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13. ABSTRACT (Maximum 200 Words)

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, for women regarding choices in breast cancer with respect to surgical treatment and adjuvant chemotherapy. Randomized trials have demonstrated that the Decision Board not only increases patient knowledge, but improves patient satisfaction, decreases decisional conflict, and facilitates shared decision-making between the physician and the patient. This present study builds on previous work and involves the development of versions of the Decision Board using different types of media in order to improve the effectiveness of these instruments. Two new versions have been produced: a computer-based version, which is presented on a laptop computer, and an easy-to-use paper based version which are being compared with a standard poster size foam-core version in a randomized trial. Important outcomes will include patient comprehension and acceptability. Currently 212 patients are entered into the study, with a target of 300 by October 2005. Newer versions of the Decision Board that are easier to use and present will lead to wider use in the community resulting in more knowledgeable and satisfied breast cancer patients.

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Table of Contents

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 moderate risk node-negative breast cancer (no chemotherapy vs. CMF (Cyclophosphamide, Methotrexate, and Fluorouracil) vs. AC (Adriamycin and Cyclophosphamide)). 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 is currently open and accruing patients. The plan is to complete accrual to the study by October 1, 2005 and submit a final report for November 1 2005.

Body

An 18 month extension of the study until November 1, 2005 was granted on April 23, 2004. Progress made towards meeting objectives since the last review is outlined below. The stratum of the trial involving the chemotherapy DB (DECIDE-C) has been actively recruiting patients since accrual was opened on April 29, 2002. The stratum of the trial involving the surgical DB (DECIDE-S) started on February 17, 2003. Both parts of the trial are running smoothly.

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

Completed, 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.

One additional surgeon was recruited to the DECIDE-S study since the last report. Prior to this surgeon accruing her first patient, the Research Coordinator and Research Assistant visited her office for a "start-up" meeting. At this "start-up" meeting the surgeon was shown how to properly present each of the three versions of the DB. The procedures for randomizing a patient to the study were discussed, including obtaining informed consent from the patient.

Task 3: Patient Recruitment and Data Collection: In Progress.

Patient recruitment to DECIDE-C opened on April 29, 2002 with the first patient randomized on May 8, 2002. There are currently 145 patients randomized to the trial by six Medical Oncologists. The current rate of accrual is 4 patients per month.

Patient Recruitment to DECIDE-S started on February 17, 2003, with the first patient randomized to the study on March 31, 2003. The addition of the new surgeon at the Juravinski Cancer Centre in July 2004 has boosted accrual to the study and should continue to do so. Total accrual to DECIDE-S is currently 67 patients. The current rate of accrual is 4 patients per month. We anticipate reaching our target sample size of 300 patients for both strata in DECIDE-C and DECIDE-S by October 2005.

Task 4: Data Entry and Analyses: In Progress.

The trial databases (both the study database and the trial management database) have been set up for the study. The study database was developed to hold the information collected on the CRFs. Programs were written to ensure correct data entry as a quality control measure. Data entry is up to date on the study.

The Trial Management System (TMS) was designed to help keep track of patient visits and the timeliness of the collection of the CRFs. The TMS generates a number of monthly reports that indicate how the trial is doing in terms of patient accrual, CRF completion,

overdue assessments, upcoming visits, and data entry (see Appendix 1 as an example). These reports are sent to all participants and have helped to ensure that the trial has run smoothly, visits are not missed, and all CRFs are collected in a timely fashion.

Key Research Accomplishments

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. Whelan T, Levine M, Willan A, Gafni A, Sanders K, Mirsky D, Chambers S, O'Brien MA, Reid S, Dubois S. Effect of a decision aid on knowledge and treatment decision making for breast cancer surgery: A Randomized Trial. *JAMA* 2004;292:435-441

2. Charles, CA, **Whelan T**, Gafni A, Farrell S, Willan A. Shared treatment decision making: what does it mean to physicians. *Journal of Clinical Oncology* 2003; 21:932-936.

3. Elit L, Charles C, Gold I, Gafni A, Farrell S, Tedford S, Dal Bello D, **Whelan T.** Women's perceptions about treatment decision making for ovarian cancer. *Gynecologic Oncology* 2003; 88:89-95.

Journal Articles Submitted for Publication:

1. Charles C, Gafni A, **Whelan T.** Treatment Decision Aids: Conceptual Issues and Future Directions. Submitted to *Health Expectations*, April 2004.

2. Wright JR, **Whelan TJ**, Schiff S, Dubois S, Crooks D, Haines P, DeRosa D, Roberts R, Gafni A, Prichard K and Levine M. Why cancer patients enter randomized clinical trials: exploring the factors that influence their decision. Submitted to *JCO* June 2004

3. Charles C, Gafni A, **Whelan T.** Self reported use of shared decision-making among breast cancer specialists and perceived barriers and facilitators to implementing this approach. Submitted to *Health Expectations*, June, 2004.

Chapters and Guidelines in Press

Abstracts:

1. O'Connor AM, Elwyn G, Barratt A, Barry M, Coulter A, Holmes-Rovner M, Llewellyn-Thomas H, Moumjid N, Stacey D, Thomson R, **Whelan T**, and the International Patient Decision Aid Standards (IPDAS) Collaboration. Reaching Consensus on International Patient Decision Aid Standards (IPDAS) for their Development and Evaluation. Accepted for presentation at the SMDM conference, October 2004

2. Butow P, Solomon M, Young J, Salkeld G, **Whelan T,** Hruby G, Tattersall M. Views of Colorectal Cancer Patients on Making Treatment Decisions and Decision Aids. Submitted to the (EACH) European Association of Communication in Healthcare Conference, Bruges, Belgium, September 14-17, 2004.

3. Charles C, Gafni, **Whelan T.** Barriers, Facilitators and Strategies to Promote Shared Decision-Making Among Cancer Physicians and Patients. Submitted to (EACH) European Association of Communication in Healthcare Conference, Bruges, Belgium, September 14-17, 2004.

4. Charles C, Gafni, **Whelan T.** Self-Reported Use of Shared Decision-Making Among Physicians Who Treat Women with Newly Diagnosed Breast Cancer. Submitted to (EACH) European Association of Communication in Healthcare Conference, Bruges, Belgium, September 14-17, 2004.

5. O'Brien MA, **Whelan TJ,** Gafni A, Charles C. Shared Decision Making in Action? The Progress of Shared Decision Making as a Scientific Field. Submitted to the (EACH) European Association of Communication in Healthcare Conference, Bruges, Belgium, September 14-17, 2004.

Presentations:

Invited:

1. **Whelan T.** The Decision Board as an Aid in Treatment Decision-Making. 21st Annual Miami Breast Cancer Conference, Miami Beach, FL, February 24-28, 2004.

Presentations at McMaster University:

2. **Whelan T.** Shared Decision-Making in Oncology. Department of Medicine, Hamilton Health Sciences Henderson Campus, February 6, 2004.

Conclusions

The study is running smoothly with adequate accrual to meeting the target of 300 patients with 212 patients currently randomized to both DECIDE-C and DECIDE-S. We anticipate reaching our target sample size by October 1, 2005.

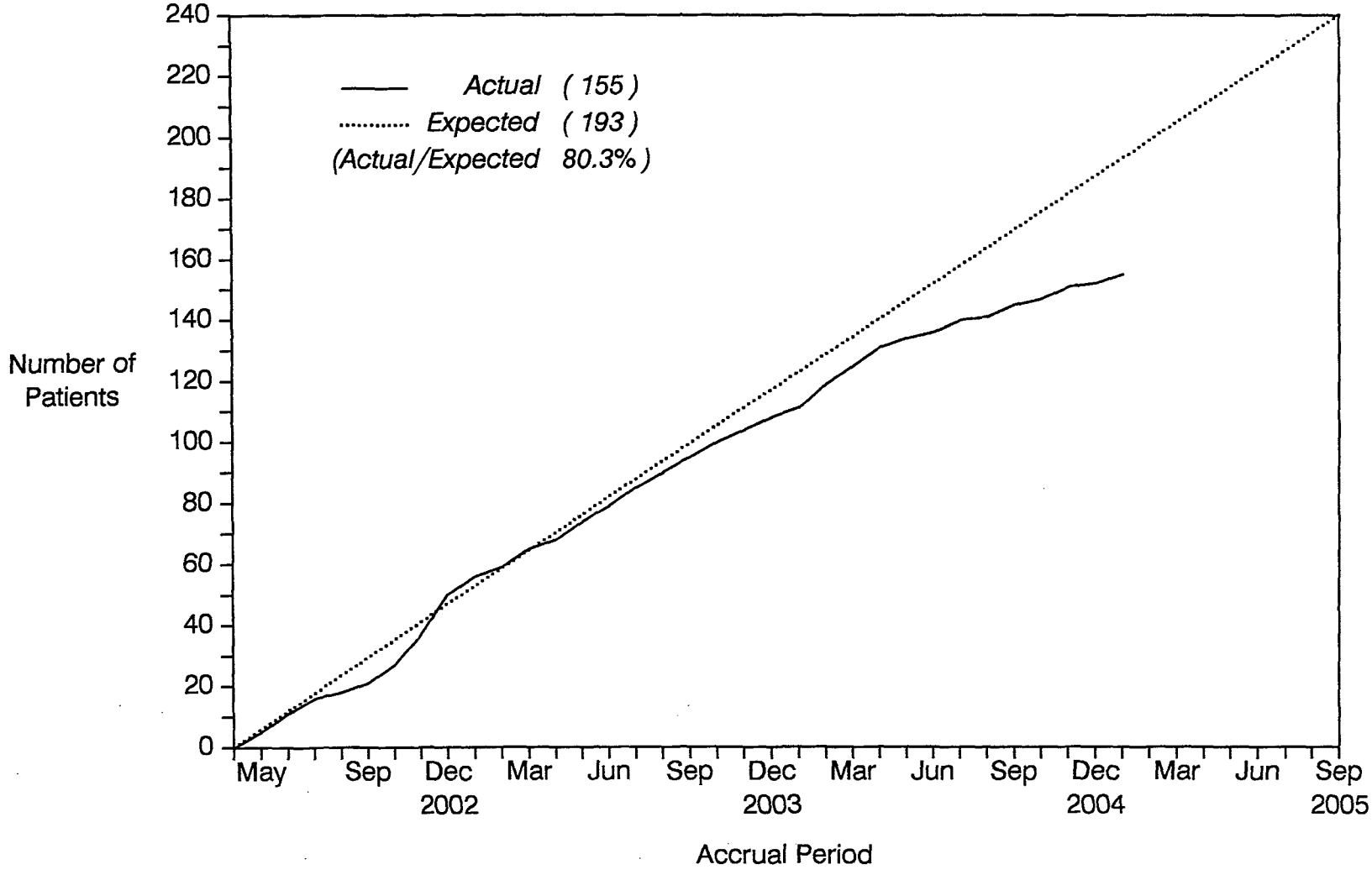
Appendix 1

Example reports from Trial Management System

Evaluation of Different Versions of the Decision Board (DECIDE-C)

PATIENT ACCRUAL as of 31 Jan 2005

Study Started April 29, 2002 Projected Sample Size: 240 Patients by September 30, 2005



Evaluation of Different Versions of the Decision Board (DECIDE-C)

Projected Follow-up Schedule, by Target Date
for 01 Feb 2005 - 31 Mar 2005

Centre: Hamilton Regional Cancer Centre

PATIENT STUDY ID	PATIENT INITIALS	ASSESSMENT	TARGET DATE
1148	D-H	3 Month Assessment	10 Feb 2005
1149	B-A	3 Month Assessment	19 Feb 2005
1141	S-H	6 Month Assessment	20 Feb 2005
1150	E-L	3 Month Assessment	23 Feb 2005
1151	B-A	3 Month Assessment	28 Feb 2005
1142	J-W	6 Month Assessment	03 Mar 2005
1152	S-M	3 Month Assessment	03 Mar 2005
1143	S-V	6 Month Assessment	14 Mar 2005
1144	J-P	6 Month Assessment	17 Mar 2005
1145	C-S	6 Month Assessment	24 Mar 2005

10 visits

Evaluation of Different Versions of the Decision Board (DECIDE-C)

Patient Follow-up Schedule

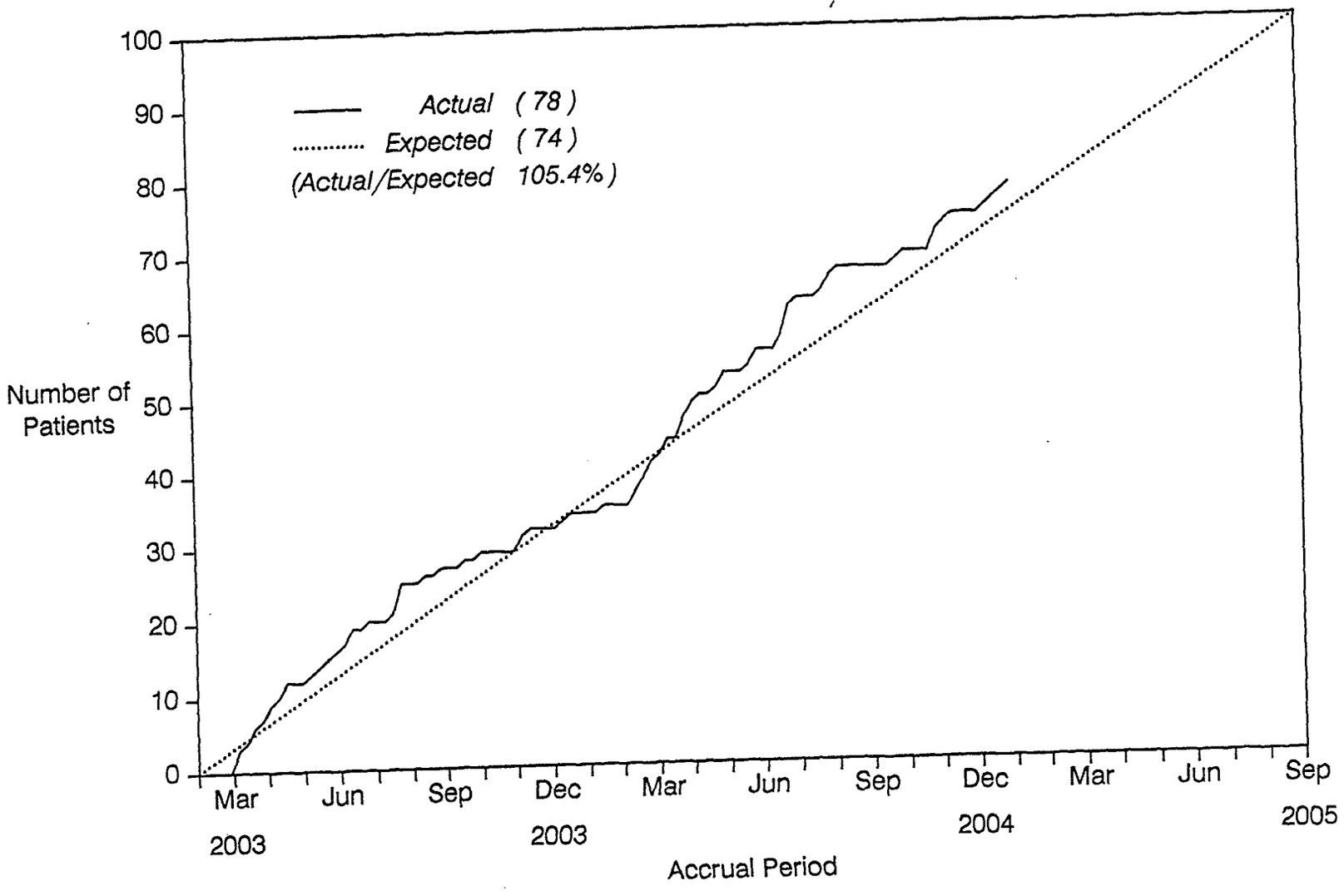
Centre: Hamilton Regional Cancer Centre
Patient ID: 1153 **Patient Initials:** W-G

ASSESSMENT	TYPE OF SCHEDULE	TARGET DATE
Baseline Assessment	Regular	04 Jan 2005
1 Week Assessment	Regular	11 Jan 2005
3 Month Assessment	Regular	04 Apr 2005
6 Month Assessment	Regular	04 Jul 2005

Evaluation of Different Versions of the Decision Board (DECIDE-S)

PATIENT ACCRUAL as of 31 Jan 2005

Study Started March 1, 2003 Projected Sample Size: 100 Patients by September 30, 2005



Evaluation of Different Versions of the Decision Board (DECIDE-S)

Projected Follow-up Schedule, by Target Date
for 01 Feb 2005 - 31 Mar 2005

Centre: Dr. Nicole Hodgson

PATIENT STUDY ID	PATIENT INITIALS	ASSESSMENT	TARGET DATE
912	D-S	3 Month Assessment	24 Feb 2005
902	S-G	6 Month Assessment	25 Feb 2005
911	G-G	6 Month Assessment	25 Feb 2005

3 visits

Evaluation of Different Versions of the Decision Board (DECIDE-S)

Patient Follow-up Schedule

Centre: Dr. Nicole Hodgson
Patient ID: 909 **Patient Initials:** S-F

ASSESSMENT	TYPE OF SCHEDULE	TARGET DATE
Baseline Assessment	Regular	05 Jan 2005
1 Week Assessment	Regular	12 Jan 2005
3 Month Assessment	Regular	05 Apr 2005
6 Month Assessment	Regular	05 Jul 2005