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14. ABSTRACT: Women with breast cancer have indicated their desire to be involved in decisions about their care. We have developed a decision aid, called the Decision Board (DB), for women regarding choices in breast cancer with respect to surgical treatment and adjuvant chemotherapy. This study builds on previous work showing that the standard DB improves patient's satisfaction with decision-making, and decreases decisional conflict. This study involves the development of versions of the DB using different types of media in order to improve the usefulness of the instrument, and to allow for information to be updated more readily. Two new versions were produced: a computer-based version, which is presented on a laptop computer, and an easy-to-use paper-based version, both were compared with a standard poster size foam-core version in a randomized trial. A total of 310 patients were accrued to the study and randomly allocated to one of the three versions of the DB. Preliminary analyses suggest that patient knowledge, decisional conflict, and satisfaction with preparation with decision-making were similar between the three versions of the DB. Usefulness of the instrument for the patient and physician also appeared similar for the different versions. This study supports that the computer or paper-based versions may now also be used to support patient involvement in treatment decision-making.					
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Introduction

The main objective of this study is to further enhance information transfer between the doctor and the patient, giving women with early stage breast cancer an opportunity to more fully participate in treatment decision-making. The study compares three versions of the decision board (DB), all containing the same information but using different forms of media. The three versions of DBs are: (i) the standard DB, which is a foam core, poster sized version with pull-out panels; (ii) the computer DB, which uses a Window's based program that resembles the standard DB and is available on a laptop computer; (iii) the paper DB, which is a small 8.5 in. x 11 in. paper version of the standard DB and also serves as the take-home brochure for the standard DB. Patients are randomly assigned to one of three versions of the DB when they attend their physician's office for consultation. The DB presents one of two treatment choices: (i) an adjuvant chemotherapy decision for women with stage I or II moderate risk breast cancer (no chemotherapy vs. CMF (Cyclophosphamide, Methotrexate, and Fluorouracil) vs. AC (Adriamycin and Cyclophosphamide) vs. ACT (Adriamycin, Cyclophosphamide and Taxol)). This stratum involving the chemotherapy decision is called DECIDE-C, and (ii) a surgical decision (mastectomy vs. lumpectomy plus radiation) for women with Stage I or II breast cancer. This stratum involving the surgical decision is called DECIDE-S. The trial was closed to accrual on May 12, 2006 with 310 patients entered. This document is the final report for this randomized controlled trial.

Body

The progress made towards meeting objectives since the last report and completing the trial are outlined below.

Task 1: Development of Computer-based Version of Decision Boards and Updating the Standard Versions of the Decision Boards Currently Used at the JCC and Outlying Communities. Completed.

Complete, see previous reports.

Task 2: Start up of the RCT. Development of Operations Manuals, Data Forms, Training of Clinicians to use Computer-Based Versions: Completed.

Complete, see previous reports.

Task 3: Patient Recruitment and Data Collection: Completed.

Patient recruitment to DECIDE-C opened on April 29, 2002 with the first patient randomized on May 8, 2002 and the last patient randomized on May 9, 2006. A total of 200 patients were entered into this stratum of the trial.

Patient Recruitment to DECIDE-S started on February 17, 2003, with the first patient randomized to the study on March 31, 2003 and the last patient randomized on May 5, 2006. A total of 110 patients were entered into this stratum of the trial.

Task 4: Data Entry and Analyses: Complete (with follow-up still on-going).

All data entry into the main database for this study is up to date and has been cleaned. The Trial Management System (TMS), designed to help keep track of patient visits and the timeliness of the collection of the case report forms (CRFs) is also up to date and very effective at ensuring that data collection is done according to study timelines and CRFs and patient assessments are not missed. This system will continue to be used, as follow-up assessments for this trial will continue to be collected until all patients have completed their final 6-month assessment.

Key Research Accomplishments

Year 8

- ◆ Completed recruitment to the trial and performed the first analysis on the database.

Year 7

- ◆ Incorporated a third chemotherapy treatment (ACT) into all three versions of the Decision Board, to ensure that the DB had the most up to date treatment options and also to ensure that recruitment to our study did not decrease.
- ◆ Continued to accrue patients to both DECIDE-C and DECIDE-S at an acceptable rate.

Year 6

- ◆ Recruited an additional surgeon for DECIDE-S Study
- ◆ Increased accrual rate in DECIDE-S and continue to accrue patients at an acceptable rate
- ◆ Continued to accrue patients to DECIDE-C at an acceptable rate

Year 5

- ◆ Start-up of the randomized control trial of DECIDE-S
- ◆ Revised the case report forms to ensure the DECIDE-C and DECIDE-S forms were compatible
- ◆ Created the Study Database
- ◆ Created the Trial Management Database
- ◆ Continued to accrue patients to the DECIDE-C study at an acceptable rate

Year 4

- ◆ Start-up of the randomized controlled trial of DECIDE-C
- ◆ Added paper version as a third treatment arm
- ◆ Enabled node-positive patients to enter (if not competing with other clinical trials)
- ◆ Added more personalized features to DECIDE-C board
- ◆ Revised the DECIDE-S version of the decision board based on feedback from the DECIDE-C version
- ◆ Created the Study Database and started data entry
- ◆ Created the Trial Management Database

Year 3

- ◆ Updated the standard version of the node-negative Decision Board
- ◆ Revised the computer version of the node-negative Decision Board
- ◆ Field testing of the computer version of the node-negative Decision Board was completed
- ◆ Completed field testing of the computer version of the node-negative Decision Board

Year 2

- ◆ Completed field testing of the computerized version of the surgery Decision Board
- ◆ Developed prototype of the computerized version of the node-negative Decision Board
- ◆ Completed field testing of the standard version of the node positive Decision Board
- ◆ Developed a prototype of the computerized version of the node-positive Decision Board
- ◆ Field testing of the computerized version of the node-positive Decision Board
- ◆ Field testing of the computerized version of the node-negative Decision Board

Year 1

- ◆ Completed a review of the literature and updated the standard version of the surgery Decision Board
- ◆ Completed a review of the literature and updated the standard version of the node-positive Decision Board
- ◆ Completed a review of the literature and updated the standard version of node-positive Decision Board
- ◆ Developed the computerized version of the surgery Decision Board

Reportable Outcomes

Publications:

Peer Reviewed Publications:

1. Charles, C, Gafni A, **Whelan T**, O'Brien M. Cultural influences on the physician-patient encounter: The case of shared treatment decision-making. Submitted to *Patient Education and Counseling* (Accepted for publication)
2. Stewart M, Brown JB, Galajda J, Dopnner A, Gavin A, Holliday RL, Whelan T, Leslie K, Cohen I, Weston W, Freeman T. Improving communication between doctors and breast cancer patients. *Annals of Family Medicine* (Submitted)
3. Elwyn G, O'Connor A, Stacey D, Volk R, Edwards A, Coulter A, Thomson R, Barratt A, Barry M, Bernstein S, Butow P, Clarke A, Entwistle V, Feldman-Steward D, Holmes-Rovner M, Llewellyn-Thomas H, Moumjid N, Mulley AI, Ruland C, Sepucha K, **Whelan T**. Developing quality guidelines for patient decision aids: an online international Delphi consensus process. *JAMA* (Accepted for publication)
4. Hack TF, **Whelan T**, Olivotto IA, Weir L, Bultz BC, Magwood B, Ashbury F, Brady J. Standardized audiotape versus recorded consultation to enhance informed consent to a clinical trial in breast oncology. *Psycho-Oncology* (Accepted for publication)

Conclusions

Study Methods

There were 310 women randomized to the physician consultation plus either the standard (106), computer (103) or paper-based (101) versions of the DB. Patients were stratified according to the type of decision (primary surgical treatment or adjuvant chemotherapy). Patients were evaluated following the consultation for their knowledge about the breast cancer treatments offered, decisional conflict, and satisfaction with preparation for decision-making using established validated instruments. Usefulness of the instrument for the patient and physician was also assessed. Patient assessments took place at baseline

(immediately after the consultation with the doctor), one week, three months and six months.

Preliminary analysis was performed for assessments that took place immediately after the consultation with the doctor. Patient knowledge, decisional conflict and satisfaction with preparation for decision-making were similar between the 3 versions of the decision board ($p \geq .05$) for each outcome. The usefulness of the instrument for the patient and physician also appeared similar for the different versions ($p \geq .05$).

Conclusions

Many women with breast cancer want to be involved in treatment decision-making. We have previously developed and evaluated the decision board, which is a visual aid administered by the clinician during the consultation that presents written and graphical information from clinical trials to patients regarding treatment options for early breast cancer. Previous studies have demonstrated that the decision board improves patient comprehension, satisfaction and comfort with decision-making. Despite these positive effects, decision boards and other patient based decision aids are not widely used in part due to lack of access and perceived difficulty in use. Computer based instruments are particularly attractive as they provide more versatility for updating and can be assessed via the internet. A potential concern is that computers may be less familiar to some patients and physicians and awkward to use. We developed computer-based instruments of the decision board for primary surgical therapy (mastectomy or breast conserving therapy) and adjuvant chemotherapy (no treatment, CMF, AC or AC + T) using a Windows type format. We also developed simple paper based versions of these instruments. We performed a randomized trial to compare the computer and paper based versions of the decision board to the proven standard version for patient knowledge, comfort and satisfaction with

preparation for decision-making. Our results support that the newer instruments are certainly as good as the previous standard instrument and supports their wider use by health personnel to facilitate patient involvement in treatment decision making.

An abstract reporting these preliminary findings has been submitted for presentation in the 29th Annual San Antonio Breast Cancer Symposium December 14-17, 2006.