ Although we demonstrated that overall patient knowledge was improved, what most improved was women knowing that survival was the same between the

438 JAMA, July 28, 2004—Vol 292, No. 4 (Reprinted)

2 treatments (BCT and mastectomy). This information is likely to have an important affect on patient decision making.

A goal of decision aids is to help patients make informed decisions reflecting their true preference for treatment. The outcomes assessed in this study included not only patient knowledge and treatment choice but also decisional conflict and satisfaction. Decisional conflict has been defined as a state of uncertainty about the course of action to take.17 Å number of factors may contribute to a patient's decisional conflict including lack of information about choices and their outcomes, unclear values, emotional distress, and feeling unsupported. The decisional conflict scale measures important attributes of quality decision making including how well informed patients feel about their options and associated benefits and risks, the clarity of their values and the support they have in making a decision. Patientcentered decision making is an important component of quality of care and is closely linked to patient satisfaction.29 In this study, patients who used the decision board had less decisional conflict and were more satisfied with the decision-making process.

We hypothesized that by providing patients with information in an explicit fashion, encouraging discussion and consideration of their values, and supporting them in decision making, patients would be encouraged to express their own treatment preferences. Consistent with this hypothesis, patients in our trial made different treatment decisions with the use of the decision aid. By improving communication, women were empowered to choose the treatment that reflected their own values. This is supported by the observations that when the decision board was used more women perceived that they were offered a clear choice and more strongly preferred the choice they made.

A number of systematic reviews of decision aids have been performed. 30-32 In the most comprehensive review to

Table 2. Patient Decisional Conflict and Satisfaction With Decision Making Scores After Consultation and 6 and 12 Months After Surgery

Treatment Group	Mean Score (SE)*					
	Decisional Conflict†			Satisfaction With Decision Making‡		
	After Consultation§	6 mo	12 mo	After Consultation	6 mo	12 mo
Decision board Control	1.40 (.05) 1.62 (.05)	1.41 (.06) 1.50 (.05)	1.52 (.07) 1.47 (.06)	4.50 (.05) 4.32 (.05)	4.49 (.07) 4.47 (.06)	4.37 (.08) 4.42 (.06)

^{*}P>.10 for between-group comparisons unless otherwise indicated. †Measured by the Decisional Conflict Scale.

Table 3. Patient Anxiety and Depression Scores After Consultation and 6 and 12 Months After Surgery

Treatment Group	Mean Score (SE)*					
	Anxiety†			Depression‡		
	After Consultation*	6 mo	12 mo	After Consultation*	6 mo	12 mo
Decision board	42.3 (1.3)	39.3 (1.3)	37.5 (1.4)	13.8 (1.0)	15.1 (1.1)	13.2 (1.3)
Control	41.9 (1.3)	38.9 (1.6)	36.6 (1.5)	13.4 (1.1)	14.2 (1.2)	12.8 (1.2)

*P>.10 for between-group comparisons at all time points.

date investigators identified more than 130 decision aids for health treatment or screening decisions but only 35 randomized trials to evaluate their effectiveness.30 These trials evaluated decision aids for screening and prevention interventions (14), hormone replacement therapy (7), elective surgical procedures (8), treatments for cardiovascular disease (3), and cancer treatments (3). The majority of the trials (26) compared decision aids to usual care. In these studies patient knowledge was significantly increased in 9 out of 9 trials. Decisional conflict was reduced in 3 of 6 studies. In 5 trials of decision aids for elective surgical procedures, patients who used the aid were significantly more likely to choose the less intensive surgical treatment in 1 trial.

Few decision aids for cancer treatments have been evaluated in randomized trials.³³ We previously reported the results of a randomized trial of a decision board for women with node negative breast cancer. 14 The instrument was shown to increase patient knowledge about breast cancer and adjuvant chemotherapy and to improve patient satisfaction with decision making. In that study, the instrument was administered by research nurses working with oncologists in comprehensive cancer centers. The decision board for breast cancer surgery was a departure from previous work. It was introduced to women of all age groups shortly after their diagnosis and administered by general surgeons. The positive results observed in this study are consistent with our previous experience and support that such instruments are effective when administered by physicians in the community. Previous randomized trials34,35 of decision aids for breast cancer patients regarding options for surgery have failed to demonstrate an effect on patient outcomes. These studies were relatively small in size, compared the decision aid to another instrument, and evaluated the administration of the decision aid after patients had met with their surgeon when many patients had already made a treatment decision.35 It is unclear whether the lack of benefits observed in these studies relate to the instruments themselves, the time of application, or the small number of patients studied.

^{*}Measured by the effective decision-making subscale of Decisional Conflict Scale.

[†]Measured by the Spielberger State Anxiety Inventory Self Evaluation Questionnaire. #Measured by the Center for Epidemiologic Studies Depression Scale

There are several potential limitations of our study. We used a cluster design to randomize surgeons rather than patients in this trial. We chose this design to avoid the contamination that might have occurred if surgeons were required to use the decision board for some patients and not others. The data demonstrated that this approach was successful, in that surgeon and patient groups were well balanced for factors that may affect communication and decision making. However as surgeons were aware that they were participating in a study, it is likely that they may have applied their best communication skills. Despite this potential effect, our results demonstrate that the addition of the decision board improved patient outcomes. A unique limitation of cluster randomization is the potential for compensatory bias,36 in which case, patients might switch surgeons in order to obtain the preferred intervention. To avoid this possibility the study was not widely advertised. In our trial, no patient switched surgeons.

One of the main outcomes assessed in this trial was patient knowledge. The patient-based questionnaire used in this study to assess knowledge was based on information identified by patients and surgeons as important in making a decision about breast cancer surgery.15 This information was also contained in the decision board to some degree. Patients who used the decision board were thus trained and perhaps better able to answer the knowledge questionnaire. To avoid this problem questions in the questionnaire were rephrased in a different frame wherever possible. To further avoid this limitation other outcomes less likely to be affected by the training were assessed including patient decisional conflict, satisfaction, and treatment choice.

The outcomes assessed in this study (patient knowledge, decisional conflict, satisfaction, and treatment choice) are not the typical classical outcomes of cancer trials such as tumor regression, disease free, or overall survival and quality of life. Nevertheless, they reflect the potential benefits patients may

accrue from decision aids and are likely to be important with respect to the clinical management of patients with chronic disease. The use of BCT and patient-perceived choice have been identified as important indicators of quality of cancer care. 37-39 It is of considerable interest that both these outcomes were increased with the use of the decision board. However, physicians should realize that the rate of BCT may not necessarily be increased with the use of a decision aid. The decision board will improve patient knowledge and a patient's ability to express a preference for treatment. However, the use of BCT in any given community will depend on a number of other important factors including stage of disease, use of screening mammography, access to radiation therapy facilities, and patient preference.

Are these results generalizable? In this study, the decision board was used by community surgeons. In academic or other practices where other formal educational interventions regarding treatment options are in place, for example counseling before patients have made their decision, then such an instrument may be less applicable. However, based on our previous experience, the decision board may still be beneficial for framing the discussion and actively engaging patients in decision making. The decision aid used in this study may be useful for physician counseling for other complex and multimodality treatments in oncology, such as the use of preoperative radiation and chemotherapy for rectal cancer and the treatment of early stage prostate cancer. It may also be applicable for complex treatment decisions for nononcological diseases such as inflammatory bowel disease. Further research is necessary to investigate the impact of the decision board in these situations.

Despite the demonstration of effectiveness of decision aids in a number of contexts, they still do not appear to be widely used. The reasons for this are likely to be multifactorial including limited applicability, poor dissemination, and difficulty changing physician be-

havior.40 In order to respond to some of these problems, we have developed computer-based versions of the decision board. Computerization of the decision board affords a number of potential benefits including ease of use, versatility in presentation, tailoring of information, and ease of modification to fit local practices. These computerbased versions are currently being evaluated in a randomized trial.⁴¹ Another potential benefit of computerbased versions is that they permit easy updating. However this technological ability has identified an important challenge. Currently, there is no formal process for updating decision aids. We suggest that as these instruments are more widely used, a formal process should be established. Currently, many decision aids are based on evidence-based guidelines. Such guidelines are usually updated based on a regular systematic review of the literature and consensus by an expert panel.⁴² Such a process could and likely should be adopted for widely used decision aids.

There is now an extensive body of knowledge supporting the use of BCT for the treatment of breast cancer with studies documenting equivalent survival for up to 20 years. 43,44 The decision board is an effective simple tool to help surgeons communicate the different treatment options to women with breast cancer. It has been shown in previous studies to be well accepted by community surgeons, to be easy to use, and to not lengthen the consultation.⁵ Although it may take time for such approaches to be more widely adopted, the systematic evaluation and reporting of such studies herein is the first step.

Author Contributions: Dr Whelan had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Whelan, Levine, Willan, Gafni, Sanders, Mirsky, Reid.

Acquisition of data: Whelan, Willan, Chambers, O'Brien, DuBois.

Analysis and interpretation of data: Whelan, Levine, Willan, Gafni, Chambers, Dubois.

Drafting of the manuscript: Whelan, Levine, Gafni. Critical revision of the manuscript for important intellectual content: Whelan, Levine, Willan, Gafni, Chambers, O'Brien, Reid, Dubois.

Statistical Analysis: Willan. Obtained funding: Whelan, Levine.

440 JAMA, July 28, 2004—Vol 292, No. 4 (Reprinted)

Administrative, technical, or material support: Whelan, Levine, Sanders, Mirsky, Chambers.

Supervision: Whelan, Gafni, Chambers, O'Brien.

Funding/Support: Dr Whelan is a Canada Research Chair funded by Health Canada. The Canadian Breast Cancer Research Initiative and the Ontario Ministry of Health and Long-Term Care, Health System-Linked Research Programme provided funding sup-

Role of the Sponsor: The study sponsors did not influ-

ence the design or conduct of the study; the collection, analysis, interpretation, or preparation of the data; or the preparation, review, or approval of the manuscript. Authors' Note: Our goal is to research methods to improve physician-patient communication in decision making. If an interested reader would like more information on the decision board, please see our Web site at http://www.fhs.mcmaster.ca/slru/sccru /decisionboard.html. The instrument can be constructed using standard audiovisual materials. Alter-

natively the instrument is available in limited quantities at cost for production, shipping, and handling (US \$250 for the instrument, 50 take-home versions, and an instrumental videotape on its administration). No conflict of interest is anticipated by its distribution.

Acknowledgment: We thank the women with breast cancer who agreed to participate in this trial at a difficult time in their lives. We also express our sincere thanks to the surgeons for their time and willingness to participate in this study.

REFERENCES

port for the study.

- 1. Fisher B, Bauer M, Margolese R, et al. Five-year results of a randomized clinical trial comparing total mastectomy and segmental mastectomy with or without radiation in the treatment of breast cancer. N Engl J Med. 1985:312:665-673.
- 2. Veronesi U, Saccozzi R, Del Vecchio M, et al. Comparing radical mastectomy with quadrantectomy, axillary dissection, and radiotherapy in patients with small
- cancers of the breast. *N Engl J Med*. 1981;305:6-11.

 3. Sarrazin D, Lê MG, Arriagada R, et al. Ten-year results of a randomised trial comparing a conservative treatment to mastectomy in early breast cancer. Radiother Oncol. 1989;14:177-184.
- 4. Blichert-Toft RC, Andersen JA, Overgaard M, Axelsson CK, Andersen KW, Mouridsen HT. Danish randomised trial comparing breast conservation therapy with mastectomy: six years of life-table analysis. J Natl Cancer Inst Monographs. 1992;11:19-25.
- 5. van Dongen JA, Bartelink H, Fentiman IS, et al. Randomized clinical trial to assess the value of breastconserving therapy in stage I and II breast cancer, EORTC 10801 Trial. J Natl Cancer Inst Monographs. 1992;11:15-18.
- 6. Lichter AS, Lippman ME, Danforth Jr, et al. Mastectomy versus breast-conserving therapy in the treatment of stage I and II carcinoma of the breast: a randomized trial at the National Cancer Institute. J Clin Oncol. 1992;10:976-983.
- 7. Early Breast Cancer Trialists' Collaborative Group. Effects of radiotherapy and surgery in early stage breast cancer. N Engl J Med. 1995;333:1444-1455
- 8. Morris AD, Morris RD, Willson JF, et al. Breastconserving therapy vs mastectomy in early-stage breast cancer: a meta-analysis of 10-year survival. Cancer J Sci Am. 1997;3:6-12.
- 9. Curran D, van Dongen JP, Aaronson NK, et al. Quality of life of early-stage breast cancer patients treated with radical mastectomy or breast-conserving procedures: results of EORTC trial 10801. Eur J Cancer. 1998; 34:307-314.
- 10. Moyer A. Psychosocial outcomes of breastconserving surgery versus mastectomy: a metaanalytic review. Health Psychol. 1997;16:284-298.
- 11. Levine MN. Gafni A. Markham B. MacFarlane D. A bedside decision instrument to elicit a patient's preference concerning adjuvant chemotherapy for breast cancer. Ann Intern Med. 1992:117:53-58.
- 12. Whelan TJ, Levine MN, Gafni A, et al. Breast irradiation post-lumpectomy: development and evaluation of a decision instrument. J Clin Oncol. 1995: 13:847-853.
- 13. Elit L, Levine MN, Gafni A, et al. Patients' preferences for therapy in advanced epithelial ovarian cancer: development, testing and application of a bedside decision Instrument. Gynecol Oncol. 1996;62: 329-335
- 14. Whelan TJ, Sawka C, Levine M, et al. Helping pa-

tients make informed choices: a randomized trial of a decision aid for adjuvant chemotherapy in lymph nodenegative breast cancer. J Natl Cancer Inst. 2003;95:

- 15. Whelan T, Levine M, Gafni A, et al. Mastectomy or lumpectomy? helping women make informed choices. *J Clin Oncol*. 1999;17:1727-1735.
- 16. Thompson SG, Pike SD, Hardy RJ. The design and analysis of paired cluster randomised trials: an application of meta-analysis techniques. Stat Med. 1997; 16:2063-2070
- 17. O'Connor AM. Validation of a decisional conflict scale. Med Decis Making. 1995;15:25-30.
- 18. Spielberger CD, Gorsuch RL, Lushene RE. STAI Manual for the State-Trait Anxiety Inventory. Palo Alto, Calif: Consulting Psychologists Press; 1970.
- 19. Devins GM, Orme CM, Costello CG. Measuring depressive symptoms in illness populations: psychometric properties of the Center for Epidemiologic Studies Depression (CES-D) scale. Psychol Health. 1988; 2:139-156.
- 20. Hsieh FY. Sample size formulae for intervention studies with cluster as the unit of randomization. Stat Med. 1988;7:1195-1201.
- 21. DerSimonian R, Laird N. Meta-analysis in clinical trials. Controlled Clinical Trials. 1986;7:177-188.
- 22. Fallowfield LJ, Hall A, Maguire GP, Baum M. Psychological outcomes of different treatment policies in women with early breast cancer outside a clinical trial. BMJ. 1990;301:575-580.
- 23. Clausen J, Hsieh YC, Acharya S, Rademaker AW, Morrow M. Results of the Lynn Sage Second-Opinion Program for local therapy in patients with breast carcinoma. Cancer. 2002;94:889-894.
- 24. Liang W, Burnett CB, Rowland JH, et al. Communication between physicians and older women with localized breast cancer: implications for treatment and patient satisfaction. J Clin Oncol. 2002;20:1008-
- 25. Jefford M, Tattersall MHN. Informing and involving cancer patients in their own care. Lancet Oncol. 2002;3:629-637.
- 26. Maguire P, Faulkner A. Communicate with cancer patients, I: handling bad news and difficult questions. *BMJ*. 1988;297:907-909.
- 27. Brown JW, Lewis RN, Harcleroad FF. AV Instruction: Technology, Media and Methods. 4th ed. New York, NY: McGraw-Hill; 1973.
- 28. Falvo DR. Effective Patient Education. 2nd ed. Gaithersburg, Md: Aspen Publishers; 1994.
- 29. O'Connor AM, Mulley AG, Wennberg JE. Standard consultations are not enough to ensure decision quality regarding preference-sensitive options. J Natl Cancer Inst. 2003:95:570-571.
- 30. O'Connor AM, Stacey D, Entwistle V, et al. Decision aids for patients facing health treatment or screening decisions [Cochrane Review on CD-

- ROM]. Chichester, England: Cochrane Library, Update software; 2004; Issue 1.
- 31. Molenaar S, Sprangers MA, et al. Decisions support for patients with early-stage breast cancer: effects of an interactive breast cancer CDROM on treatment decision, satisfaction, and quality of life. J Clin Oncol. 2001:19:1676-1687.
- 32. Estabrooks C, Goel V, Thiel E, et al. Decision aids: are they worth it? a systematic review. J Health Serv Res Policy, 2001:6:170-182.
- **33.** Whelan TJ, O'Brien MA, Villasis-Keever M, et al. Impact of Cancer-Related Decision Aids. Evidence Report/Technology Assessment Number 46. Rockville, Md: Agency for Healthcare Research and Quality; July 2002. AHRQ Publication No. 02-E004.
- 34. Street RL Jr, Voight B, Geyer C Jr, Manning T, Swanson GP. Increasing patient involvement in choosing treatment for early breast cancer. Cancer. 1995; 76:2275-2285.
- 35. Goel V, Sawka CA, Thiel EC, Gort EH, O'Connor AM. Randomized trial of a patient decision aid for choice of surgical treatment for breast cancer. Med Decis Making. 2001;21:1-6.
- 36. Murray DM. Design and Analysis of Group-Randomized Trials. New York, NY: Oxford University Press; 1998.
- 37. NIH Consensus Conference. Treatment of earlystage breast cancer. JAMA. 1991;265:391-395
- 38. Guadagnoli E, Weeks JC, Shapiro CL, Gurwitz JH, Borbas C, Soumerai SB. Use of breast-conserving surgery for treatment of stage I and stage II breast cancer. J Clin Oncol. 1998;16:101-106.
- 39. Mandelblatt JS, Ganz PA, Kahn KL. Proposed agenda for the measurement of quality-of-care outcomes in oncology practice. J Clin Oncol. 1999;17: 2614-2622.
- 40. Graham ID, Logan J, O'Connor A, et al. A qualitative study of physicians' perceptions of three decision aids. Patient Educ Couns. 2003;50:279-283.
- 41. Whelan T, Gafni A, Charles C, Levine M. Lessons learned from the decision board: a unique and evolving decision aid. Health Expectations. 2000;3: 69-76
- 42. Browman GP, Levine MN, Mohide EA, et al. The practice guidelines development cycle: a conceptual tool for practice guidelines development and implementation. J Clin Oncol. 1995:13:502-512.
- 43. Fisher B, Anderson S, Bryant J, et al. Twentyyear follow-up of a randomised trial comparing total mastectomy, lumpectomy, and lumpectomy plus irradiation for the treatment of invasive breast cancer. N Engl J Med. 2002;347:1233-1241.
- 44. Veronesi U, Cascinelli N, Mariani L, et al. Twentyyear follow-up of a randomised study comparing breast-conserving surgery with radical mastectomy for early breast cancer. N Engl J Med. 2002;347:1227-1232