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13. ABSTRACT ***(Maximum 200 Words)***
Women with breast cancer have increasingly indicated a desire for more information about their disease and the need to be involved in making decisions about their care. We have developed two decision aids called Decision Boards (DB) to help clinicians inform patients about their treatment options. One DB involves the surgical decision between mastectomy and lumpectomy plus radiation; the other involves the decision between chemotherapy options for the treatment of node-negative breast cancer. The objectives of this study are to; i) develop computer based versions of both the DB for the surgical treatment of breast cancer and the DB for chemotherapy for node-negative breast cancer; and ii) to compare the relative effectiveness of the computer-based versions with standard versions for women with early breast cancer. In the third year, we have revised the standard and computer versions of the node-negative chemotherapy decision board. Both computer-based versions (for surgery and chemotherapy) have now been developed, revised and field-tested. Both instruments have been shown to be easy to use and understand, and acceptable to patients and physicians. We are now in a position to begin the randomized trial comparing the computer-based versions to the standard versions.

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Introduction

Women with breast cancer have increasingly indicated a desire for more information about their disease and a need to be involved in decisions about their care. The main objective of the study is to further enhance information transfer between the physician and patient, giving women with early stage breast cancer an opportunity to more fully participate in treatment decision making. In this study, computer-based versions of decision aids (called Decision Boards) have been developed for the surgical treatment of early breast cancer and chemotherapy for node-negative breast cancer. The computer versions were based on previous Decision Boards and have been developed through an iterative process with focus groups of patients and clinicians. Feasibility testing confirmed good overall patient understanding and acceptability. The computer versions will now be compared with standard versions in a randomized trial. We hypothesize that the many advantages of computer-based versions will improve the versatility of the instrument as well as patient and physician acceptability.

Body

Progress was made this year towards meeting objectives as outlined below. Key accomplishments include: updating of the standard Decision Board for chemotherapy in node-negative breast cancer and development of a computer version of this instrument. Field testing of the instrument has been completed and we are now prepared to begin the randomized trial. Unfortunately, progress this year was significantly delayed due to a combination of several events beyond our control: i) Strike action at McMaster University: Employees were on strike for a 6-week period from the beginning of March to mid April, thus there were no staff available to work on this study. ii) The lack of a research coordinator: Upon returning to work following the strike action, the research coordinator resigned. Unfortunately, it took considerable time to hire someone and we were without a research coordinator for a seven-week period from June 1st to July 23rd, 2001. iii) The principal investigator sustained a severe injury and was unable to work for a further 6 weeks. iv) Competing trials. The intention was to perform an RCT of computer-based versions of the instrument for breast cancer surgery, for chemotherapy for node-negative breast cancer and chemotherapy for node-positive breast cancer. We were relying on accruing patients with node-positive breast cancer who were eligible for chemotherapy. Unfortunately, a large multi-centered randomized trial was initiated in Canada in node-positive breast cancer making it difficult to use our instrument at our Center. As a result, we have had to reconsider the trial focusing primarily on the breast cancer surgery instrument and the chemotherapy for node-negative breast cancer instrument. This forced us to go beyond our Center and to recruit other Centers to participate in the study in order to reach accrual targets.

Despite several setbacks, important progress has been made and we are in a position to begin the randomized trial. Accomplishments that have occurred over the last year are:

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 (Months 1-12).

The computer version of the surgical Decision Board was developed and pilot tested last year. This year, following completion of a randomized trial comparing the standard Decision Board for chemotherapy for node-negative breast cancer plus the medical consultation to the medical consultation alone, we identified several areas for improvement in the original instrument based on our experience. This has involved restructuring the instrument to identify not only the option for chemotherapy, but also two different regimens, Cyclophosphamide, Methotrexate, Flourouracil (CMF) and Adriamycin and Cyclophosphamide (AC). This instrument was developed in an iterative format through focus groups with patients and with physicians. Key changes include: information displayed in easy-to-read bullet form, large print size, different background colors, separate panels to describe side effects and side effect profiles highlighting differences between the two regimens and the use of additional cards to describe the implications of cancer recurrence and other outcomes associated with chemotherapy, e.g., menopause (Appendix A). The instrument was then piloted on five patients. The instrument was well accepted. Further minor changes to print size and use of headings, where necessary, were added.

The computer-based version of the Decision Board for chemotherapy for node-negative breast cancer was based on the updated standard version. As with the computer-based version of the surgical Decision Board, the program for the instrument was written using Pascal Borland Delphi Version 3. Through the use of active components on the visual display, e.g., buttons, tabs and hypertext links, the user is given access to progressive depths of information on selected topics. The chemotherapy instrument opens with a screen requesting specific information related to the patient's extent of disease (i.e., Estrogen receptor status, tumour size and tumour grade). Programming permits subsequent information to be tailored to the individual patient. The user is then presented with an overview panel which contains a grid similar to the standard version with the headings, treatment choice, side effects, and outcome along the top, and options listed along the side of no chemo, chemotherapy, CMF and AC (Appendix B). Clicking on the appropriate box on the overview panel opens panels of information. Successive panels can then be opened similar to opening windows on the standard version. For example, the no chemotherapy scenario describes that the patient will be followed regularly even if she did not choose chemotherapy. No side effects are associated with this option and the outcome of recurrence is described using a probability wheel based on the patient's extent of disease. For the option of chemotherapy, general information about how chemotherapy is administered is given followed by a description of the side effects associated with chemotherapy followed by a description of the decrease in recurrence obtained for the patient. CMF and AC options describe differences in how these regimens are administered and associated side effects. A separate panel in the outcomes section describes how the chance of recurrence is the same with either type of chemotherapy.

Field testing of the node-negative chemotherapy Decision Board was completed on 15 patients at the Hamilton Regional Cancer Centre. Based on feedback from this field testing, the instrument only requires some minor changes prior to starting the randomized trial.

Our results showed that, of all patients approached to participate in the pilot study, 100% agreed and all patients completed the interview.

In terms of acceptability, patients were asked how understandable was the information presented in the decision board, how easy it was to follow the information being presented, whether the decision board helped them to decide on treatment, helped them ask questions and would they recommend it to other patients. All patients found the Decision Board to be very easy (73%) or easy (27%) to understand. All patients found the information presented very easy (91%) or easy (9%) to follow. All patients indicated that the board was very helpful (64%) or somewhat helpful (36%) in deciding upon treatment. Patients were asked if the decision board helped them to think of questions to ask their doctor or nurse; 82% felt that the Decision Board either definitely helped (37%) or helped (45%) them think of questions to ask their doctor or nurse. However, 18% of patients felt that the Decision Board did not help them to think of questions to ask because all of the information they required was already contained on the board. When asked if patients would recommend the Decision Board to others, all indicated that they would definitely recommend (82%) or recommend (18%) it to others.

In terms of the satisfaction of the medical oncologists with the instrument, all indicated that the computerized Decision Board was easy to use and very helpful in presenting information at a level that patients could understand. All of the medical oncologists felt that the Decision Board was very helpful as a reminder to cover all of the necessary information with the patient.

Task 2: Start up of the RCT (Months 13-16). Development of Operations Manual, data forms, training of clinicians to use computer-based versions.

An acronym (DECIDE) was developed for the randomized trial of both the surgical treatment options and the chemotherapy treatment options. This acronym takes letters from the title of the study: **D**evelopment and **E**valuation of **C**omputer-based versIons of the **D**ecision Board for **E**arly Breast Cancer. To differentiate between the surgical and chemotherapy aspects of the study, we have added the letters "S" for surgical and "C" for chemotherapy (i.e., DECIDE – S and DECIDE – C).

For DECIDE-S, eight community surgeons have been approached and have agreed to participate in the study. These physicians have been trained in using the instrument and are prepared to begin the trial.

For DECIDE-C, five medical oncologists at the Hamilton Regional Cancer Centre have agreed to participate in the study. Two other cancer centers have been approached (Toronto Sunnybrook Regional Cancer Centre and the Princess Margaret Hospital) and have agreed in principle to participate in this study. It is expected that in total 8-10 medical

oncologists will participate. Although involving other centers will increase the complexity of the study, we have successfully used this approach in our previous trial of the original Decision Board. It is also felt that this will increase the generalizability of our study findings.

Operations manuals and data forms have been developed both for DECIDE-S (Appendix C) and DECIDE-C (Appendix D). Take-home versions of the computerized decision board for DECIDE – C has also been developed an example of this can be found in Appendix E.

Task 3: Patient recruitment and data collection (Months 16-39)

We recognize that, due to circumstances beyond our control, we are approximately 20 months behind in our initial statement of work. We plan to initiate the randomized trial prior to December 2001. Our intention is to begin the study at cancer centers and then in community surgeon offices. We believe that we are now on track with two well developed and tested computer-based versions of the Decision Board. Our plan is to work with surgeons and oncologists that we have worked with previously. We anticipate that we should be able to complete the trial as planned, but delayed by 20 months. Additional funds will not be requested. The study will be supported with funding not utilized in Year 3.

Key Research Accomplishments

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

- Standard version of node-negative Decision Board was updated
- Computer version of node-negative Decision Board was revised
- Field testing of the computer version of the node-negative Decision Board was completed
- Operations manuals for DECIDE-S and DECIDE-C were completed

Conclusions

Standard versions of Decision Board for breast cancer surgery and chemotherapy in node-negative breast cancer have been updated.

Computer versions of both instruments have both undergone extensive development and field-testing. Operations manuals for DECIDE-S and DECIDE-C also have been developed.

The iterative process for developing and testing of the decision aids has created a sense of ownership among the surgeons and oncologists involved in the study. We believe that we are well posed to begin the randomized trial of the computer versions of the Decision Board.

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Appendices

Appendix A: Standard version of the node-negative Decision Board

Appendix B: Computer version of the node-negative Decision Board

Appendix C: Operations manual for the Surgical Decision Board

Appendix D: Operations manual for the Computerized Decision Board

Appendix E: Take-home version of the Computerized Decision Board

Appendix A

Standard Version of the node-negative Decision Board

(Including additional information cards)

7 pages

C M F

CMF Treatment Cycle

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Week 1							
Week 2							
Week 3	No Chemotherapy						
Week 4	No Chemotherapy						

X 6 =

- "treatment cycle" lasts **4 weeks**
- 3 chemotherapy drugs:
- **Cyclophosphamide**
  - pills taken by mouth
  - every day for first 2 weeks of every *treatment cycle*
- **Methotrexate** and **Fluorouracil**
  - given intravenously
  - two times – Day 1 of first week and second week in each *treatment cycle*
- takes about 20 minutes to receive intravenous drugs
- *treatment cycle* repeated 6 times for a total of 6 months

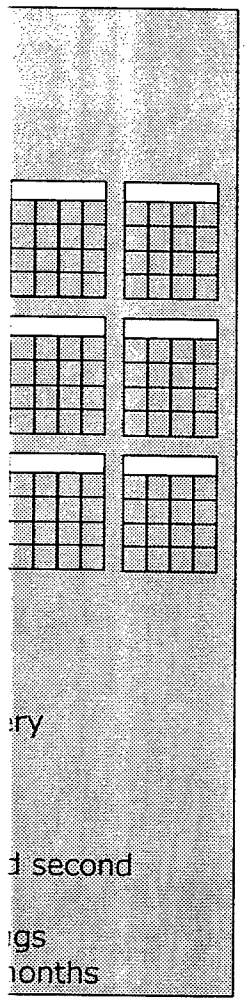
A C

AC Treatment Cycle

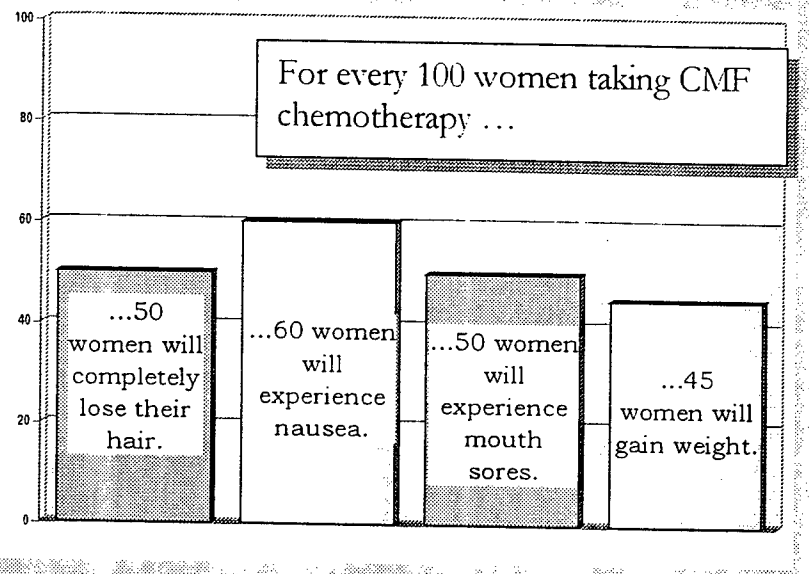
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Week 1		No Chemotherapy					
Week 2	No Chemotherapy						
Week 3	No Chemotherapy						

X 4 =

- "treatment cycle" lasts **3 weeks**
- 2 chemotherapy drugs
  - **Adriamycin** and **Cyclophosphamide**
    - given intravenously
    - one time only – first day of each *treatment cycle*
- takes about 60 minutes to receive intravenous drugs
- *treatment cycle* repeated 4 times for a total of **3 months**



Side Effects of CMF Chemotherapy



- With CMF, very few women will experience serious side effects such as infection (1 in 100), leukemia (1 in 500) and heart damage (virtually none).

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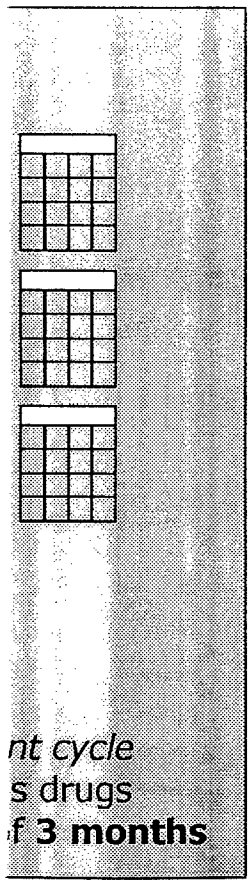
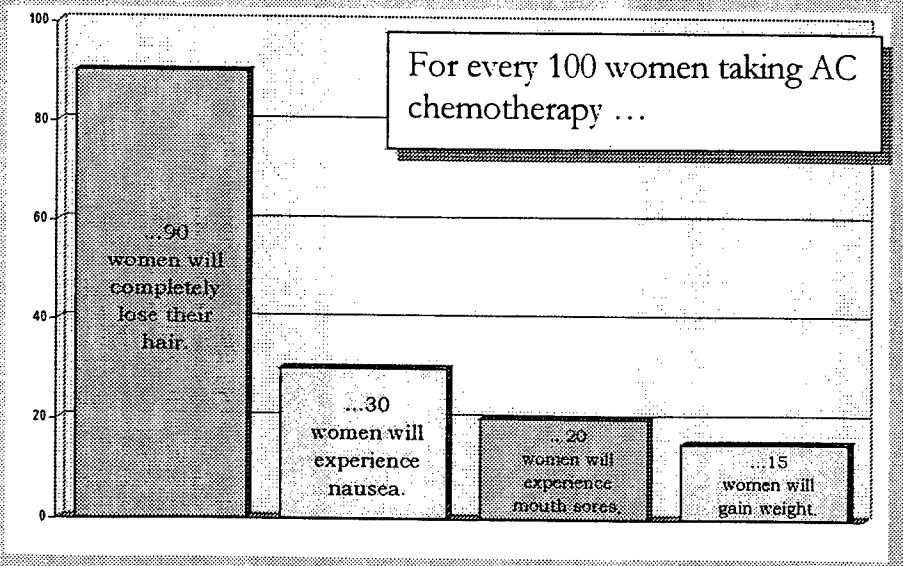
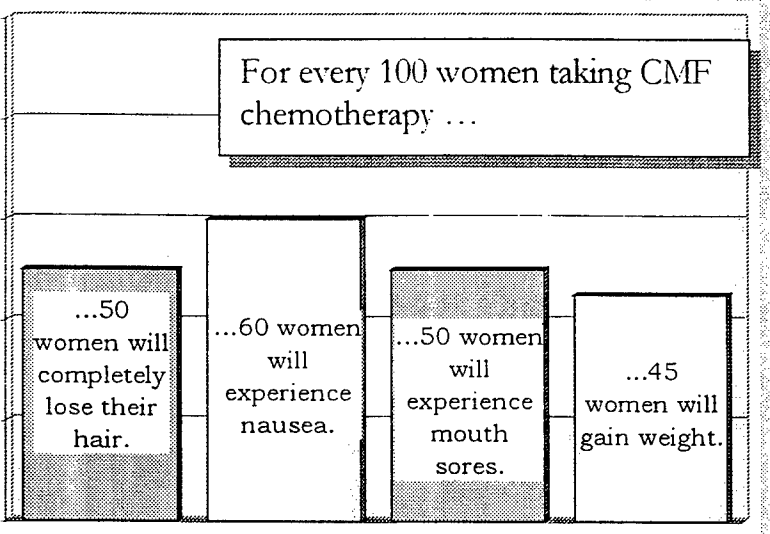


Side Effects of AC Chemotherapy



With AC, few women will experience serious side effects such as infection (2 in 100), leukemia (1 in 200) and heart damage (1 in 500).

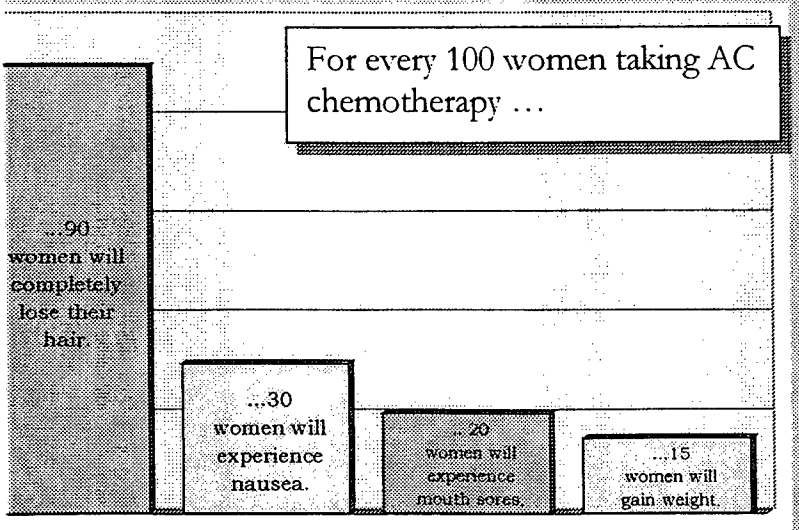
Side Effects of CMF Chemotherapy



With CMF, very few women will experience serious side effects such as infection (1 in 100), leukemia (1 in 500) and heart damage (virtually none).

The chances of remaining cancer free are the same with either type of chemotherapy

Side Effects of AC Chemotherapy



AC, few women will experience serious side effects side
ts such as infection (2 in 100), leukemia (1 in 200) and
t damage (1 in 500).

DECISIO

TREATMENT CHOICES

NO CHEMO

What happens if I decide not to have chemotherapy?

- followed at cancer centre on a regular basis
  - Physical examination
  - Blood work (at some visits)
- yearly mammogram
- other tests, if doctor feels they are necessary

CHEMOTHERAPY

What is chemotherapy?

- A treatment program using drugs that fight cancer cells

How is chemotherapy given?

- combination of 2 or 3 drugs are given together by:
  - injections (at cancer centre) and pills (taken at home), or injections only (at cancer centre)
- drugs are given in a "treatment cycle"
- each treatment cycle lasts three to four weeks
- during each treatment cycle there are 2 to 3 weeks when no chemotherapy is given
- treatment cycle is repeated 4 to 6 times
- takes 3 to 6 months to finish all treatment cycles

What happens after finishing chemotherapy?

- followed at cancer centre on a regular basis
  - Physical examination
  - Blood work (at some visits)
- yearly mammogram
- other tests, if doctor feels they are necessary

1

DECISION BO

TREATMENT CHOICES

What happens if I decide not to have chemotherapy?

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  - Blood work (at some visits)
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- No c

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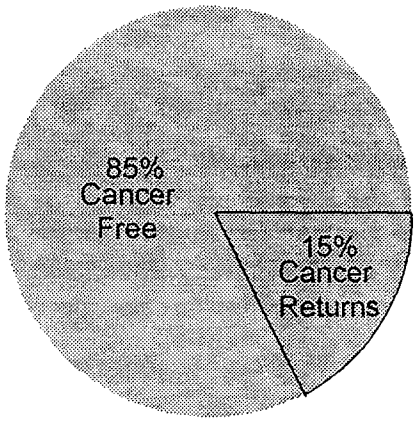
BOARD

SIDE EFFECTS

- No chemotherapy side effects

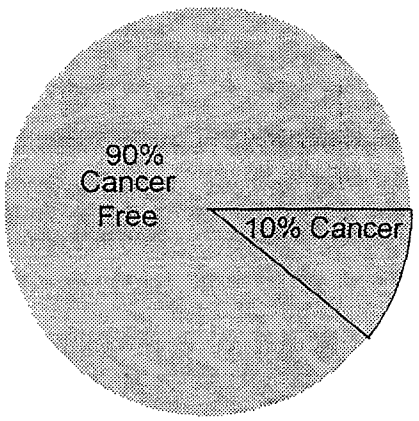
OUTCOME



What are the Side Effects of Chemotherapy?

Side effects can occur with any type of chemotherapy:

- Common
  - Loss of energy and tiredness
  - Loss of hair or thinning of hair over the entire body
  - Stomach upset (nausea) and vomiting
  - Weight gain
  - Mouth sores (tenderness)
  - Sad or unhappy moods
- Uncommon
  - Early menopause
  - Diarrhea or constipation
  - Low bloods counts
  - Infection which may require hospitalization
  - Blood clots
- Very rarely
  - Heart damage
  - Leukemia

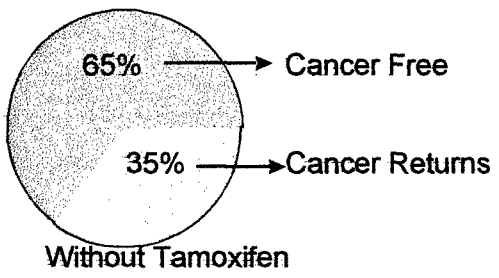


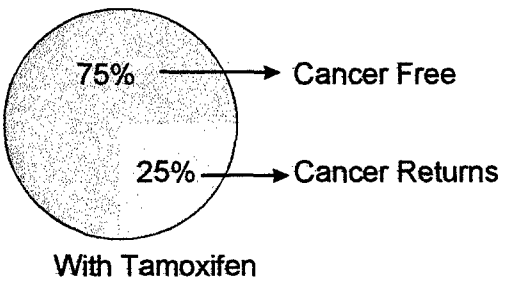
INTRODUCTION

Recently, you had surgery for cancer of the breast. The surgeon has removed the cancerous lump *(called a lumpectomy)* or the breast with the cancer *(called a mastectomy)* and some of the lymph nodes or glands under your arm. No cancer has spread to these nodes.

Even though the cancer was removed we know, from other patients like you, that there is a chance the cancer will come back. It may come back in the breast or on the chest wall where the surgery was performed (local recurrence) or it may come back in other parts of the body, such as the bone, lung, or liver (distant recurrence). Cancer that comes back in the breast or on the chest wall can be treated with further surgery. Breast cancer that comes back in other parts of the body can be treated, but usually cannot be cured.

It is important for you to know that Tamoxifen will reduce your chances of cancer coming back. Approximately 35 out of 100 women with breast cancer like you will experience the cancer coming back in the next seven years without Tamoxifen. With Tamoxifen, 25 out of 100 women will experience the cancer coming back.





Recent scientific studies have shown that chemotherapy in addition to Tamoxifen may further prevent the cancer from returning. It must be emphasized that, as far as we can tell, there is no evidence that your cancer has spread. We are talking about chemotherapy as an additional treatment to help prevent the cancer from coming back, but it may not work in all cases.

Chemotherapy drugs given by mouth (orally) and by injection (intravenously) can cause side effects. These side effects are only temporary. Balanced against them is the hope that the cancer can be prevented from coming back. We would like to discuss the benefits and side effects of two types of chemotherapy given to women with your type of cancer.

THE DECISION BOARD

To present the information in a more detailed way we will use a visual aid called the Decision Board. Using this board, we will present the following: a description of your treatment choices, the side effects of each choice and the outcome (chance of recurrence) for each choice.

Please ask questions if anything becomes unclear to you.

The Decision Board is an aid to help you participate in making a decision between receiving chemotherapy or not. Many times patients expect or prefer their doctor to make decisions for them, and often this is appropriate. However, in your situation, although there is some benefit from chemotherapy, there are also side effects. Therefore, your participation in the decision making process is very important.

Please remember that there is no right or wrong decision. We want you to make the decision that is best for you personally.

MENOPAUSE

- For women who have not reached menopause, treatments for breast cancer may cause a loss of menstrual periods.
- Younger women, those in their 20's and early 30's, are more likely to experience irregular periods or a temporary loss of periods during treatment. Their regular periods are likely to start again after finishing chemotherapy and they will continue to be fertile. Women over the age of 40 are more likely to experience a permanent loss of periods.
- Hormone replacement therapy, a treatment often given to relieve menopausal symptoms, is not recommended for women with breast cancer. At this point, we do not know enough about how hormone replacement therapy might affect the cancer.

CANCER FREE

- All tests and examinations in the coming 7 years show that you are free of cancer.
- You will continue to be followed on a regular basis.
- Even though all the examinations show you are cancer free, from time to time, you may worry about the cancer coming back.

CANCER RETURNS

- Breast cancer may come back in the next 7 years.
- Breast cancer can come back in the same breast or the chest wall (local recurrence).
- When cancer returns in the breast or on the chest wall, it is often seen as a small lump. The lump is painless but may cause worry or upset. It is usually removed by a surgeon.
- Recurrence of cancer in the breast or chest wall is rare and can often be successfully treated.
- Breast cancer can come back in other parts of the body, such as the bone, liver or lung (distant recurrence).
- Many women whose cancer comes back in other parts of the body receive further treatment: chemotherapy, hormonal therapies, radiation therapy and/or pain medication.
- Unfortunately, a patient whose breast cancer comes back in other parts of the body can be treated but usually cannot be cured.

SUMMARY

We have discussed your choices of no chemotherapy or chemotherapy, the side effects associated with each choice and the chance of cancer returning for each choice.

Chemotherapy reduces the chances of cancer returning but is associated with side effects.

We have discussed 2 types of chemotherapy, CMF and AC. Each reduces the chance of cancer returning by the same amount, but they have different side effects. CMF has less hair loss but lasts for 6 months. AC has more hair loss but lasts for 3 months.

Please keep in mind that we can predict what will happen to groups of women but we cannot predict what will happen to you as an individual.

Also remember that as you talk with others who have experienced cancer or when you see the experience of others through television or movies, your experience with side effects such as nausea or vomiting may not be the same as it was for them.

Appendix B

Computerized Version of the node-negative Decision Board

(Including example panels)

5 pages

Decision Board for Chemotherapy for Node Negative Breast Cancer - No Chemo vs CMF vs AC. Patient specific info: ER+ positive. Size: 1.1-1.9 cm. Grade: III. Tamoxifen: Y ...

	Description of Choice	Side Effects of Choice	Outcomes for Choice
No Chemo	• Regular follow-up at the Cancer Centre	• No chemotherapy side effects	75% cancer free 25% cancer returns
Chemo	• Injections or pills for 3-6 months • Regular follow-up at the Cancer Centre	• Tiredness • Hair loss • Nausea and vomiting • Weight gain	85% cancer free 15% cancer returns
CMF	• 2 weeks of treatment (one injection per week and pills each day), then 2 weeks of no treatment • Treatment lasts 6 months	• Lower chance of hair loss • Higher chance of nausea and weight gain	The chances of cancer returning are the SAME with either type of chemotherapy
AC	• One injection every 3 weeks • Treatment lasts 3 months	• Higher chance of hair loss • Very rarely leukemia or heart damage	The chances of cancer returning are the SAME with either type of chemotherapy

General Info	*Introduction*	*Decision Board*	*Menopause*	*Summary*

Decision Board for Chemotherapy for Node Negative Breast Cancer - No Chemo vs CMF vs AC For patient specific info: ER: positive Size: 2.2-9 cm Grade: III

Description of Choice | Side Effects of Choice | Outcomes for Choice

No Chemo

Chemo

CMF

AC

General Info

CMF Chemotherapy

Description

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Week 1							
Week 2							
Week 3	No Chemotherapy						
Week 4	No Chemotherapy						

x 6 =

6 months

- "Treatment cycle" lasts **4 weeks**
- 3 chemotherapy drugs:
  - Cyclophosphamide
    - pills taken by mouth
    - every day for first 2 weeks of each treatment cycle
  - Methotrexate and Fluorouracil
    - given intravenously
    - two times: Day 1 of first week and Day 1 of second week in each treatment cycle
    - takes about 20 minutes to receive intravenous drugs
- Treatment cycle is repeated 6 times for a total of **6 months**

Decision Board for Chemotherapy for Node-Negative Breast Cancer - No Chemo vs CMF vs AC For patient specific info: ER: positive Size: 2.2-9 cm Grade: III

Description of Choice | Side Effects of Choice | Outcomes for Choice

No Chemo

Chemo

CMF

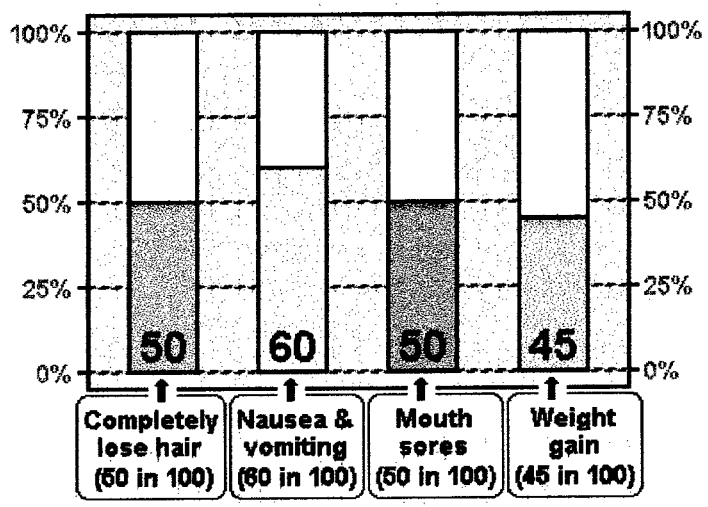
AC

General Info

CMF Chemotherapy

Side Effects

- For every 100 women, common side effects will occur in:



- With CMF, very few women will experience serious side effects such as infection (10 in 1000), leukemia (2 in 1000) or heart damage (virtually none).

Decision Board for Chemotherapy for Node-Negative Breast Cancer - No Chemo vs CMF vs AC. For patient-specific info: ER: positive Size: 2-2.9 cm Grade: III

Description of Choice | Side Effects of Choice | Outcomes for Choice

No Chemo

Chemo

CMF

AC

General Info

AC Chemotherapy
Description

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Week 1			No Chemotherapy				
Week 2			No Chemotherapy				
Week 3			No Chemotherapy				

x 4 =

3 months

- "Treatment cycle" lasts **3 weeks**
- 2 chemotherapy drugs:
  - Adriamycin and Cyclophosphamide
    - given intravenously
    - one time only: first day of each treatment cycle
    - takes about 60 minutes to receive intravenous drugs
- Treatment cycle is repeated 4 times for a total of **3 months**

Decision Board for Chemotherapy for Node-Negative Breast Cancer - No Chemo vs CMF vs AC. For patient-specific info: ER: positive Size: 2-2.9 cm Grade: III

Description of Choice | Side Effects of Choice | Outcomes for Choice

No Chemo

Chemo

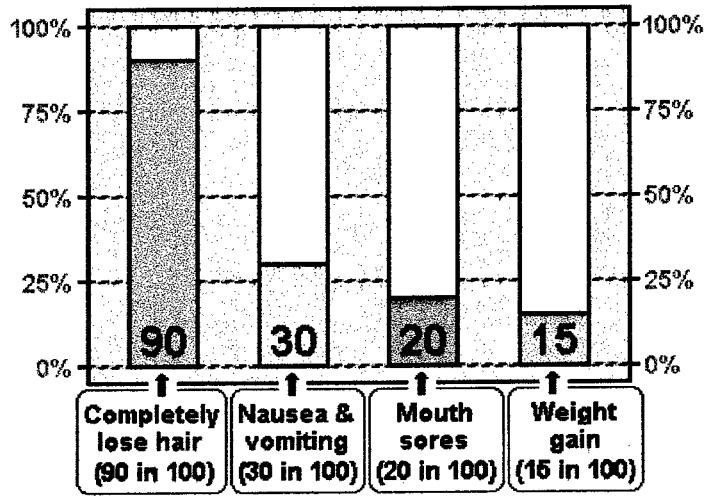
CMF

AC

General Info

AC Chemotherapy
Side Effects

- For every 100 women, common side effects will occur in:



- With AC, very few women will experience serious side effects such as infection (20 in 1000), leukemia (5 in 1000) or heart damage (2 in 1000).

Appendix C

Operations Manual for the Surgical Decision Board

(DECIDE – S)

39 pages

Development and Evaluation of Computer-based Versions of the Decision Board for Early Breast Cancer

Surgery Version

DECIDE - S

Operations Manual

October 2001

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Contact Information

Principal Investigator		Research Coordinator	
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Phone:	(905) 387-9711 ext. 64501	Phone:	(905) 387-9711 ext. 64510
Fax:	(905) 575-6308	Pager:	(905) 546-9071
Email:	tim.whelan@hrcc.on.ca	Fax:	(905) 575-6308
		Email:	shelley.chambers@hrcc.on.ca

The Study

Study Objectives

Primary Objective

- To enhance information transfer and decision making for women with early stage breast cancer.

Technical Objectives

1. To develop a computer-based version of the Decision Board for the choice between Mastectomy vs Lumpectomy plus Radiation in women with newly diagnosed carcinoma of the breast with clinical stage I or II disease who have not yet received definitive surgical treatment.
2. To compare the relative effectiveness of the computer-based version with the Standard Decision Board for women with node negative breast cancer.

The Study (con't)

Main Study Design

This study involves two separate clinical trials running in parallel and involving two different patient populations. Both of these trials involve the comparison of a Standard Decision Board and a Computerized Version of the Decision Board.

One of these trials (DECIDE – S) is the focus of this manual, and involves the decision of mastectomy vs lumpectomy plus radiation in women with newly diagnosed carcinoma of the breast with clinical stage I or II disease who have not yet received definitive surgical treatment.

The other trial (DECIDE – C) involves women with early stage, node negative breast cancer (stage I or II) who have received definitive surgical treatment and are eligible to receive adjuvant chemotherapy. (There is a separate Operations Manual for this study).

DECIDE - S

The DECIDE – S Trial is a multicentre randomized trial of 100 newly diagnosed breast cancer patients with clinical stage I or II who have not yet had definitive surgery. There will be a 1:1 randomization to the Standard Decision Board Arm or the Computerized Decision Board Arm after the patient has provided written informed consent (see Randomization Section). The allocated Decision Board will be presented to the patient and a take-home version of the allocated Decision Board will be given to the patient. The patient will then complete their questionnaires either at home or on the telephone to the Research Coordinator of the study.

The physician or nurse presenting the Decision Board will also complete a questionnaire.

The Study (con't)

Shared Decision Making

In medical practice, a decision can be arrived at by several different methods or models: the passive, the shared or the informed. The passive model explicitly assumes a passive role for the patient in the treatment decision-making process. The physician controls the encounter offering the patient selected information and encouraging the patient to consent to what the physician considers best. The role of the physician in this model is the guardian of the patient's best interest. At the other extreme is the informed model whereby the patient is supplied with sufficient information and is able to make the decision completely on her own. In this model, medical decision-making authority is vested clearly in the patient, while the physician's role is relegated to transmitting medical information and using his/her technical skills as the patient directs.

Between these two extremes is the model of shared decision making. This approach is unfortunately poorly defined in the literature and is essentially an intermediate model between the two above. We would suggest that it involve sharing of information between physician and patient and sharing in the decision-making process and the decision. As a prerequisite, it requires: at least two participants who are willing to participate in the process (this would often be the physician and the patient, but could include the nurse, other doctors, family members or friends), information sharing and active participation in the decision-making process. For the patient, this would involve listening to and understanding information presented, describing personal values in relation to the outcomes, and trying to weigh the benefits and risks to formulate a treatment preference. For the physician, it would involve clearly presenting patients with the necessary information, elucidating patient's values regarding the various outcomes, and helping them with the balancing of the benefits and the risks to make a treatment decision.

Shared decision making is not the answer for everyone.

Organizational Structure

Supportive Cancer Care Research Unit (SCCR Unit)

- The SCCR Unit is located at the Hamilton Regional Cancer Centre in Hamilton, Ontario. The SCCR Unit is responsible for the overall study execution, including case report form development, data collection, review, and analysis; development of a study database and quality assurance.

Steering Committee

- The Steering Committee is the major decision making body for the study.

Steering Committee Members

Tim Whelan

Mark Levine

Amiram Gafni

Jim Julian

Ken Sanders

Susan Reid

Mary Ann O'Brien

Shelley Chambers

Adjudication Committee

Adjudication Committee

- The adjudication committee has the primary responsibility of determining the eligibility of patients for this trial. If required, each member of the adjudication committee will review the eligibility criteria of a patient and determine if she actually met the criteria.

Members of the Adjudication Committee

- Still to be determined.

Recruitment / Randomization

Patient Screening

- All patients who meet the inclusion criteria for the trial will be screened for eligibility and recorded on the Eligibility Assessment Case Report Form (CRF).

Inclusion Criteria

*Both answers must be **YES** to be recorded on the Eligibility Assessment CRF.*

The patient:

- Is a woman who has newly diagnosed carcinoma of the breast diagnosed by either cytology (needle aspirate) or pathological examination (core or open biopsy), or, if no biopsy is available, a strong clinical suspicion of breast cancer.
- Clinical Stage I or II breast cancer defined as:

  Stage I – Tumour is 2 cm or less (maximum dimension) and localized to the breast with no involvement of regional nodes,

  <u>or</u>

  Stage II – Tumour is more than 2 cm, but not larger than 5 cm in its greatest dimension, or has metastasized to the axillary nodes which are not fixed.

Patient Eligibility

Exclusion Criteria

*All answers must be **NO** for the patient to be eligible.*

The patient:

- Has Clinical Stage 0 disease (DCIS, non invasive breast cancer)
- Has Clinical Stage III disease (tumour > 5 cm or evidence of inflammatory or advanced disease)
- Has Clinical Stage IV disease
- Has breast of insufficient size to perform a lumpectomy (defined as the surgical excision of the tumour with a rim or normal tissue)
- Has a diffusely abnormal mammogram that would preclude a lumpectomy
- Has serious non-malignant disease (e.g., cardiovascular disease, respiratory, renal, etc. that would preclude definitive surgical treatment)
- Is not a candidate for breast irradiation (e.g., previous breast irradiation, pregnant, etc.)
- Has a clinical suspicion of bilateral breast cancer
- Has had previous surgery for breast cancer
- Is unable to speak or read English fluently.
- Is mentally incompetent including any psychiatric or addictive disorder that would preclude shared decision- making.

Informed Consent

Patient Information and Consent

- It is the responsibility of the Surgeon to ensure that the patient has been given both written and verbal information regarding the objectives and procedures of the trial. The patient must be informed about their right to withdraw from the trial at any time. If the patient should refuse to participate in the trial, she should be ensured that she will receive optimal and appropriate care and that her decision will not prejudice any further treatment she may receive.
- An explanation of whom to contact with questions or concerns will be given.
- It should be pointed out that any personal identifying information will not be published and will be kept strictly confidential.

Obtaining Informed Consent

- After the Surgeon has informed the patient about the trial, she will be asked if she is willing to participate in the trial.
- The patient must sign and date the Consent Form. A witness (other than the Investigator, most likely the receptionist) must also sign and date the form.

Filing the Consent Form

- A copy of the signed and dated Consent Form must be kept in the patient's chart.

Consent Form

- A copy of the Consent Form is on the next page.

Consent Form

Decision Board for Early Breast Cancer

CONSENT FORM FOR PARTICIPANTS

Why is this study being done?

Research shows that patients have a desire for better communication with their doctors. Women with breast cancer have shown a need for more information about their disease and desire to be more involved in making decisions about their care. The aim of this study is to improve the transfer of information between the doctor and the patient and to improve decision making for women with breast cancer.

What is the study about?

A decision aid, called the *Decision Board,* has been developed to provide information to patients about treatment choices in breast cancer. It also helps patients make decisions about their treatment choices. The information provided on the Decision Board is based on high quality research results. With more treatments becoming available and a desire for detailed information, there is a need to present the various choices to women in different ways. Presently, the standard Decision Board presents written and pictorial information about treatment choices. A computer version of the Decision Board allows information to be personalized for each woman's own needs.

This study will test a computer version of the Decision Board. The computer version will be compared to the standard Decision Board. It will try to answer important questions. How well do patients understand the information? How satisfied are they with the information? How satisfied are they with the way the Decision Board helps them make a decision?

We would like to invite you to take part in this research. At the moment, we do not know if there is a difference between the standard Decision Board or the computer version. The only way to know whether there is a difference between the two presentations is to compare similar groups of patients at the same time. The only fair way to decide which presentation the patient gets is to decide this by chance, a method called randomization (like tossing a coin or picking a

Participant's initials: _____ Witness' initials: _____ Date: _____

number from a hat). This will be done by a computer to ensure that there is an equal chance of each patient receiving a particular presentation. If you agree to take part in this study, the research assistant will find out which presentation you will get by calling the research office. The benefit to taking part in this study is that women will be assured of receiving all information about their breast cancer, outlook and choices for treatment. There is no specific risk associated with participation in the study. Your choice of treatment will take place regardless of which Decision Board version is presented.

What is your involvement in the study?

If you agree to take part in this study, the doctor will explain your treatment choices at your appointment using the standard Decision Board or the computer version. A few days following your visit, you will be contacted by telephone, or at your next scheduled appointment, by the research assistant. You will be asked about your breast cancer and the different treatments available. You will be asked about the benefits and risks or side effects associated with the different treatment choices. You will also be asked about your satisfaction with the information presented and the decision-making process. Some basic information about your personal characteristics will also be collected. This interview will take about 15 minutes. There will not be any more involvement on your part following this interview. There will be no cost to you for participation in the study. You will receive a copy of the consent form.

Participant's agreement to take part in this study:

I have read the information about the Development and Evaluation of Computer-based Versions of the Decision Board for Early Breast Cancer Study.

I agree to take part in this study with the understanding that information will be collected and used for research purposes only and will be treated as confidential. No participant names will be identified in any report of this study. I have been informed about the purpose of the study. I know that I am under no obligation to participate and may withdraw at any time. My present or future medical treatment will not be affected in any way if I choose not to take part in this study.

Representatives from the U.S. Army Medical Research and Materiel Command may inspect the records of the research in their duty to protect human subjects in research.

You should also understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the Principal Investigator before you enrol in this study.

Participant's initials: _____ Witness' initials: _____ Date: _____

If you have any questions about the study, please contact the Principal Investigator, Dr. Tim Whelan at (905) 387-9495, ext. 64501 or the Research Coordinator at (905) 387-9495, ext. 64510.

The name of an individual not directly involved in this study who can provide answers to questions about my rights as a research subject is Leslee Schynal who is located at the Hamilton Health Sciences Corporation, Henderson Hospital, 711 Concession Street, Hamilton, Ontario, telephone number (905) 389-4411, Ext. 42136.

Participant's name: _____ (Please use block letters.)

Participant's address: _____

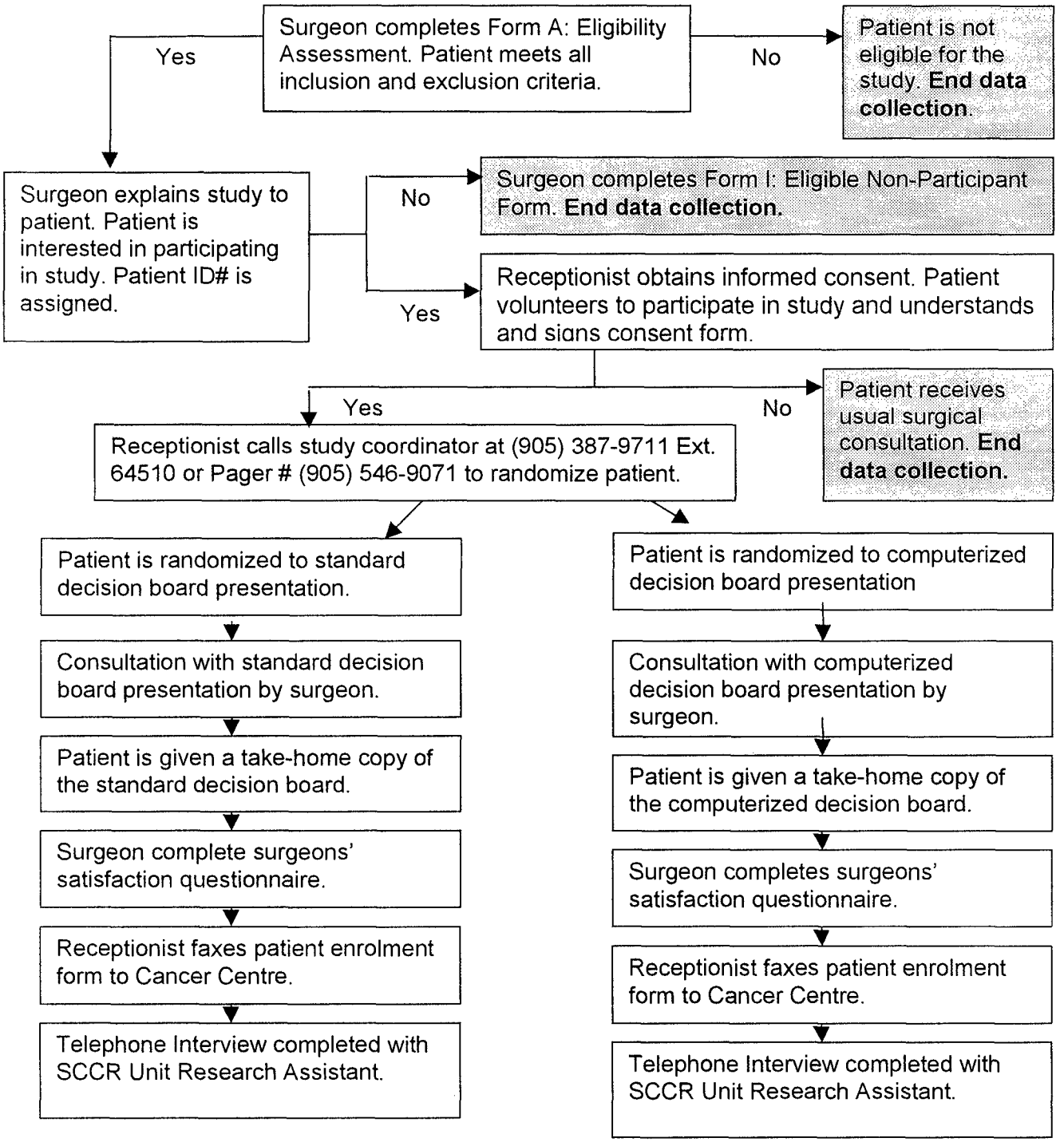
Participant's signature: _____ Date: ___/_____/____
dd mmm yy

Witness' name: _____ (Please use block letters.)

Witness' signature: _____ Date: ___/_____/_____
dd mmm yy

END OF FORM

Schemata


Surgeon completes Form A: Eligibility Assessment. Patient meets all inclusion and exclusion criteria.
Yes
No
Patient is not eligible for the study. **End data collection.**
Surgeon explains study to patient. Patient is interested in participating in study. Patient ID# is assigned.
No
Surgeon completes Form I: Eligible Non-Participant Form. **End data collection.**
Yes
Receptionist obtains informed consent. Patient volunteers to participate in study and understands and signs consent form.
Yes
No
Patient receives usual surgical consultation. **End data collection.**
Receptionist calls study coordinator at (905) 387-9711 Ext. 64510 or Pager # (905) 546-9071 to randomize patient.
Patient is randomized to standard decision board presentation.
Consultation with standard decision board presentation by surgeon.
Patient is given a take-home copy of the standard decision board.
Surgeon complete surgeons' satisfaction questionnaire.
Receptionist faxes patient enrolment form to Cancer Centre.
Telephone Interview completed with SCCR Unit Research Assistant.
Patient is randomized to computerized decision board presentation
Consultation with computerized decision board presentation by surgeon.
Patient is given a take-home copy of the computerized decision board.
Surgeon completes surgeons' satisfaction questionnaire.
Receptionist faxes patient enrolment form to Cancer Centre.
Telephone Interview completed with SCCR Unit Research Assistant.

Ineligible / Non Consenting Patients

Ineligible Patients

- **Patients who do not meet the Inclusion Criteria**

Patients who have a "NO" answer to at least on Inclusion Criteria are not eligible for the trial and should not be approached for informed consent to the trial. An Eligibility Assessment CRF should not be completed for these patients.

- **Patients who meet at least one Exclusion Criteria**

Patients who have a "YES" answer to at least one Exclusion Criteria are not eligible for the trial. An Eligibility Assessment CRF must be completed for these patients, however, these patients should not be approached for informed consent to the trial.

Non-consenting patients

- If a patient is eligible for the trial but does not consent.
  - Complete the Eligibility Assessment CRF.
  - Indicate the reason that the patient did not consent to the trial.
  - Sign and date the Eligibility Assessment CRF.

Patient Randomization

When to Randomize a patient

- Once a patient is determined as eligible to participate in the trial (i.e., met all of the Inclusion Criteria and did not meet any Exclusion Criteria) and has signed and dated the Consent Form, the patient is eligible for randomization.
- The patient must be randomized prior to any discussion regarding surgical treatment options.

Prior to Randomization

- You will need to have the following information available prior to calling to randomize the patient:
  - The patient chart number
  - The patient initials
  - Name of the Surgeon treating the patient

Who to call for Randomization

The Supportive Cancer Care Research Unit will be responsible for the central randomization of all patients into the trial. Please page:

905-546-9071

key in the telephone number where you can be reached.

If your page is not answered within a few minutes, please call:

905-387-9495 ext. 64510 or 64501

and the SCCR Unit Staff will assist you.

Patient Randomization (con't)

Process of Randomization

Once you have reached an authorized SCCR Unit staff member, you are ready to randomize the patient.

- You will be asked to supply:
  - The patient initials
  - The patient's chart number
  - The patient's Surgeon
  - The date of randomization (today's date)
- You will be given (and must record on the Eligibility Assessment CRF):
  - The Patient Study ID Number (PID)
  - Decision Aid Arm to which the patient will be allocated, either:
    - Standard Decision Board, or
    - Computerized Decision Board

Study ID Number

The Patient Study ID Number is a 4-digit number which incorporates a one-digit Centre ID number (i.e., each Surgeon's office would be assigned a one digit Centre number) and a three-digit sequential patient number and is in the form of:

____ ____ ____ ____

Centre Patient Number

The Patient Study ID Number is to be recorded at the top of every CRF page and on each page of any source document.

Randomization Log

The Randomization Log sheet is found in this binder and is comprised of multiple pages to record all patients randomized to the study. The patient name, study ID and date of randomization are to be recorded in this Log. This Log provides a means for you to connect the Study ID number with the patient name.

Decision Aid Board of the Trial

Standard Decision Board Arm

- The Standard Decision Board is a visual aid with both written and graphical information that is approximately two feet wide and one and a half feet tall. It has information windows that are initially closed. The windows are systematically opened to present the information on the two treatment options, related side effects, and the results of the treatment choice for the breast and for survival. When all of the windows are eventually opened it allows the patient to compare the treatment options. The instrument also consists of additional information that is presented to patients on separate information cards.

Computerized Decision Board Arm

- The Computerized Decision Board is similar to the Standard Decision Board except for the fact that the decision board is presented using a laptop computer. Upon opening the decision board program on the laptop, there will be "windows" that have the appearance of being closed. These windows will be systematically opened to present the two treatment options, related side effects, and the results of the treatment choice for the breast and for survival. When the windows are closed, highlighted bullet points emphasizing the main points in each window will remain on the screen giving the appearance of open windows, similar to the Standard Decision Board.

Sample Size

- There will be 100 patients randomized to the trial, with 50% randomized to the Standard Decision Board Arm and 50% to the Computerized Decision Board Arm.

Administration of the Standard Decision Board

Before Administering the Standard Decision Board

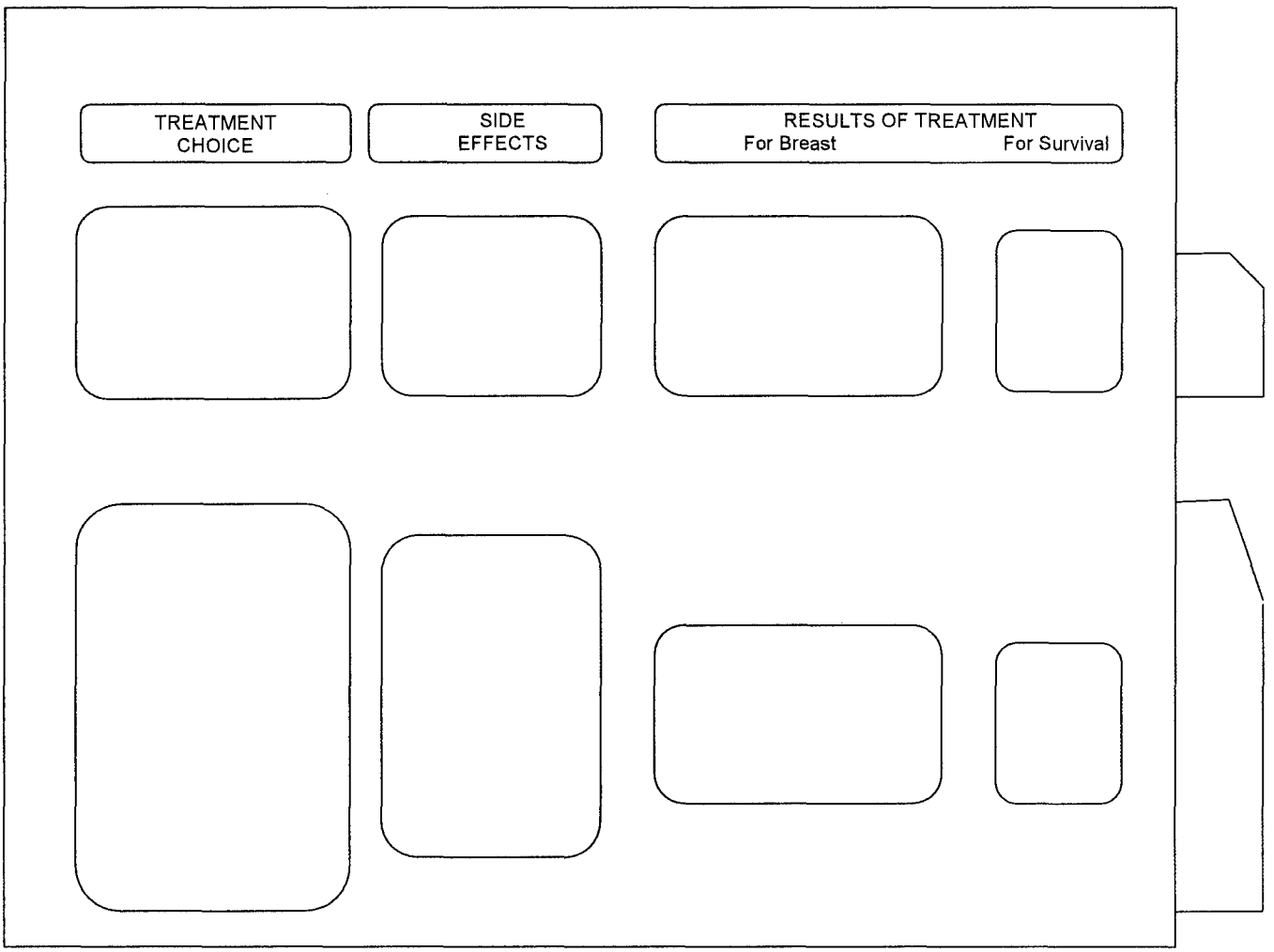
Familiarize yourself with the Decision Board

- See the diagram showing the Decision Board on the next page.

All Windows Closed

- Ensure that all information windows on the Decision Board are closed before starting the presentation of the Decision Board.

Standard Decision Board Layout



Before Administering the Standard Decision Board

Prepare the appropriate Take-home version of the Decision Board

There are two different take-home versions of the Decision Board, one mentions an Axillary Node Dissection and the other one does not. Ensure you have the proper version of the take-home that matches the decision board you have shown the patient.

Laminated information cards

- The laminated information cards are stored at the back of the Decision Board in a plastic pouch. Pull all of the cards out of the pouch and have them ready and in a convenient location to go over with the patient.
- The Cards that are available are:

  Introduction

  Decision Board

  Summary Chemotherapy and Hormonal Treatments for Breast Cancer Card (optional)

  Breast Reconstruction Card (optional)

  Sentinel Node Biopsy Card (optional)

Administration of the Standard Decision Board

Step 1. Introduction card	• Show the patient the card entitled "Introduction" • Read the card with the patient
Step 2. Decision Board card	• Show the patient the card entitled "Decision Board" • Read the card with the patient • Emphasize that there is no right or wrong choice
Step 3. Open the first window, first row *Mastectomy Treatment Choice*	• Pull the upper Slider Tab 1 to the right • Read the information behind the first window of the first row beside *Mastectomy* and underneath *Treatment Choices* • Discuss the information with the patient • If the patient desires information on treatments in addition to surgery available to treatment breast cancer, show her optional card entitled "Chemotherapy and Hormonal Therapy". • Ask if the patient has any questions.
Step 4. Open the second window, first row *Side-effects – Mastectomy*	• Pull upper Slider Tab to the right again • Read the information behind the second window beside *Mastectomy* under *Side Effects*. • Read the information with the patient. • If the patient desires information on reconstruction, show her the optional card entitled "Breast Reconstruction". • Read the information behind the second window beside *Mastectomy* under *Side Effects* • Ask if the patient has any questions

Administration of Standard Decision Board (con't)

Step 5. Open last window, first row *Results of Choice for Survival – Mastectomy*	• Pull the upper Slider Tab to the right again. • Read the information behind the third window beside *Mastectomy* under *Results of Choice for Survival.* • Emphasize that the chance of surviving breast cancer is the same with either Mastectomy or Lumpectomy plus Radiation.
Step 6. Open first window, lower row *Treatment Choice – Lumpectomy plus Radiation*	• Pull the lower Slider Tab to the right. • Read the information behind the first window beside *Lumpectomy plus Radiation* under *Treatment Choice.* • Ask if the patient has any questions.
Step 7. Open second window, lower row *Side Effects – Lumpectomy plus Radiation*	• Pull the lower Slider Tab to the right again • Read the information behind the second window beside *Lumpectomy plus Radiation* under *Side Effects.* • Ask if the patient has any questions.
Step 8. Open third window, lower row *Results of Choice for the Breast – Lumpectomy plus Radiation*	• Pull the lower Slider Tab to the right again. • Read the information behind the third window beside *Lumpectomy plus Radiation* under *Results of Choice for the Breast.* • Ask if the patient has any questions.
Step 9. Open last window, lower row	• Pull the lower slider tab to the right again. • Read the information behind the last window beside *Lumpectomy plus Radiation* under *Results of Choice for Survival.* • Emphasize that the chance of surviving breast cancer is the same with either Lumpectomy plus Radiation or Mastectomy.

Step 10. Hand the patient the appropriate Take-Home version of the Decision Board	• After the patient has been presented with the Decision Board, she should be given the Take-home version of the Decision Board that matches the information presented to her by the Surgeon and also includes the information discussed in the optional cards (i.e., chemotherapy and hormonal therapy; breast reconstruction; sentinel node biopsy).
Step 11. Remind patient that a Research Assistant will get in touch with her.	• Remind the patient that a research assistant will be calling her to talk about the decision board experience.

Take-home Version of the Standard Decision Board

Take-home version of the Standard Decision Board	The take-home version of the decision board is an exact replica of the decision board the patient was administered and also includes the information discussed in the optional cards (i.e., introduction, decision board, cancer free / cancer returns, menopause and summary). It is very important that the patient receives the correct take-home version of the Decision Board, otherwise they may be very confused if the information they were told by the doctor does not match the information they were given to read.
Who receives the Take-home version of the Standard Decision Board	All consenting patients who are randomized to the Standard Decision Board Arm of the Trial will receive a take-home version matching the information they were presented regarding their treatment choice.
Appropriate Take-home version of the Standard Decision board	There are two different take-home versions of the Decision Board. One version mentions an axillary node dissection while the other does not. Ensure that the patient receives the take-home version that matches the information presented to her.

Administration of the Computerized Decision Board

Before administering the Computerized Decision Board

Turn on the Laptop Computer prior to seeing the patient as it takes a while for the computer to warm up.

- The laptop computer takes a while to warm up, therefore, it is a good idea to have it turned on and the Decision Board Program loaded and already at the first screen before the patient is seen.

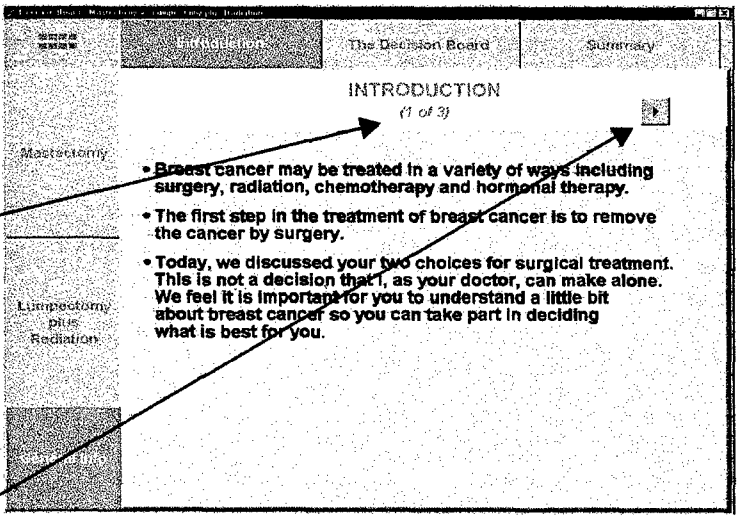
Prepare the appropriate Take-home version of the Computerized Decision Board

- There are two different take-home versions of the Computerized Decision Board, one for patients who will be receiving an axillary node dissection and one for those patients who will not be having an axillary node dissection.

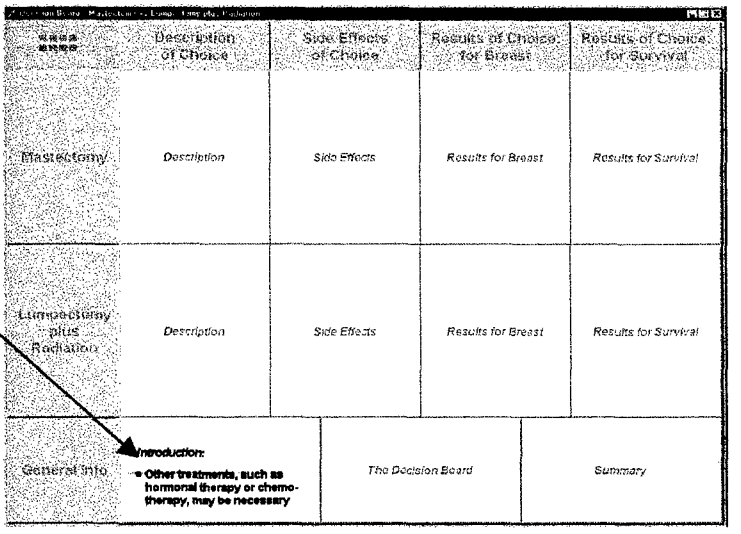
Navigating Through the Program
Comparison panels
Main navigational buttons

This panel has 3 pages. Clicking anywhere inside the panel while on Page 1 or Page 2 will bring up the next page. Clicking anywhere on the last page will close the panel and display a summary. All pages of a panel need to be visited before the panel can be closed back to the main screen.

Alternatively, clicking on the arrow in the upper right of the Introduction panel will bring up the next page.



Upon closing after visiting each page of a panel, a short summary appears.

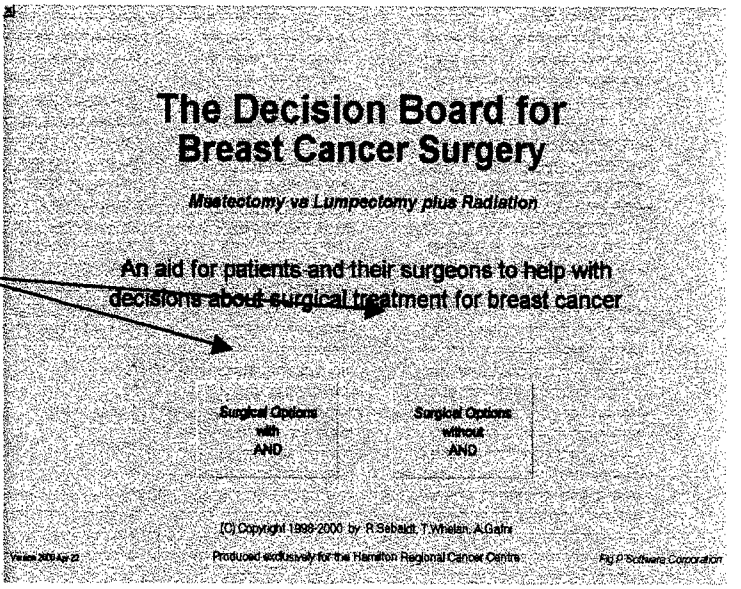


Steps of Administration for Computerized Decision Board

Step 1: Using the keyboard, copy the patient ID number from the patient's enrolment package onto the opening screen.

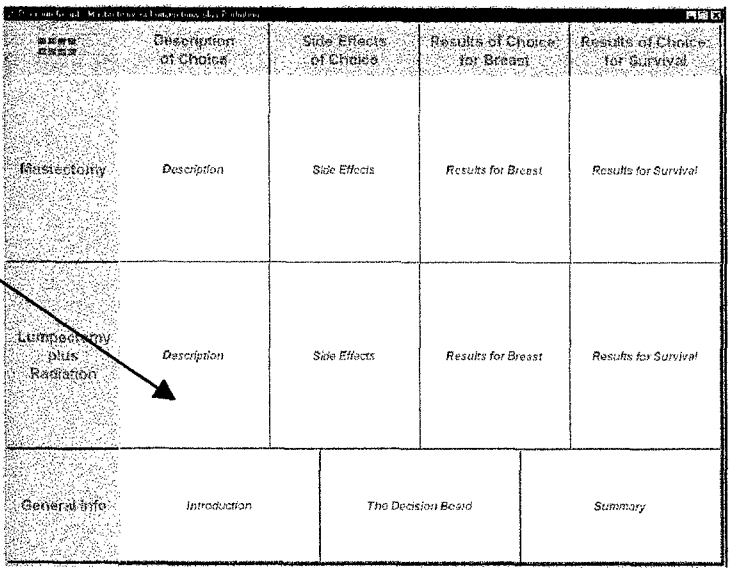
Step 2: Using the cursor, click on the presentation appropriate for this patient to enter the main decision board.

Select either the presentation with or without Axillary Node Dissection.



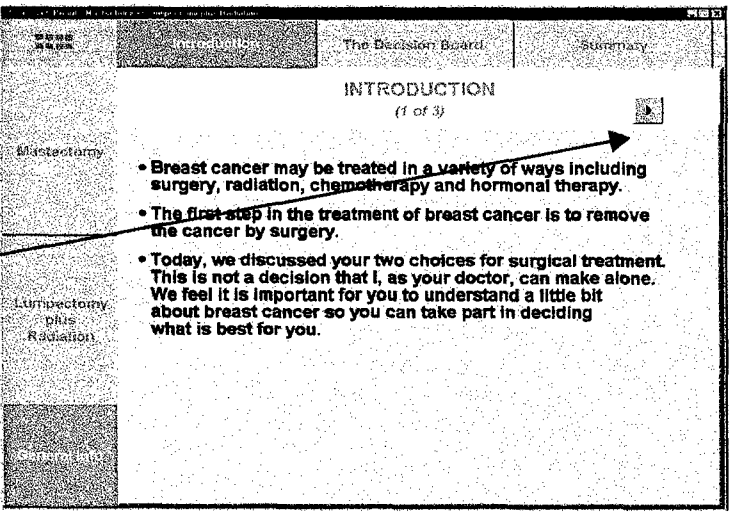
Step 3: Open the Introductory Panel

Using the mouse, move the cursor on the box labelled "Introduction" and click once.



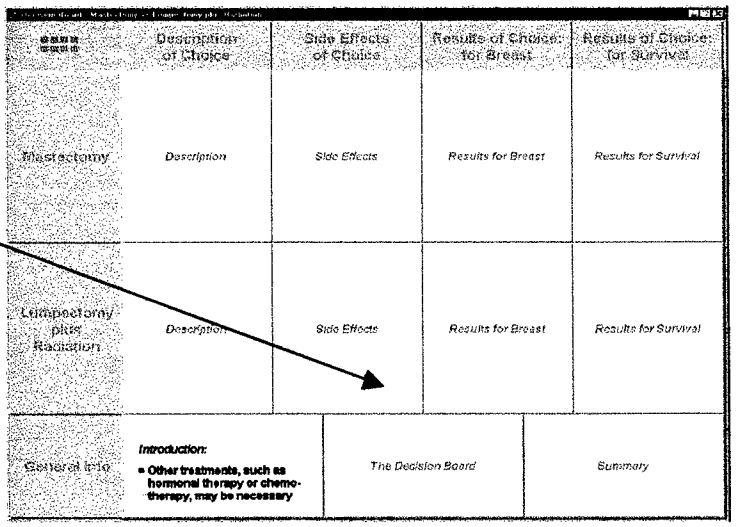
Step 4: Read the 3 pages of information contained in the "Introduction" with the patient.

Review each of the three pages of this panel with the patient by either clicking anywhere inside the Introduction panel or by clicking on the arrow in the upper right of the panel to move to the next page.

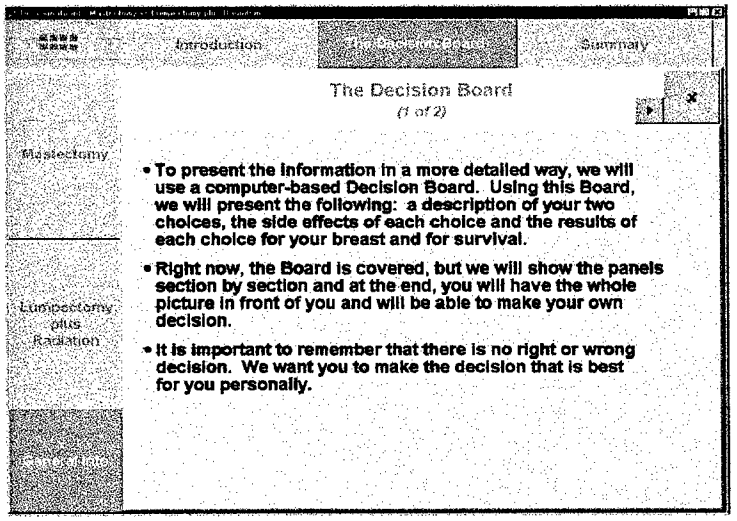


Step 5: Open the panel labelled "The Decision Board".

Using the mouse, move the cursor on the box labelled "The Decision Board" and click once.

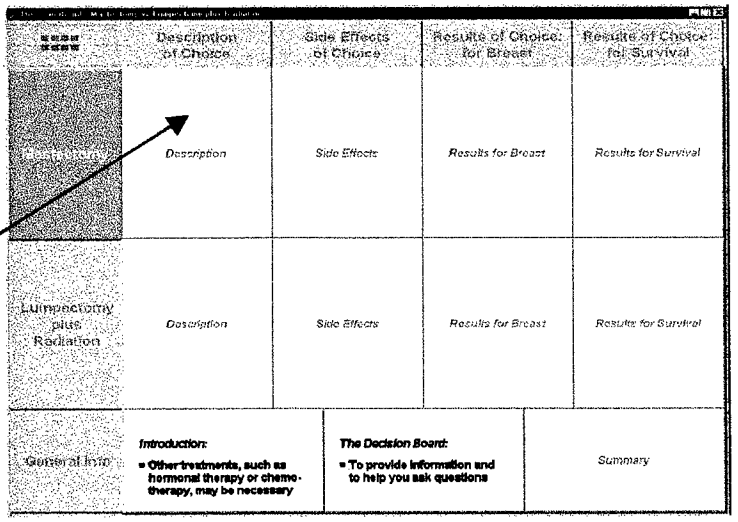


Step 6: Read the 2 pages of information contained in "The Decision Board" with the patient.

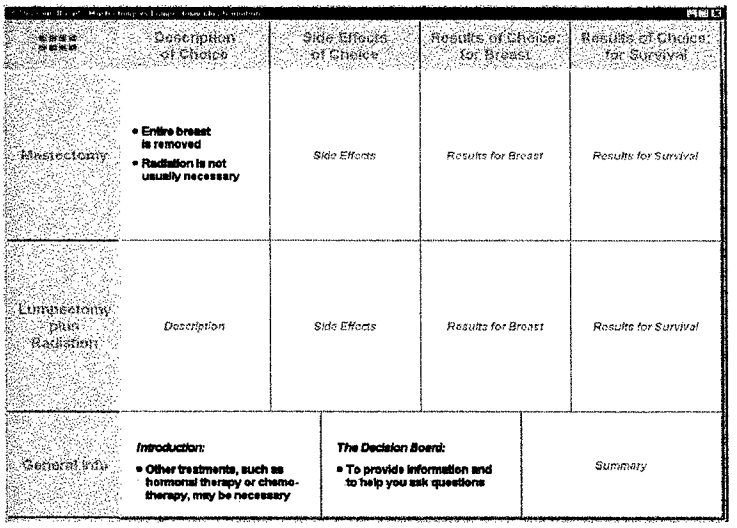


Step 7: Open the information contained in the panel under Mastectomy and Description of Choice with the patient.

Using the mouse, move the cursor on the box labelled "Description" under Description of Choice beside Mastectomy and click once.

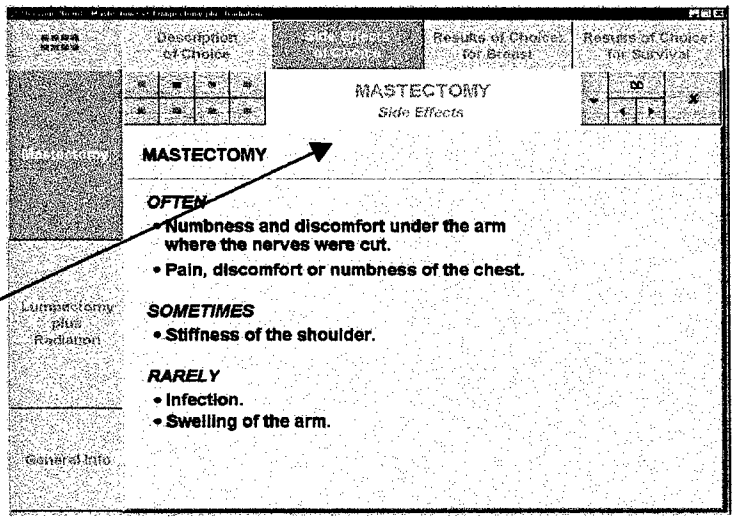


Step 8: Review the information contained in the panel under Mastectomy and Description of Choice with the patient.

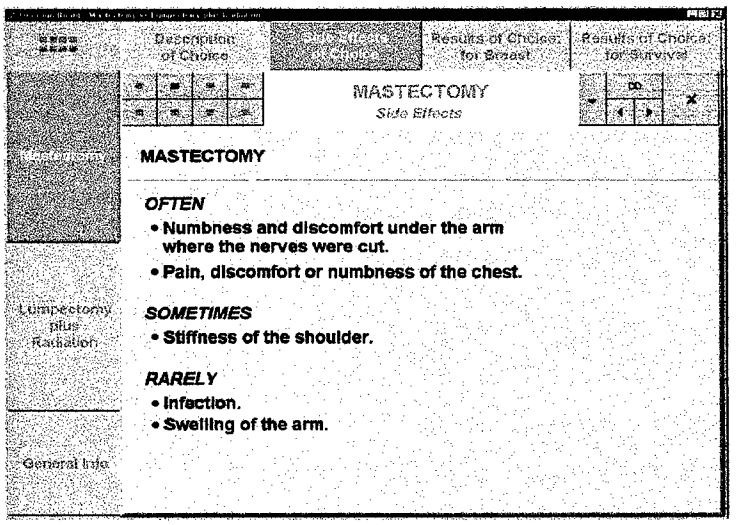


Step 9: Open the information contained in the panel under Mastectomy and Side Effects of Choice.

Using the mouse, move the cursor on the box labelled "Side Effects" under Side Effects of Choice beside Mastectomy and click once.

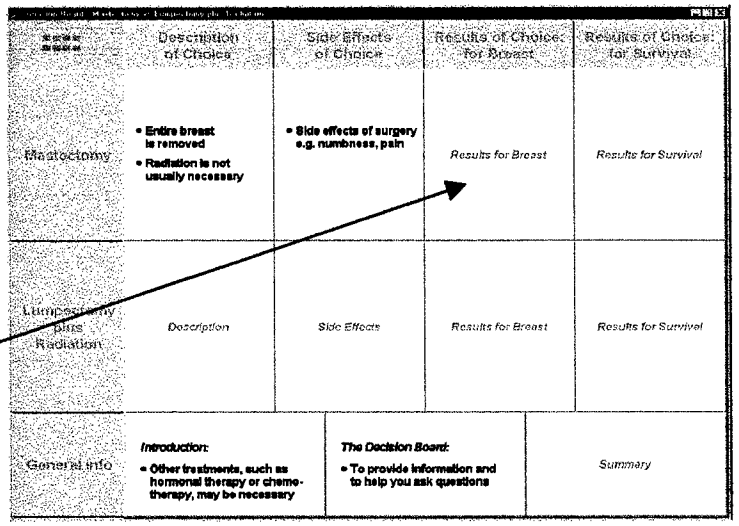


Step 10: Review the information contained in the panel under Mastectomy and Side Effects of Choice with the patient.



Step 11: Open the information contained in the panel under Mastectomy and Results of Choice for the Breast.

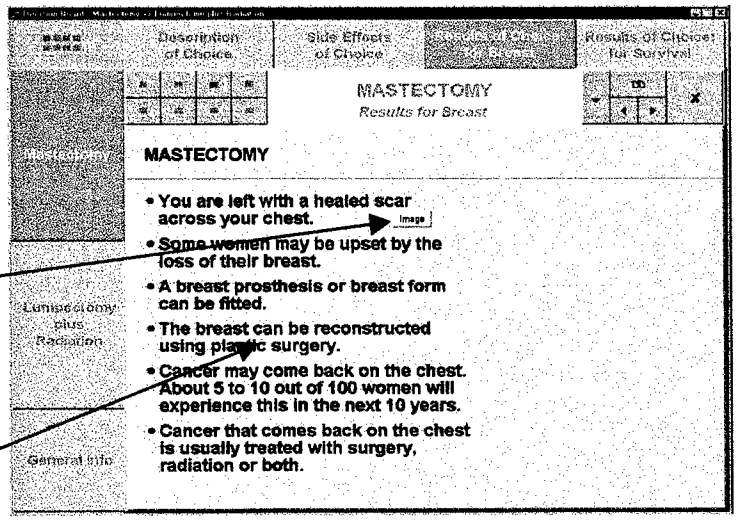
Using the mouse, move the cursor on the box labelled "Results for Breast" under Results of Choice for the Breast beside Mastectomy and click once.



Step 12: Review the information in the panel under Mastectomy and Results of Choice for Breast with the patient.

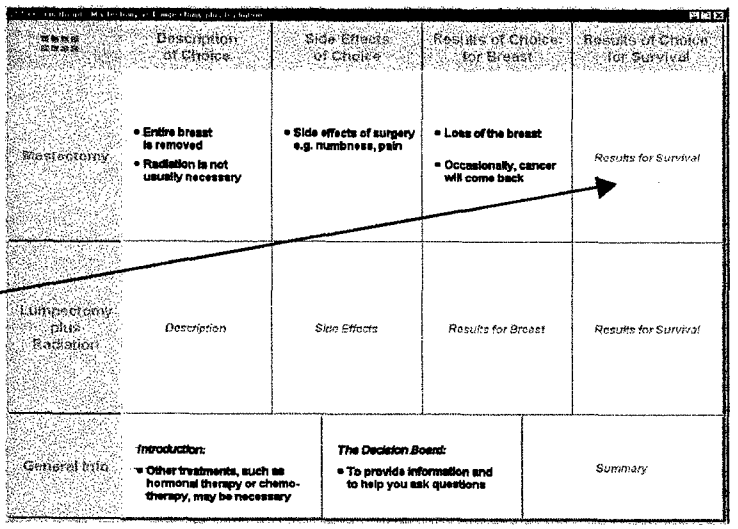
Click on the box labelled "Image" to show a drawing of what the chest may look like following a mastectomy.

Place the cursor on the words "plastic surgery" to open a panel which briefly describes surgical techniques used to reconstruct the breast.



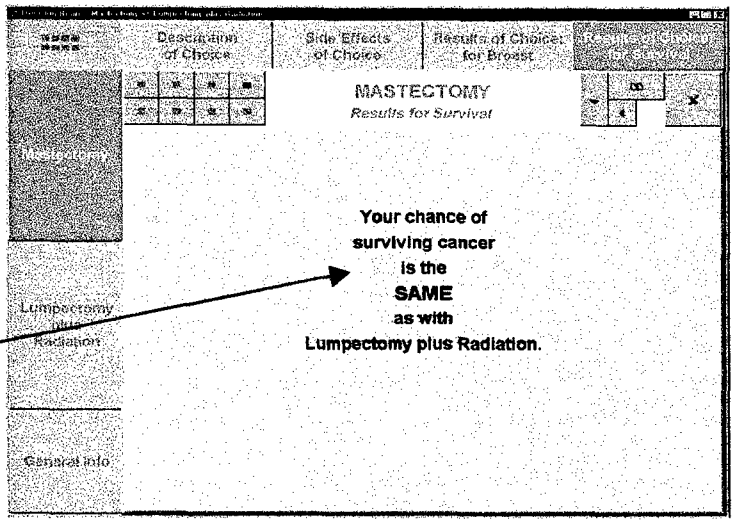
Step 13: Open the information contained in the panel under Mastectomy and Results of Choice for Survival.

Using the mouse, move the cursor on the box labelled "Results for Survival" under Results of Choice for Survival beside Mastectomy and click once.



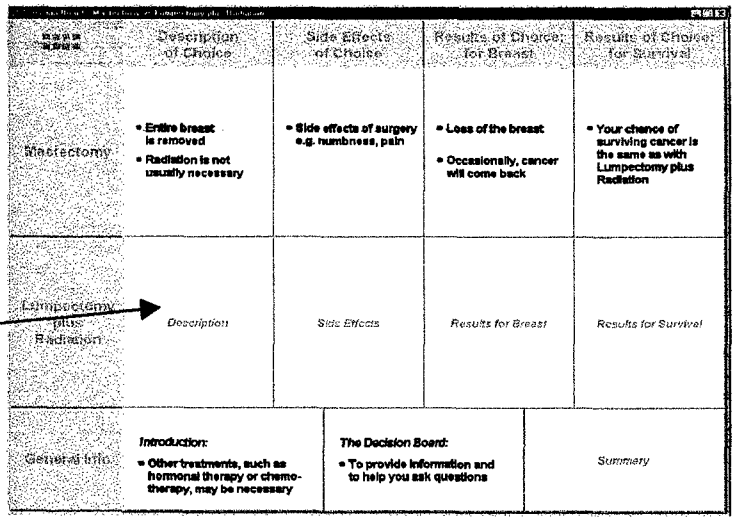
Step 14: Review the information contained in the panel under Mastectomy and Results of Choice for Survival with the patient.

Emphasize that neither procedure is better than the other in terms of surviving breast cancer



Step 15: Open the information contained in the panel under Lumpectomy plus Radiation and Description of Choice with the patient.

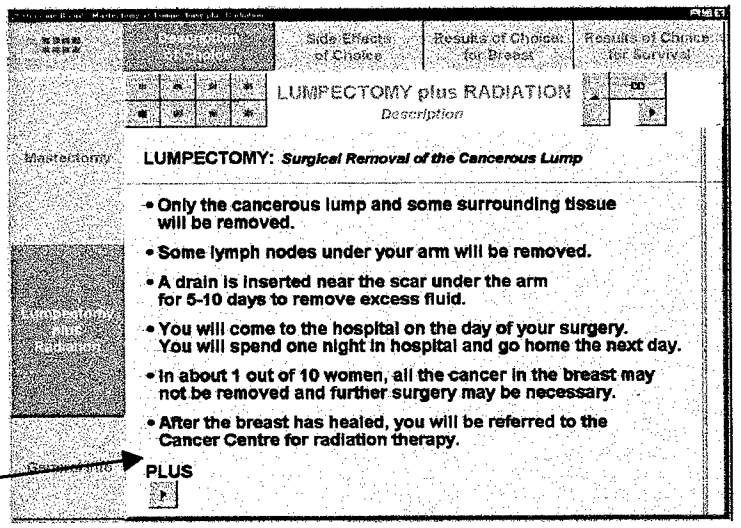
Using the mouse, move the cursor on the box labelled "Description" under Description of Choice beside Lumpectomy Plus Radiation and click once.



Step 16a: Review the information contained in the panel under Lumpectomy plus Radiation and Description of Choice in the panel labelled "Description" with the patient.

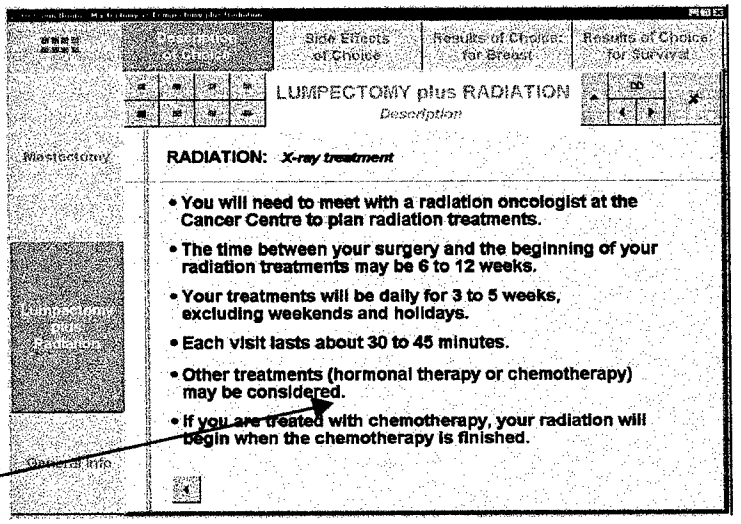
This panel has two parts: the first describes the lumpectomy procedure, the second describes the radiation treatment.

Click anywhere on the open description of lumpectomy or the arrow to move to the second section describing radiation treatment.



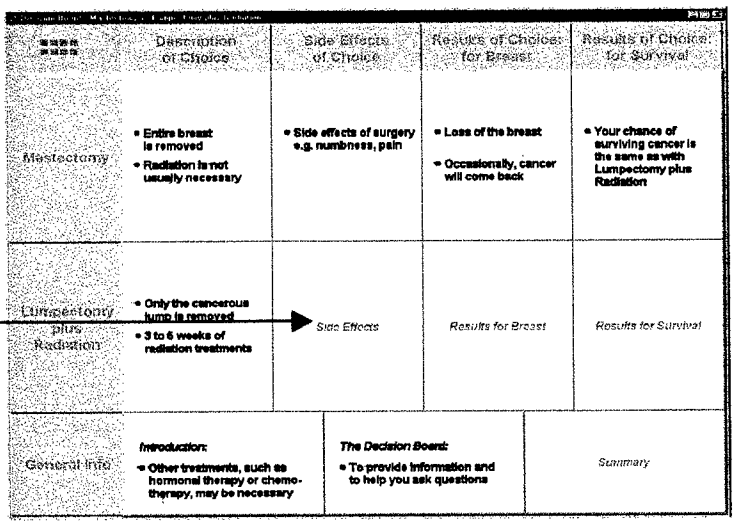
Step 16b: Move to the second part of the panel describing radiation therapy in the panel under Lumpectomy plus Radiation and Description of Choice in the panel labelled " Description."

To show the patient additional information on hormonal therapy of chemotherapy, using the mouse, move the cursor over the words until a hand appears and click.



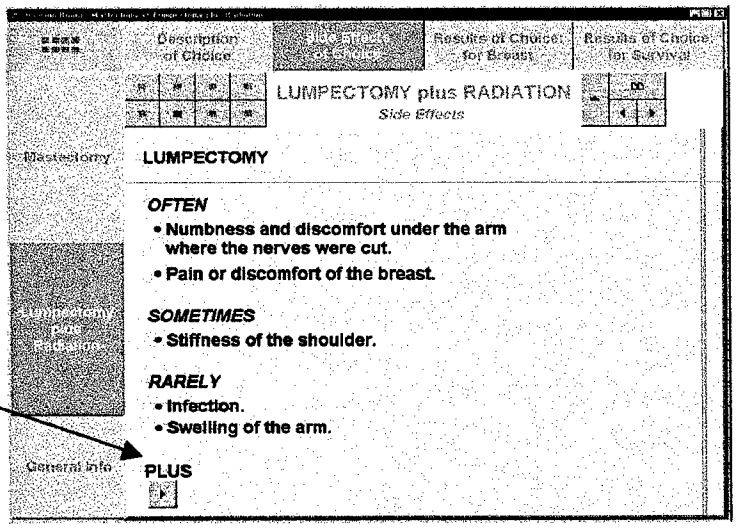
Step 17: Open the information contained in the panel under Lumpectomy plus Radiation and Side Effects of Choice.

Using the mouse, move the cursor on the box labelled "Side Effects" under Side Effects of Choice beside Mastectomy and click once.

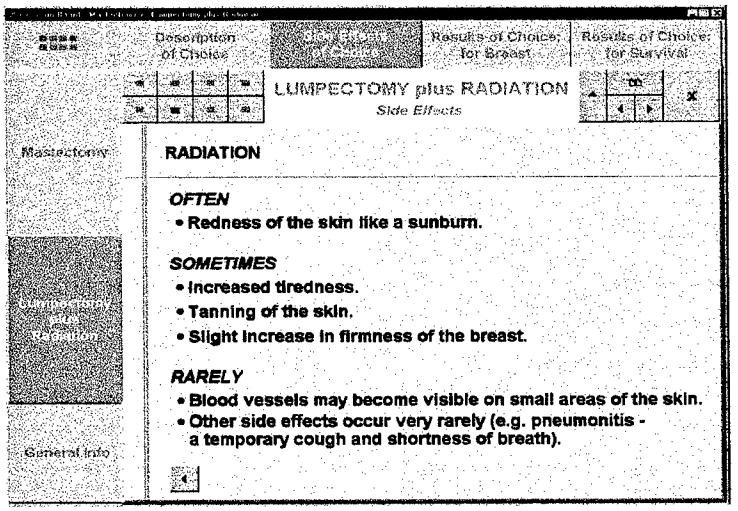


Step 18a: Review the information contained in the panel under Lumpectomy plus Radiation and Side Effects of Choice with the patient.

Click anywhere on the open side effects of lumpectomy panel or on the arrow to move to the second section describing radiation treatment.

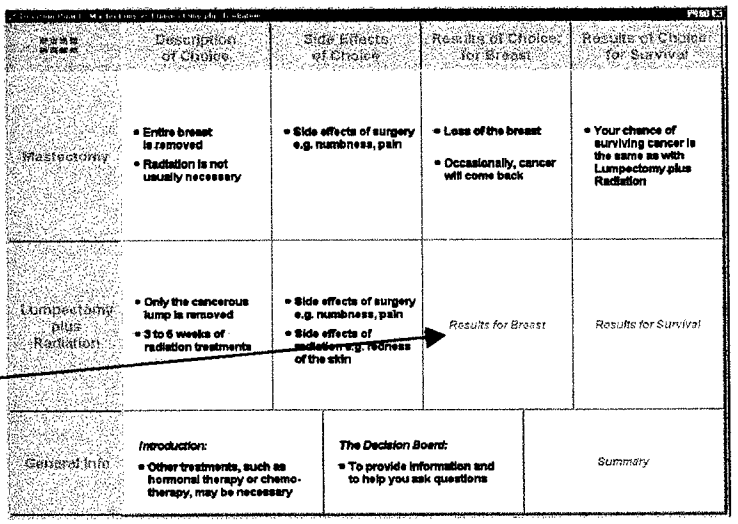


Step 18b: Move to the second part of the panel describing radiation therapy in the panel under Lumpectomy plus Radiation and Description of Choice. Review the information with the patient.



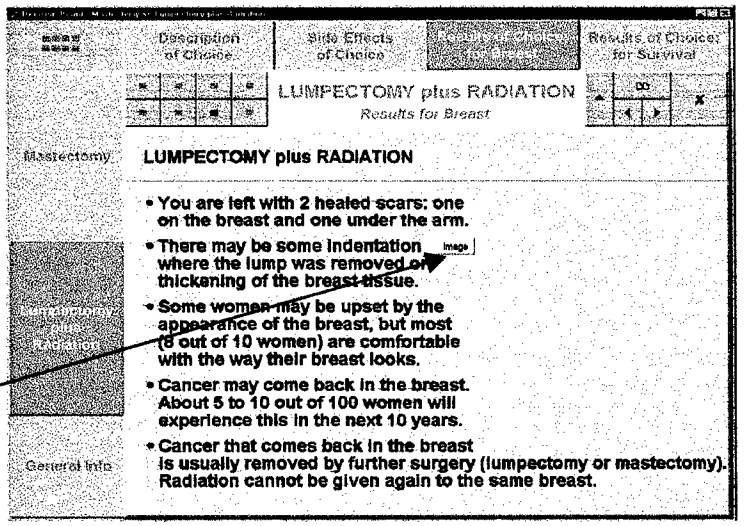
Step 19: Open the information contained in the panel under Lumpectomy plus Radiation and Results of Choice for the Breast.

Using the mouse, move the cursor on the box labelled "Results for Breast" under Results of Choice for Breast beside Lumpectomy plus Radiation and click once.



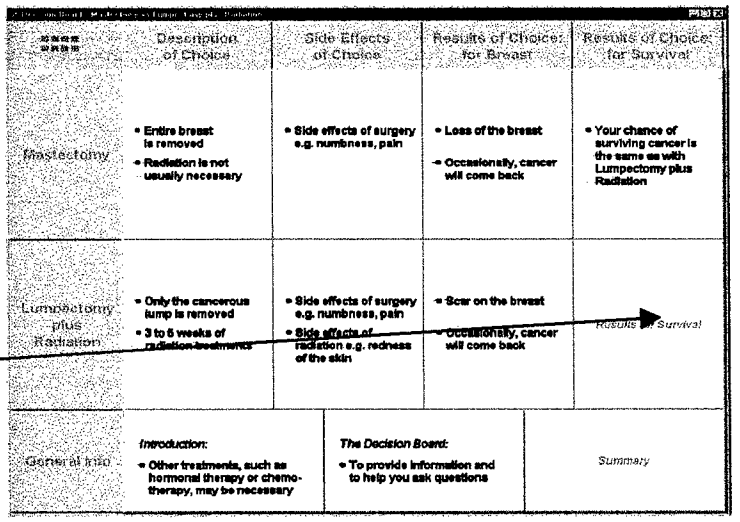
Step 20: Review the information contained in the panel under Lumpectomy plus Radiation and Results of Choice for the Breast with the patient.

Click on the box labelled "Image" to show a drawing of what the breast may look like following a lumpectomy.



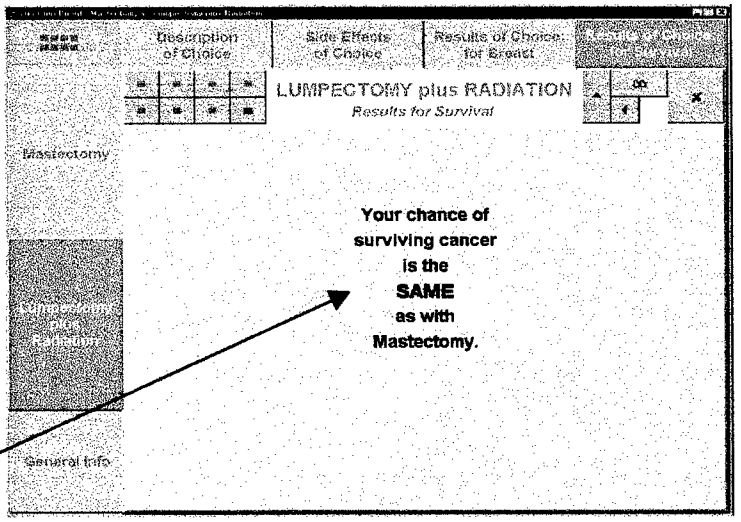
Step 21: Open the information contained in the panel under Lumpectomy plus Radiation and Results of Choice for the Breast.

Using the mouse, move the cursor on the box labelled "Results for Survival" under Results of Choice for Survival beside Lumpectomy plus Radiation and click once.



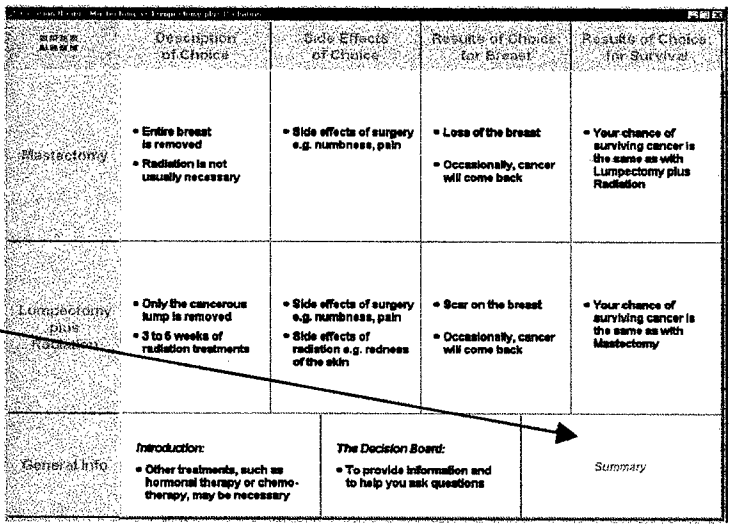
Step 22: Read the information contained in the panel under Lumpectomy plus Radiation and Results of Choice for Survival with the patient.

Emphasize that neither procedure is better than the other in terms of surviving breast cancer



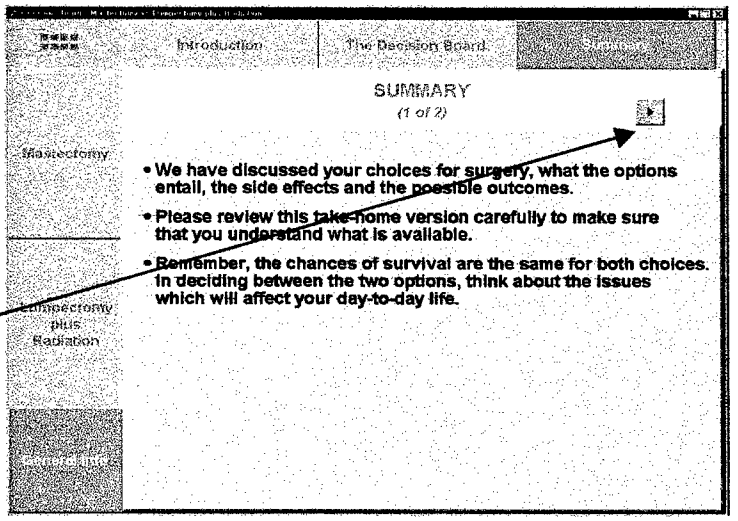
Step 23: Open the Summary Panel

Click on the panel labelled "Summary Panel".



Step 24: Review the information contained in the Summary Panel with the patient.

Review both of the two pages of this panel with the patient by either clicking anywhere inside the Introduction panel or by clicking on the arrow in the upper right of the panel to move to the next page.



Take-home version of the Computerized Decision Board

Take-home version of the Computerized Decision Board	♦ The take-home version of the decision board is an exact replica of the decision board the patient was administered. ♦ It is very important that the patient receives the correct take-home version of the Decision Board, otherwise they may be very confused if the information they were told by the doctor does not match the information they were given to read.
Who receives the Take-home version of the Computerized Decision Board	♦ All consenting patients who are randomized to the Computerized Decision Board Arm of the Trial will receive a take-home version matching the information they were presented regarding their treatment choice.
Appropriate Take-home version of the Computerized Decision Board	♦ There are two take-home versions of the computerized decision board. One version is for patients who will be having an axillary node dissection and the other for patients who will not be having an axillary node dissection.

Appendix D

Operations Manual for the Computerized Decision Board

(DECIDE – C)

49 pages

Development and Evaluation of Computer-based Versions of the Decision Board for Early Breast Cancer

Chemotherapy Version

DECIDE - C

Operations Manual

October 2001

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Contact Information

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Phone:	(905) 387-9711 ext. 64501	Phone:	(905) 387-9711 ext. 64510
Fax:	(905) 575-6308	Fax:	(905) 575-6308
Email:	tim.whelan@hrcc.on.ca	Email:	shelley.chambers@hrcc.on.ca

The Study

Study Objectives

Primary Objective

- To enhance information transfer and decision making for women with node negative breast cancer.

Technical Objectives

1. To develop a computer-based version of the Decision Board for the choice between no chemotherapy and adjuvant chemotherapy (Cyclophosphamide, Methotrexate and Flourouracil (CMF) or Adriamycin and Cyclophosphamide (AC)) in women with node negative breast cancer.
2. To compare the relative effectiveness of the Computer-based version with the Standard Decision Board for women with node negative breast cancer.

The Study (con't)

Main Study Design

This study involves two separate clinical trials running in parallel and involving two different patient populations. Both of these trials involve the comparison of a Standard Decision Board and a Computerized Version of the Decision Board.

One of these trials (DECIDE – C) is the focus of this manual, and involves women with early stage, node negative breast cancer (stage I or II) who have received definitive surgical treatment and are eligible to receive adjuvant chemotherapy.

The other trial (DECIDE – S) involves the decision of lumpectomy plus radiation versus mastectomy in women with newly diagnosed carcinoma of the breast with clinical stage I or II disease who have not yet received definitive surgical treatment. (There is a separate Operations Manual for this study).

DECIDE - C

The DECIDE – C Trial is a multicentre randomized trial of 100 patients with clinical stage I or II node negative disease with tumour size ≤ 5 cm. There will be a 1:1 randomization to the Standard Decision Board Arm or the Computerized Decision Board Arm after the patient has provided written informed consent (see Randomization Section). The allocated Decision Board will be presented to the patient and a take-home version of the allocated Decision Board will be given to the patient. The patient will be asked to complete questionnaires either at their one-week follow-up appointment with their Medical Oncologist, at their first chemotherapy appointment or by mail or telephone (for those who choose not to receive chemotherapy).

The physician or nurse presenting the Decision Board will also complete a questionnaire.

The Study (con't)

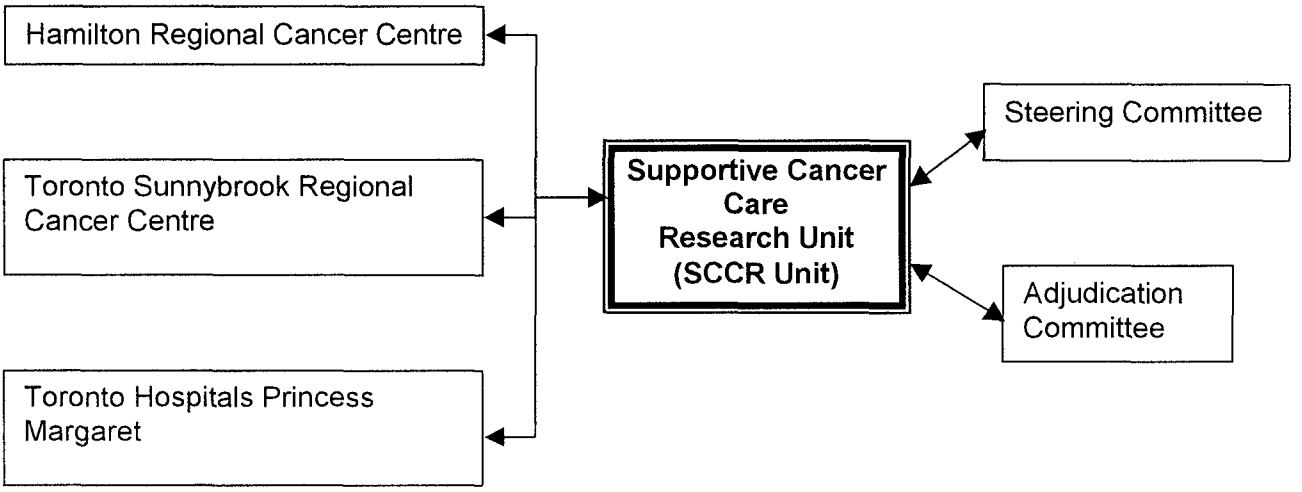
Shared Decision Making

In medical practice, a decision can be arrived at by several different methods or models: the passive, the shared or the informed. The passive model explicitly assumes a passive role for the patient in the treatment decision-making process. The physician controls the encounter offering the patient selected information and encouraging the patient to consent to what the physician considers best. The role of the physician in this model is the guardian of the patient's best interest. At the other extreme is the informed model whereby the patient is supplied with sufficient information and is able to make the decision completely on her own. In this model, medical decision-making authority is vested clearly in the patient, while the physician's role is relegated to transmitting medical information and using his/her technical skills as the patient directs.

Between these two extremes is the model of shared decision making. This approach is unfortunately poorly defined in the literature and is essentially an intermediate model between the two above. We would suggest that it involve sharing of information between physician and patient and sharing in the decision-making process and the decision. As a prerequisite, it requires: at least two participants who are willing to participate in the process (this would often be the physician and the patient, but could include the nurse, other doctors, family members or friends), information sharing and active participation in the decision-making process. For the patient, this would involve listening to and understanding information presented, describing personal values in relation to the outcomes, and trying to weigh the benefits and risks to formulate a treatment preference. For the physician, it would involve clearly presenting patients with the necessary information, elucidating patient's values regarding the various outcomes, and helping them with the balancing of the benefits and the risks to make a treatment decision.

Shared decision making is not the answer for everyone.

Organizational Structure



Administration of the Standard Decision Board

Step 1. Alleviate patient concerns about being presented with chemotherapy options	• In many cases the patient was informed by her surgeon that chemotherapy would not be required for her type of cancer. Alleviate the patient's concerns before embarking of the presentation of the Decision Board.
Step 2. Introduction card	• Show the patient the card entitled "Introduction" • Read the card with the patient
Step 3. Decision Board card	• Show the patient the card entitled "Decision Board" • Read the card with the patient • Emphasize that there is no right or wrong choice
Step 4. Open the first window, first row *Treatment Choices – No Chemo*	• Pull Slider Tab 1 to the right • Read the information behind the first window of the first row beside *No Chemo* and underneath *Treatment Choices* • Discuss the information with the patient • Ask if the patient has any questions
Step 5. Open the second window, first row *Side-effects – No Chemo*	• Pull Slider Tab 1 to the right again • Read the information behind the second window beside *No Chemo* under *Side Effects* • Describe to the patient that because no chemotherapy was given, there would be no side effects associated with this treatment. However, if the patient is taking tamoxifen she may experience some side effects associated with that treatment. • Ask if the patient has any questions

Administration of Standard Decision Board (con't)

Step 6. Open circular window, first row *Outcome – No Chemo*	• Pull Slider Tab 2 to the right • Reveal the probability wheel on the first row beside *No Chemo* and underneath *Outcome*
Step 7. Discuss Probability Wheels and what they mean	• Describe the probability wheel in the following way: " The circle describes the chance of remaining cancer-free for the next seven years. The chances are based on the information we have gathered on your type of cancer. The pink area of the circle corresponds to the chance of being cancer-free within seven years. The blue area of the circle corresponds to the chance of the cancer coming back within the next seven years. We have no way of telling when it might come back; it could be in several months or anytime during the next seven years, or not at all. The larger the pink area in the circle, the greater the chance of being cancer-free for the next seven years. In the same way, the larger the blue area, the greater the chance of the cancer coming back in the next seven years."
Step 8. Cancer Free / Cancer Return Card	• Read the patient the Cancer Free / Cancer Returns Card with the patient. • Review and discuss the information with the patient. • Ask if the patient has any questions
Step 9. Open First Window, second row *Treatment Choices - Chemotherapy*	• Pull Slider Tab 3 to the right. • Read the information behind the first window of the second row beside *Chemotherapy* and underneath *Treatment Choices.* • Review the information with the patient • Ask if the patient has any questions

Administration of Standard Decision Board (con't)

Step 10. Open the second window, second row *Side effects - Chemotherapy*	• Pull Slider Tab 3 to the right again • Read the information behind the first window of the second row beside *Chemotherapy* and underneath *Side Effects* • Review the information with the patient • Ask if the patient has any questions
Step 11. Menopause Card	• If it is relevant to discuss how chemotherapy may effect menopause, please read the Menopause Card with the patient. • Ask if the patient has any questions
Step 12. Open the circular window, second row *Outcome - Chemotherapy*	• Pull Slider Tab 4 to the right • Reveal the probability wheel on the second row beside *Chemotherapy* and underneath *Outcome*
Step 13. Discuss Probability Wheels and what they mean	• Describe the probability wheel again if necessary: " The circle describes the chance of remaining cancer-free for the next seven years. The chances are based on the information we have gathered on your type of cancer. The pink are of the circle corresponds to the chance of being cancer-free within seven years. The blue area of the circle corresponds to the chance of the cancer coming back within the next seven years. We have no way of telling when it might come back; it could be in several months or anytime during the next seven years, or not at all. The larger the pink area in the circle, the greater the chance of being cancer-free for the next seven years. In the same way, the larger the blue area, the greater the chance of the cancer coming back in the next seven years." • Show the patient that the risk of the cancer coming back has now decreased by (*indicate appropriate percentage)* with chemotherapy • Ask for if the patient has any questions

Administration of the Standard Decision Board (con't)

Step 14. Cancer Free / Cancer Returns Card	• If necessary, hand the Cancer Free / Cancer Returns Card to the patient again • Review the information with the patient
Step 15. Two types of chemotherapy offered	Explain to the patient that there are two types of chemotherapy offered to patients in the same situation as the patient and these are CMF and AC.
Step 16. Open the first window, third row *Treatment Choices - CMF*	• Pull Slider Tab 5 to the right • Read the information behind the first window of the third row, beside *CMF* and underneath *Treatment Choices* • Review the information with the patient. • Ask if the patient has any questions
Step 17. Open the second window, third row *Side Effects - CMF*	• Pull Slider Tab 5 to the right again • Read the information behind the second window of the third row, beside *CMF* and underneath *Side Effects* • Review the information with the patient • Ask if the patient has any questions
Step 18. Open the small rectangular window between the third and fourth row *Outcomes – CMF and AC*	• Pull Slider Tab 6 to the right • Read the information behind the small rectangular window between the third and fourth window. • Review the fact that the chances of remaining cancer free are the same with either type of chemotherapy. • Point to the probability wheel above that relates to the chemotherapy option. • The choice between the two chemotherapy treatments relates to the duration of treatment and the side effects of each treatment.

Step 19. Open the first window, fourth row *Treatment Choices - AC*	• Pull Slider Tab 7 to the right • Read the information behind the second window of the third row, beside *AC* and underneath *Treatment Choices* • Review the information with the patient • Ask if the patient has any questions
Step 20. Open second window, fourth row *Side-Effects - AC*	• Pull Slider Tab 7 to the right again • Read the information behind the second window, fourth row, beside *AC* and underneath *Side Effects* • Review the information with the patient • Ask if the patient has any questions
Step 21. Point to the small rectangular window between the third and fourth row again *Outcomes – CMF and AC*	• Emphasize again that the chances of remaining cancer free are the same with either type of treatment. • Point again to the probability wheel that relates to the chemotherapy option above.
Step 22. Summary	• **Highlight that there is no right or wrong answer** • The patient is choosing between having chemotherapy and not having chemotherapy • Emphasize that if they do choose chemotherapy, they have the choice of either CMF or AC and remind the patient of the side effects and the benefits of each. • This choice is dependent upon the patient's preference regarding the duration of treatment and the side effects of each treatment. • Each type of chemotherapy has the same benefit. • **Remember, their no right or wrong choice**
Step 23. Hand the patient the appropriate Take-home version of the Decision Board	• After the patient has been presented with the Decision Board, she should be given the Take-home version of the Decision Board that matches the Probability Wheels presented as well as any information regarding tamoxifen treatment.

Take-home Version of the Standard Decision Board

Take-home version of the Standard Decision Board	♦ The take-home version of the decision board is an exact replica of the decision board the patient was administered and also includes the information discussed in the optional cards (i.e., introduction, decision board, cancer free / cancer returns, menopause and summary). ♦ It is very important that the patient receives the correct take-home version of the Decision Board, otherwise they may be very confused if the information they were told by the doctor does not match the information they were given to read.
Who receives the Take-home version of the Standard Decision Board?	♦ All consenting patients who are randomized to the Standard Decision Board Arm of the Trial will receive a take-home version matching the information they were presented regarding their treatment choice.
Appropriate Take-home version of the Standard Decision board	♦ There are four different probability sliders that can be presented to patients based on their disease characteristics, however, there are five different take-home versions of the Decision Board. The reason for the discrepancy is that some patients who are ER negative have the same outcome probabilities as those who are ER positive. However, patients who are ER positive are presented information about tamoxifen while patients who are ER negative are not. Therefore, although the outcome probabilities presented are the same, the other information varies and requires a separate take-home version. The take-home versions of the Standard Decision Board are colour coded so that they can easily be distinguished from each other. The colour on the front of the Take-home pamphlet matches the colour indicated below and the colour indicated on the back of the probability slider. The version number on the bottom right-hand corner of the pamphlet also matches the Probability Slider Number presented.

Matching the Take-home version with the administered Probability Slider

(Patients with the following combination of characteristics are not found on this table a they generally are not offered chemotherapy: (ER+, < 1cm, any grade) OR (ER+, 1- < 2 cm, grade 1 or 2).

ER Status	Disease Characteristics		Outcome Probabilities		Wheel Slider Number	Take-home version colour
	Tumour Size	Tumour Grade	No Chemo	Chemotherapy		
ER -	1 - < 2 cm	GII and GIII	65% Cancer Free 35% Cancer Returns	75% Cancer Free 25% Cancer Returns	1	Blue
	≥ 2 cm	GI and GII				
ER -	≥ 2 cm	GIII	50% Cancer Free 50% Cancer Returns	65% Cancer Free 35% Cancer Returns	2	Pink
ER +	1 - < 3 cm	GII	85% Cancer Free 15% Cancer Returns	90 % Cancer Free 10% Cancer Returns	3	Green
	2 - < 3 cm	GI				
ER +	1 - < 2 cm	GIII	75% Cancer Free 25% Cancer Returns	85% Cancer Free 15% Cancer Returns	4	Yellow
	≥ 3 cm	GI and GII				
ER +	≥ 2 cm	GIII	65% Cancer Free 35% Cancer Returns	75% Cancer Free 25% Cancer Returns	5	Purple

Administration of the Computerized Decision Board

Before administering the Computerized Decision Board

Turn on the Laptop Computer prior to seeing the patient as it takes a while for the computer to warm up.

- The laptop computer takes a while to warm up, therefore, it is a good idea to have it turned on and the Decision Board Program loaded and already at the first screen before the patient is seen.

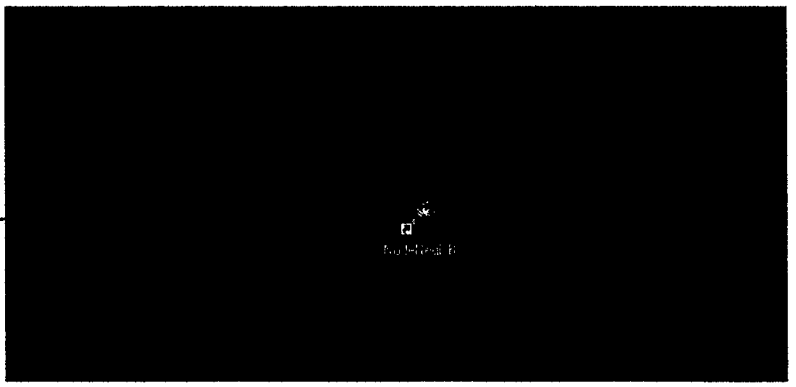
Prepare the appropriate Take-home version of the Computerized Decision Board

- There are five different take-home versions of the Computerized Decision Board based on the patient's disease characteristics. The take-home version of the Decision Board that matches the Probability Wheels that will be presented to the patient should be out and ready to hand to the patient after the presentation of the Decision Board (see Take Home Version of the Computerized Decision Board section of this manual).

Administration of the Computerized Decision Board

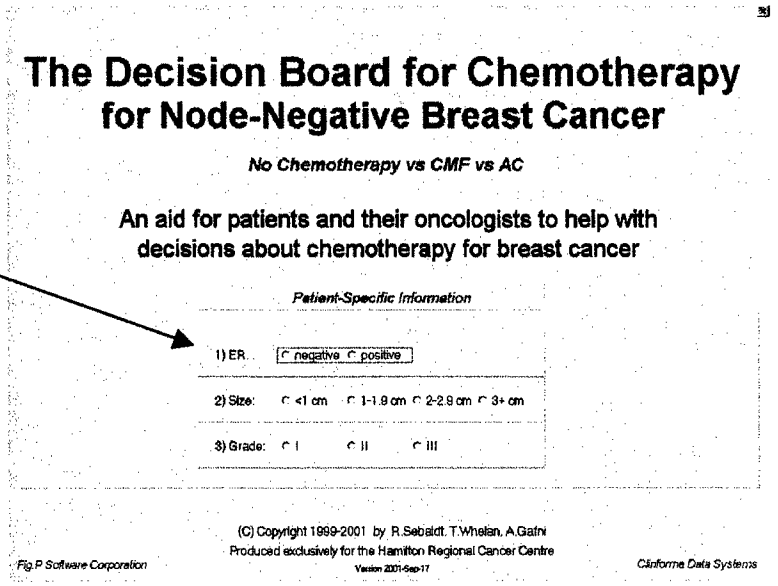
The computer decision board is quite user friendly once you get the hang of moving around in it. The programming allows flexibility to move anywhere you want to go with one click of the mouse.

Open the Computerized Node Negative Decision Board by double clicking on the icon that looks like a torch and is called "NodeNegDB".



Step 1:

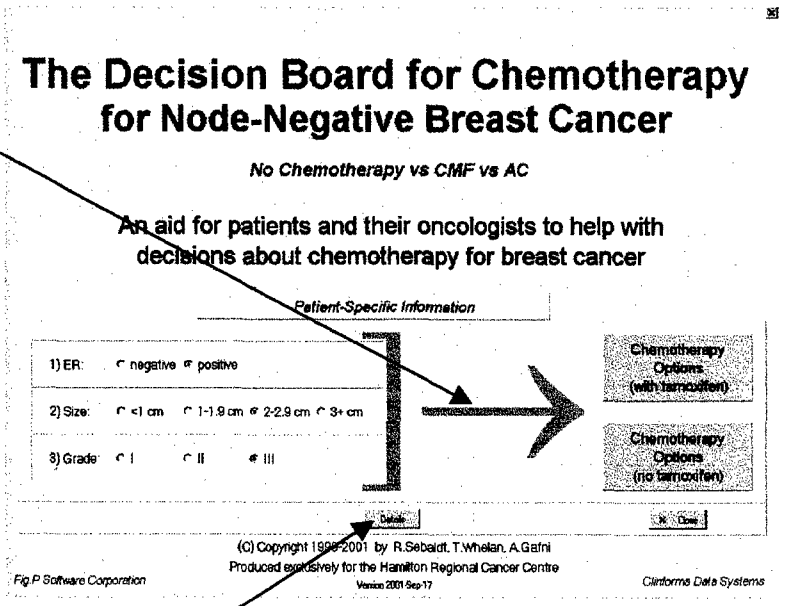
- On the opening screen use the mouse to click on the patient specific disease characteristics including; ER status, tumour size and tumour grade.



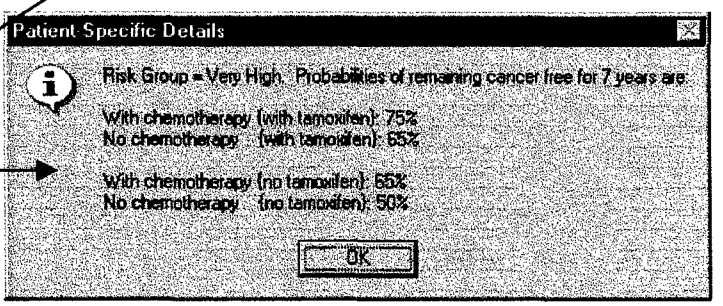
Administration of the Computerized Decision Board (con't)

Step 2a:

- For ER positive patients, notice that a large dark grey arrow appears guiding you to two options:
  - Chemotherapy with tamoxifen, and
  - Chemotherapy without tamoxifen
- Click on the appropriate box, depending upon the patient's choice regarding taking tamoxifen.

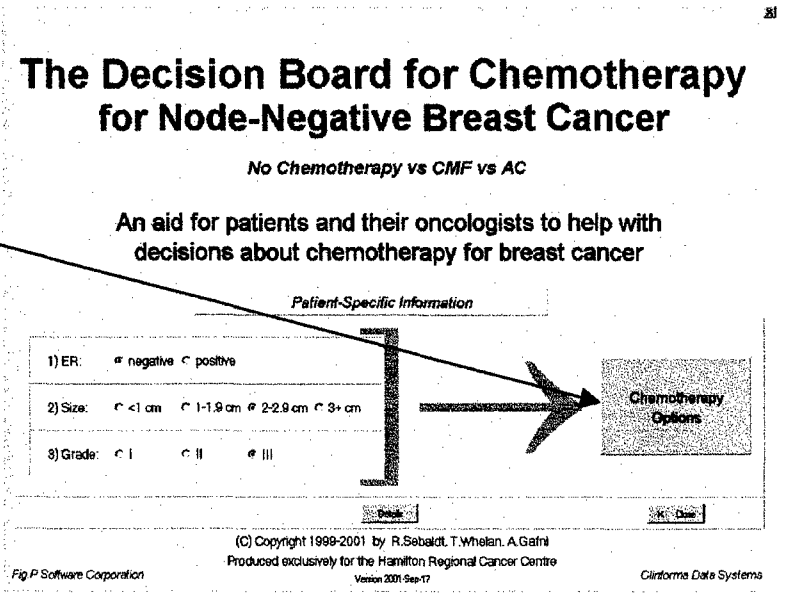


To ensure you are presenting recurrence rates you feel are appropriate for the patient, you can check by clicking with the mouse on the "details" icon after you have inputted the patient specific disease characteristics. A "Patient Specific Details" box will pop up and the recurrence rates that will be shown in the outcome "pies".



Step 2b:

- For ER negative patients, this screen will appear. You will notice that you are guided to only one box entitled "Chemotherapy Options" because Tamoxifen is not a treatment option for patients with ER negative disease.

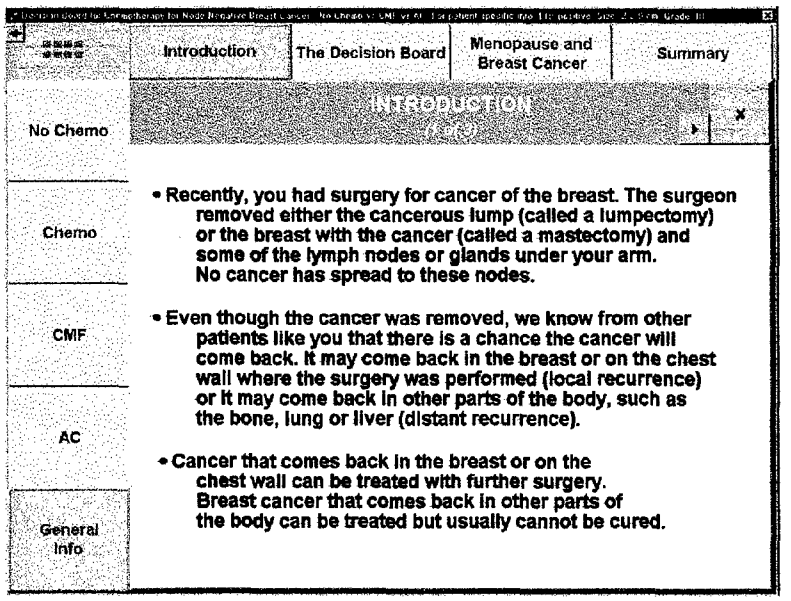


Administration of the Computerized Decision Board (con't)

Step 3:

- Read the introduction with the patient.

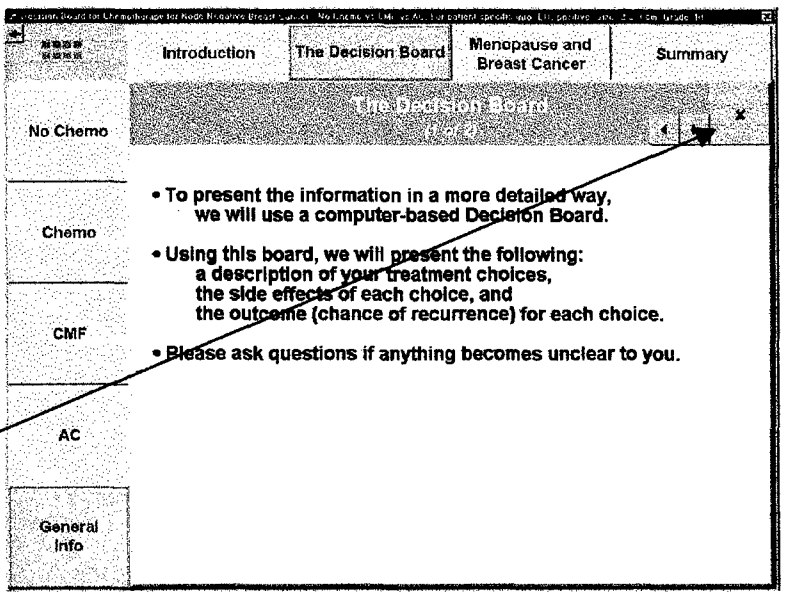
Note that the Introduction panel automatically pops up once the appropriate option is chosen from the opening screen.



Step 4:

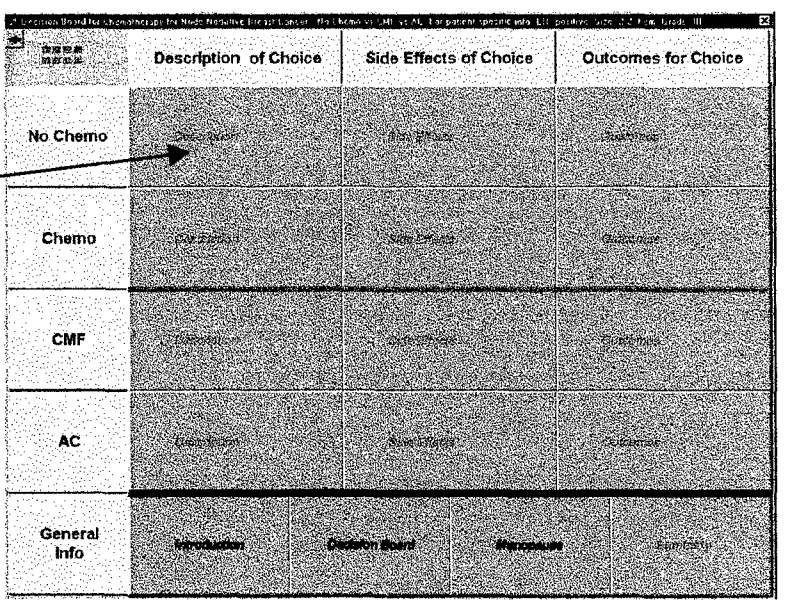
- Read the Decision Board Description with the patient.
- You will notice that the Decision Board panels (2 pages) automatically scroll through after the Introduction.

To exit the Introduction and Decision Board panels simply click the red X in the top right of the screen.



Step 5:

- Open the "No Chemo" Treatment description.



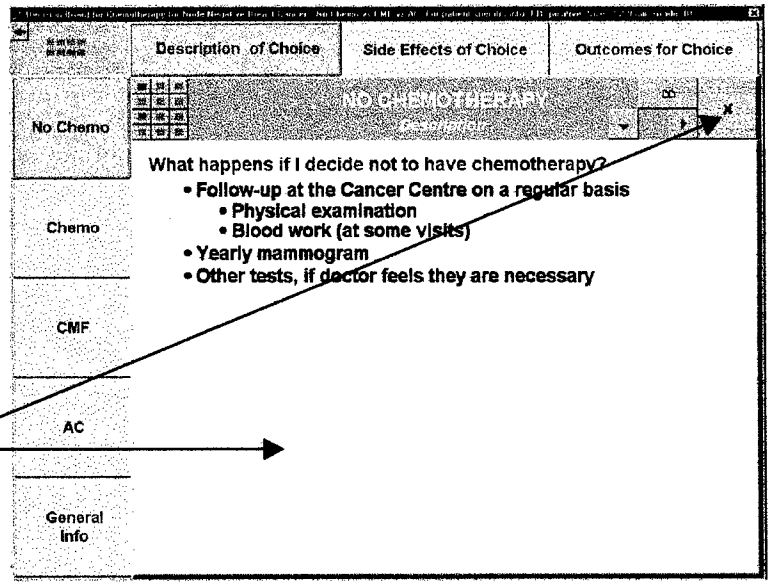
Administration of the Computerized Decision Board (con't)

Step 6:

- Read the description for "No Chemotherapy to the patient.

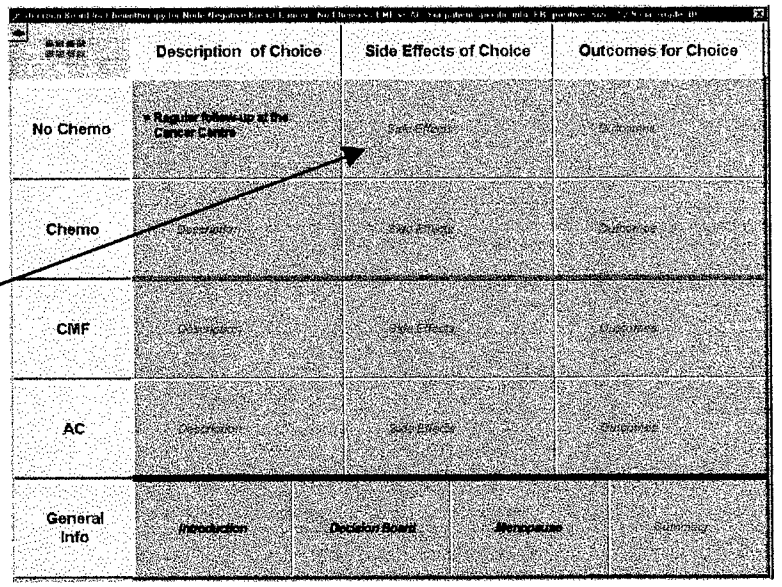
Ask if the patient has any questions.

To exit any panels opened from the main decision board screen, simply click anywhere within the screen or click the red X.



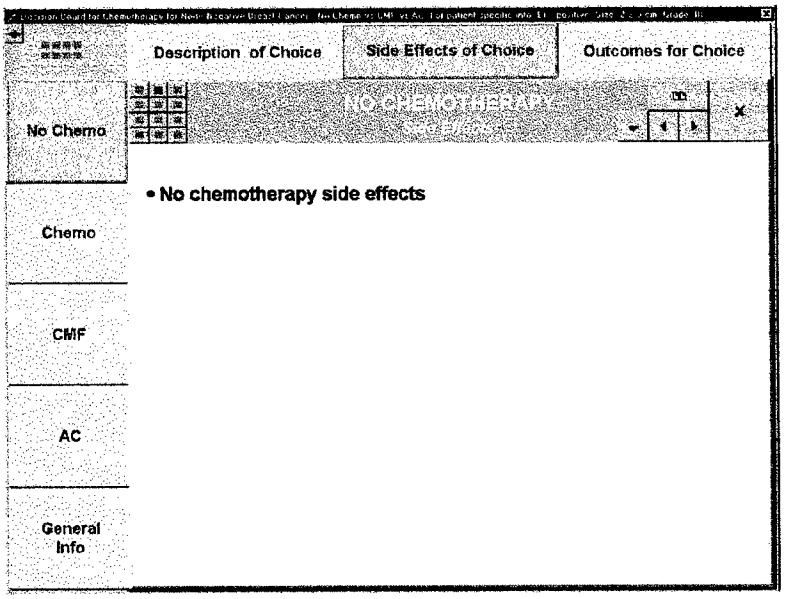
Step 7:

- Open the "No Chemo" side effects window.



Step 8:

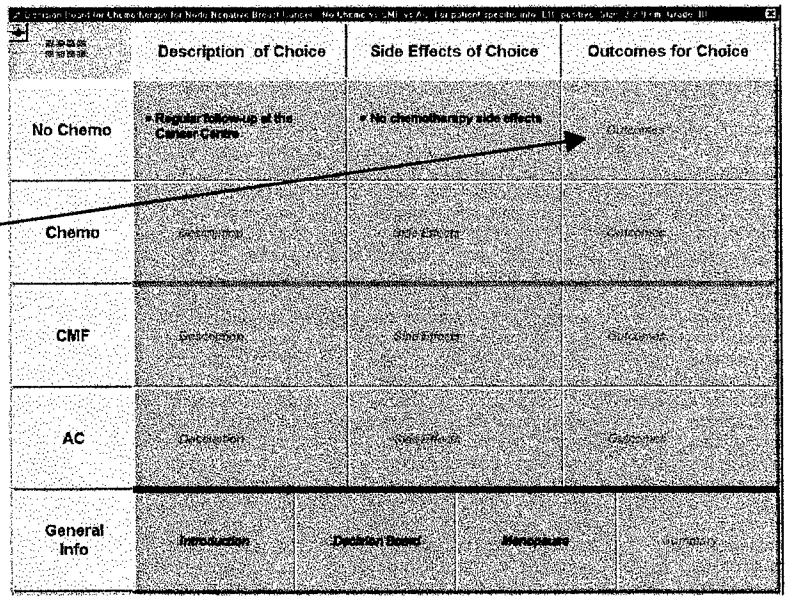
- Describe to the patient that because no chemotherapy would be given, she would experience no side effects related to chemotherapy.
- However, if the patient is taking Tamoxifen, there may be some side effects associated with that treatment.



Administration of the Computerized Decision Board (con't)

Step 9:

- Open the "Outcome" window for "No Chemo".

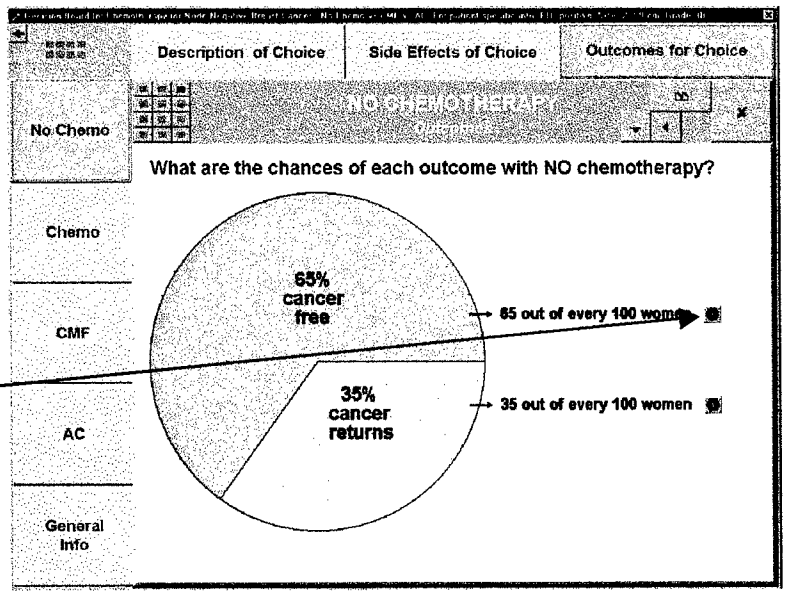


Step 10:

- Discuss probability wheels and what they mean.

Step 11:

- Open the "Cancer Free" description by clicking on the " i " icon across from the pink portion of the pie.

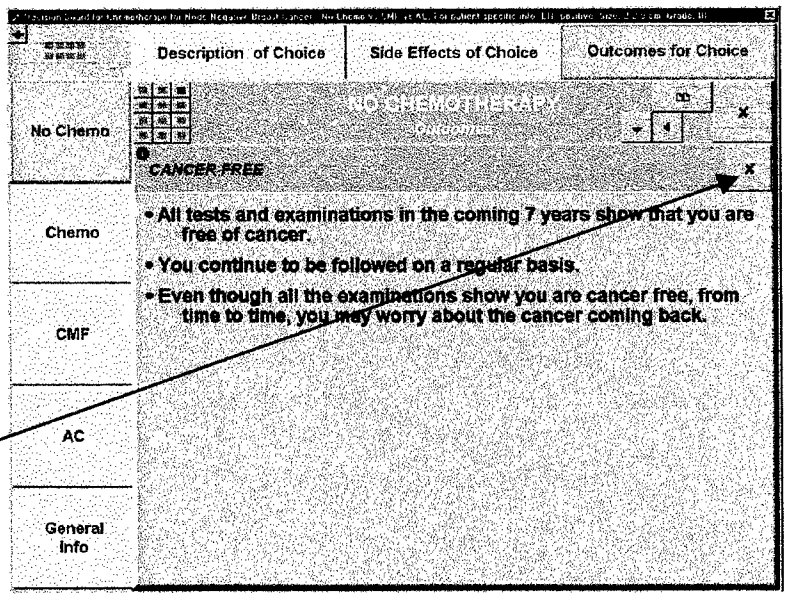


Step 12:

- Read the information contained in the "Cancer Free" panel with the patient.

Ask if the patient has any questions.

To close the "Cancer Free" panel simply click on the lower red X across from the blue "CANCER FREE" title.

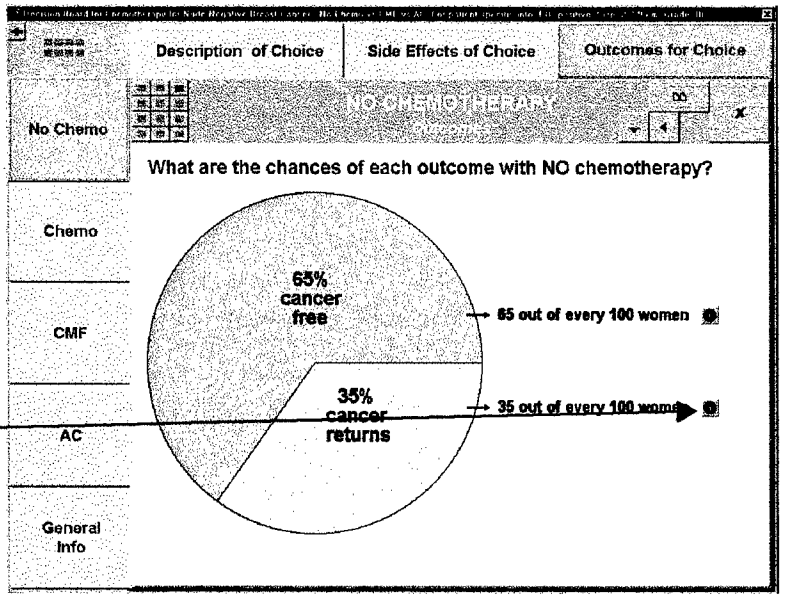


Administration of the Computerized Decision Board (con't)

Once the "Cancer Free" panel is closed, you will automatically come back to the "No Chemotherapy Outcomes" screen.

Step 13:

- Open the "Cancer Returns" description by clicking on the " i " icon across from the blue portion of the pie.

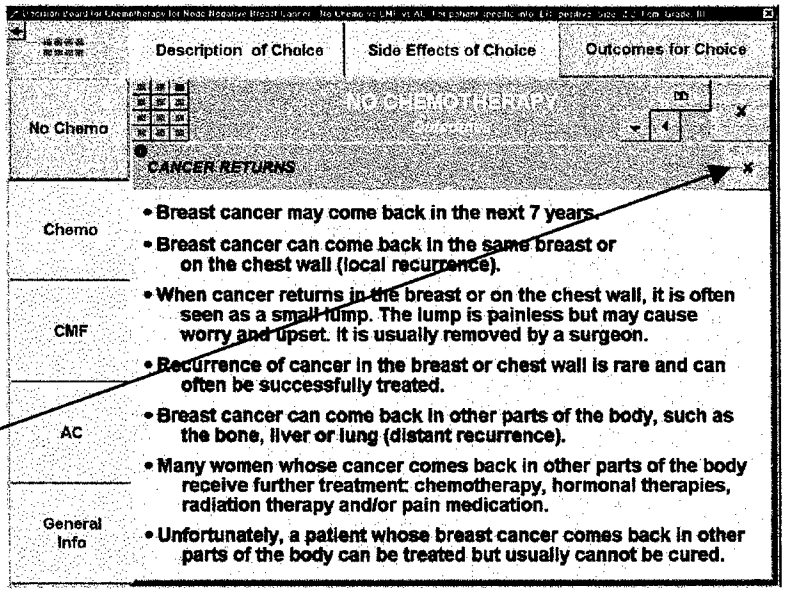


Step 14:

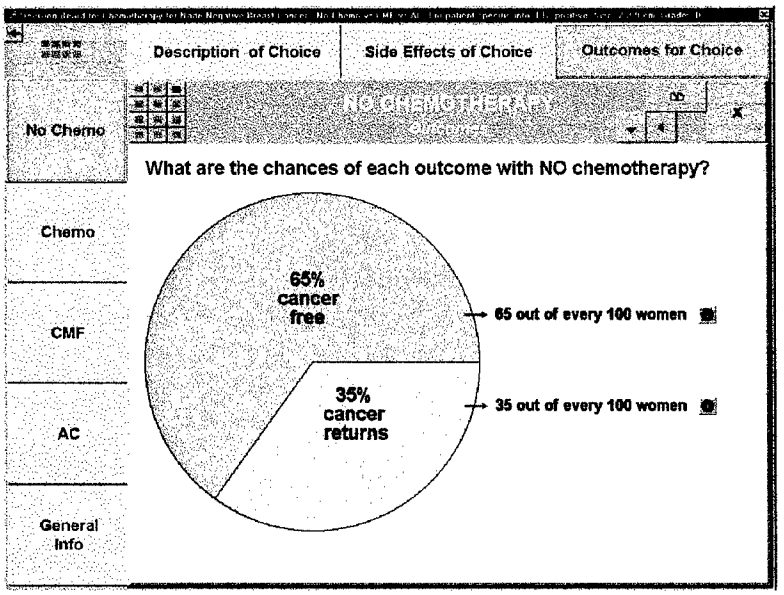
Read the information contained in the "Cancer Returns" panel with the patient.

Ask if the patient has any questions.

To close the "Cancer Returns" panel simply click on the lower red X across from the blue "CANCER FREE" title.



Exit out of the "No Chemotherapy Outcomes" screen by clicking anywhere within the screen or clicking the red X.

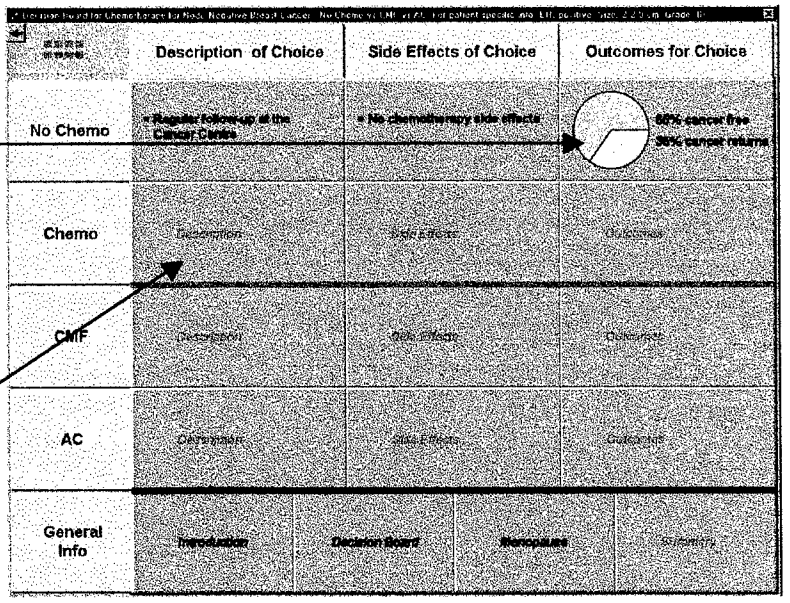


Administration of the Computerized Decision Board (con't)

Notice that the outcome pie remains on the main decision board once it has been opened.

Step 15:

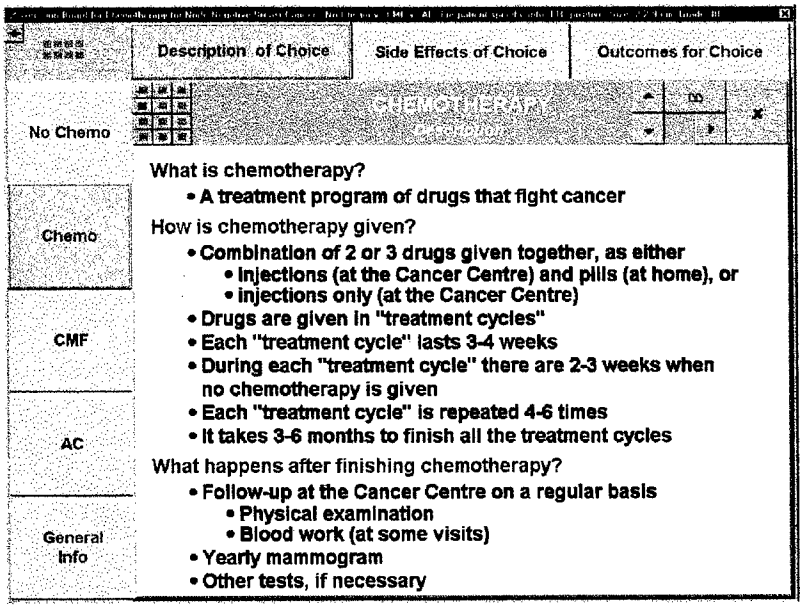
- Open the Chemotherapy Treatment Description window.



Step 16:

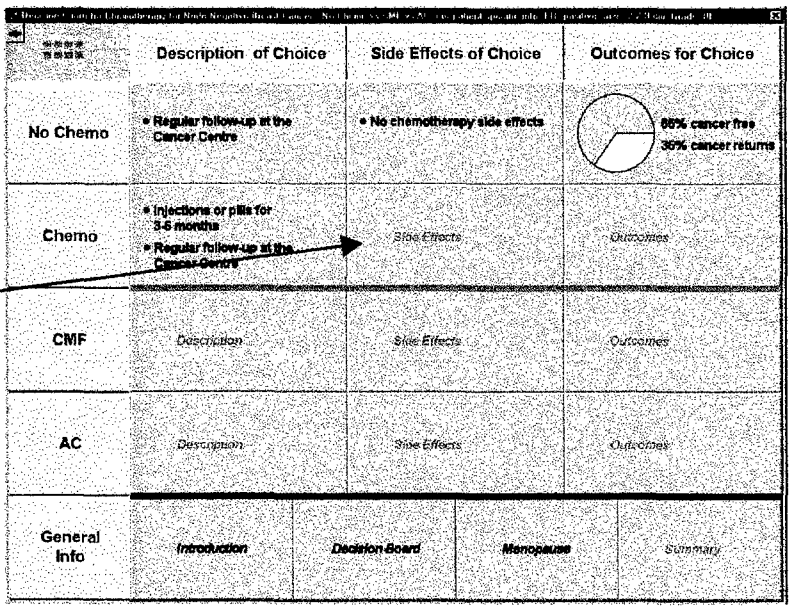
- Read the description for "Chemotherapy" to the patient.

Ask if the patient has any questions.



Step 17:

- Open the "Side Effects of Chemotherapy" window.

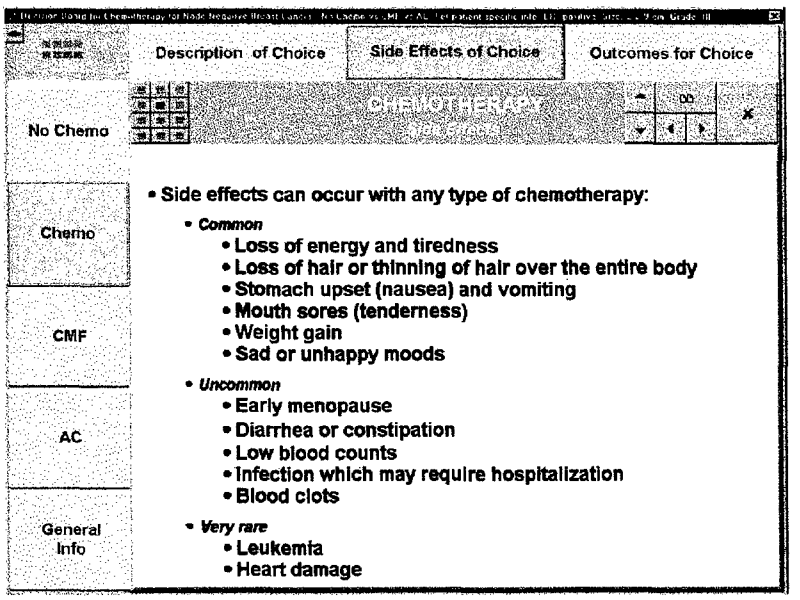


Administration of the Computerized Decision Board (con't)

Step 18:

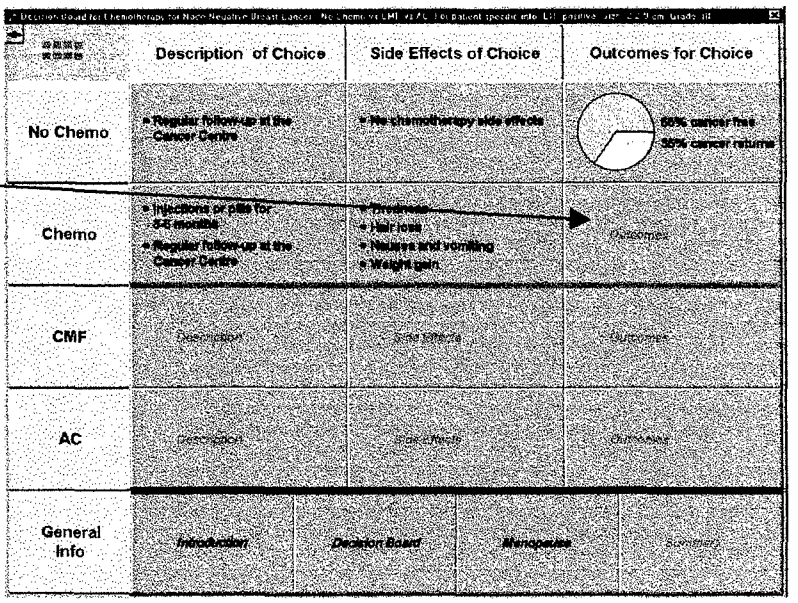
- Read and describe the side effects that the patient could experience with chemotherapy.

Ask if the patient has any questions.



Step 19:

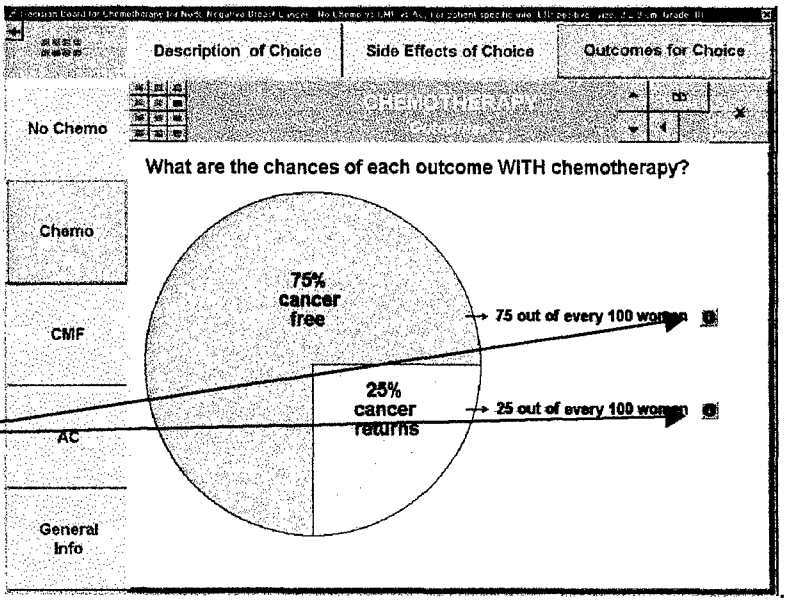
- Open the outcome window for chemotherapy treatment.



Step 20:

- Ensure that the patient understands the probability wheels and what they mean.

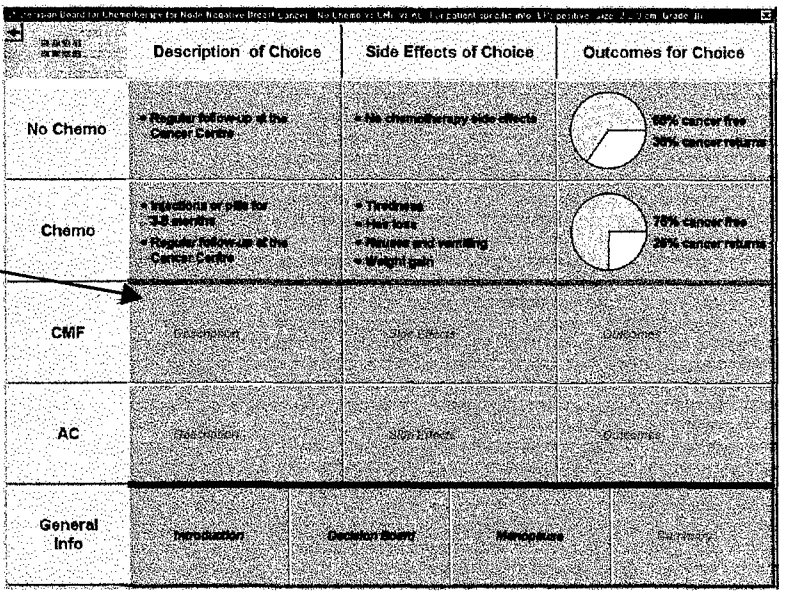
If required open the "Cancer Free" and "Cancer Returns descriptions by clicking on the " i " icons across the outcome pie and review the information with the patient.



Administration of the Computerized Decision Board (con't)

Step 21:

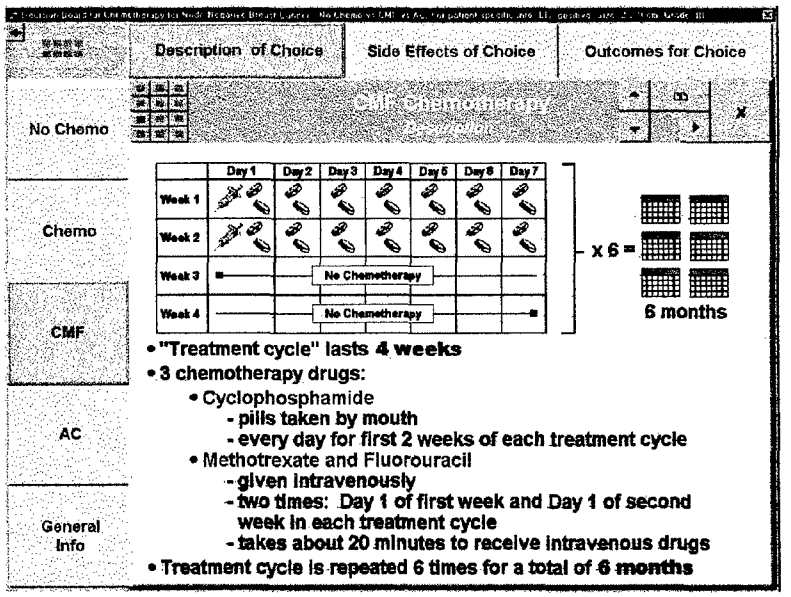
- Open the CMF Description panel



Step 22:

- Read and explain the CMF Chemotherapy description to the patient.

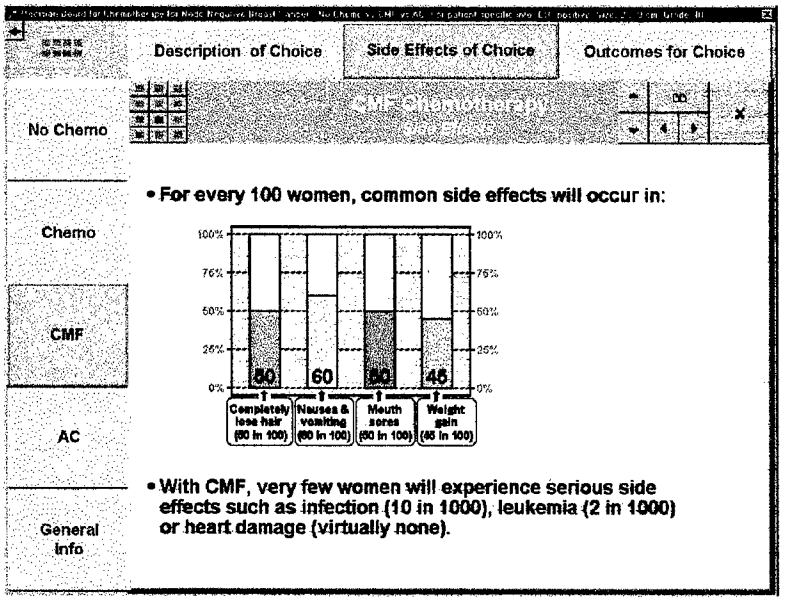
Ask if the patient has any questions.



Step 23:

- Review the CMF specific side effects with the patient and explain the information provided in the graph.

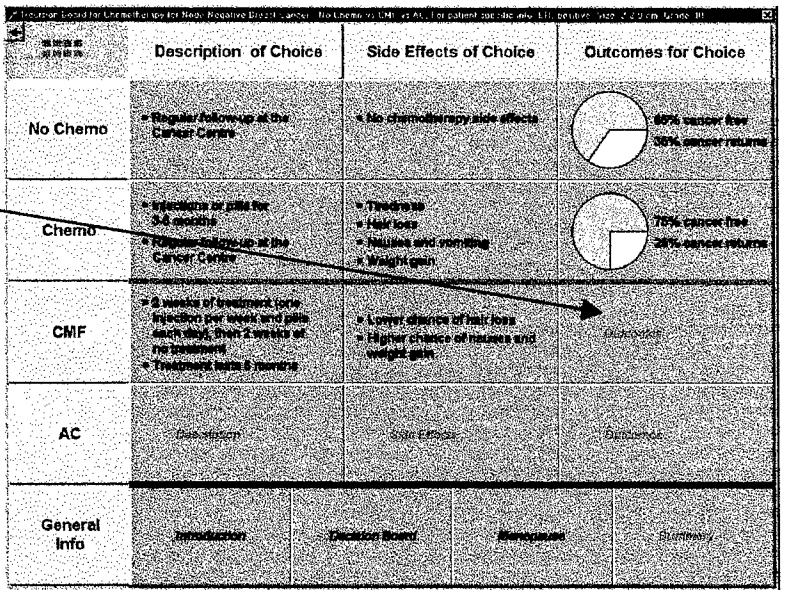
Ask if the patient has any questions.



Administration of the Computerized Decision Board (con't)

Step 24:

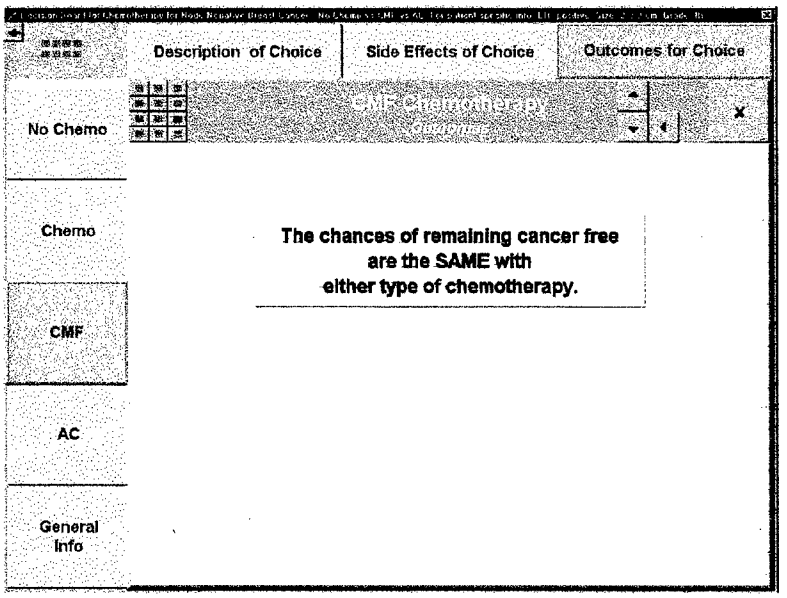
- Open the CMF Outcome panel.



Step 25:

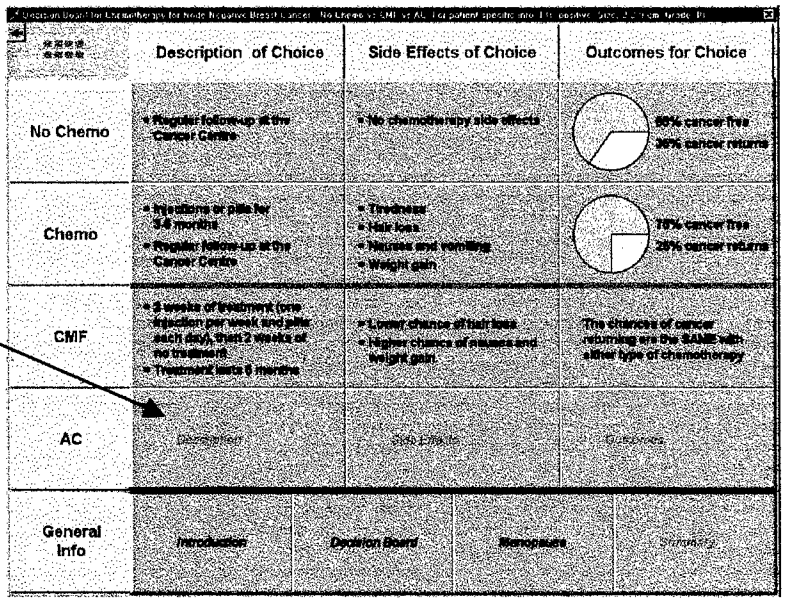
- Explain that the chances of remaining cancer free are the SAME with either type of chemotherapy the patient may choose.

You may want to refer back to the outcome pies shown earlier.



Step 26:

- Open the AC Description Panel.

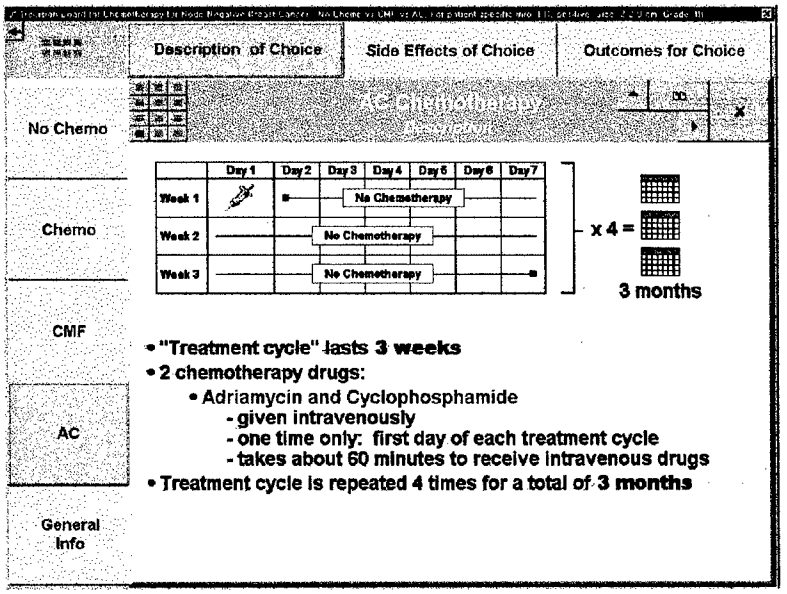


Administration of the Computerized Decision Board (con't)

Step 27;

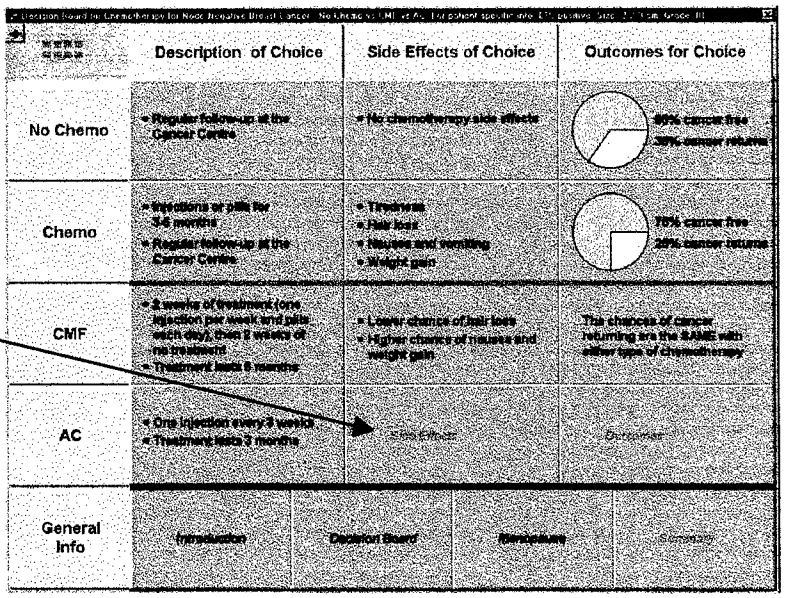
- Read and explain AC Chemotherapy Treatment to the patient.

Ask for and answer any questions the patient may have.



Step 28:

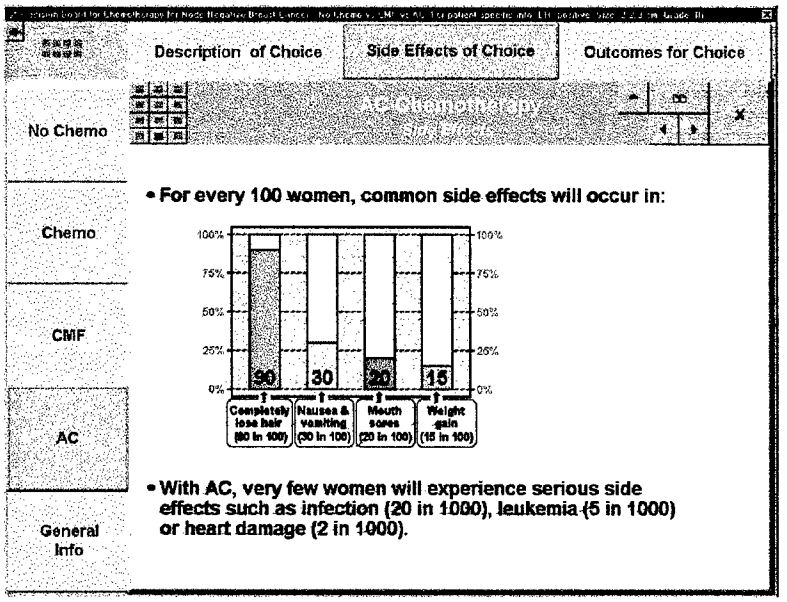
- Open the AC side effects panel.



Step 29:

- Review the side effects related to AC Chemotherapy with that patient.

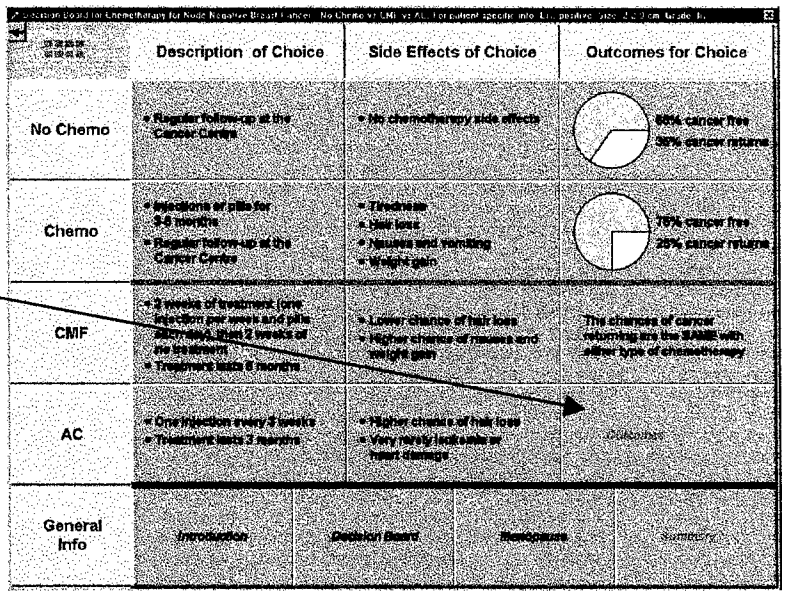
Ask for and answer any questions.



Administration of the Computerized Decision Board (con't)

Step 30:

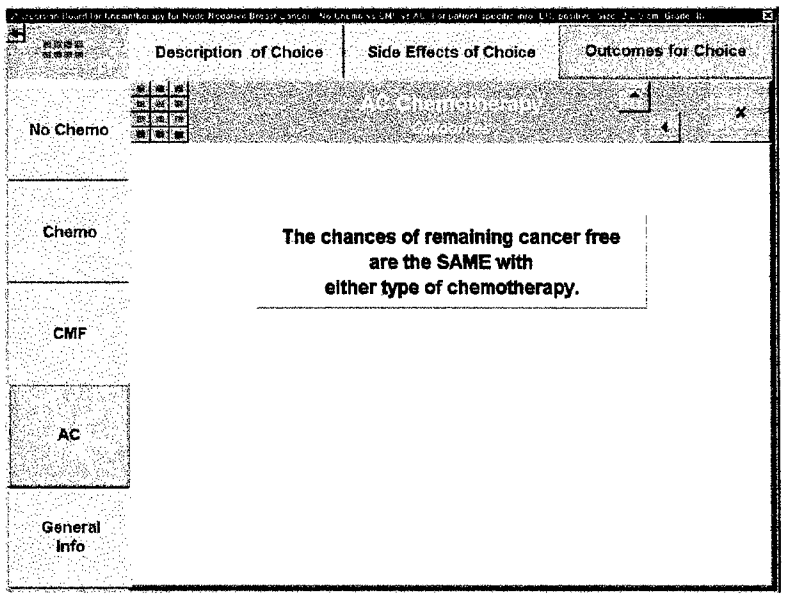
- Open the AC Outcomes panel.



Step 31:

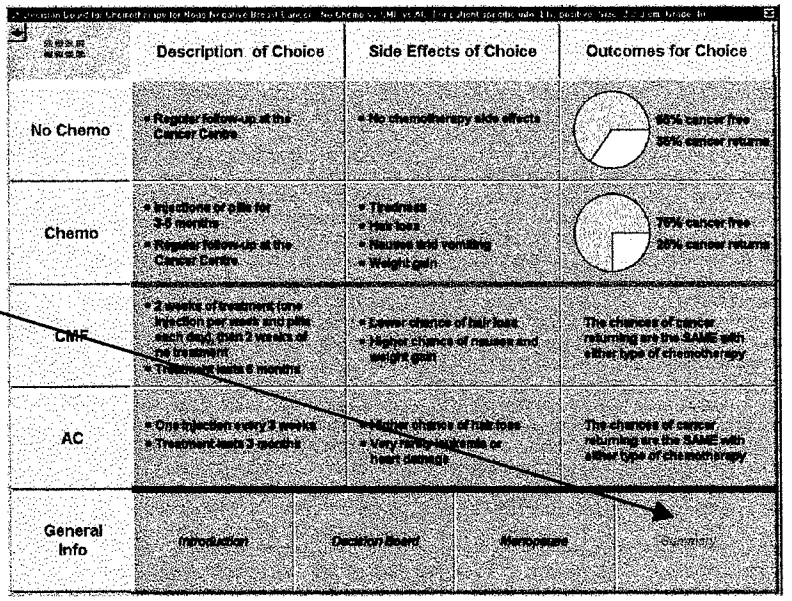
- Explain that the chances of remaining cancer free are the SAME with either type of chemotherapy the patient may choose.

You may want to refer back to the outcome pies shown earlier.



Step 32:

Open the Summary panel.



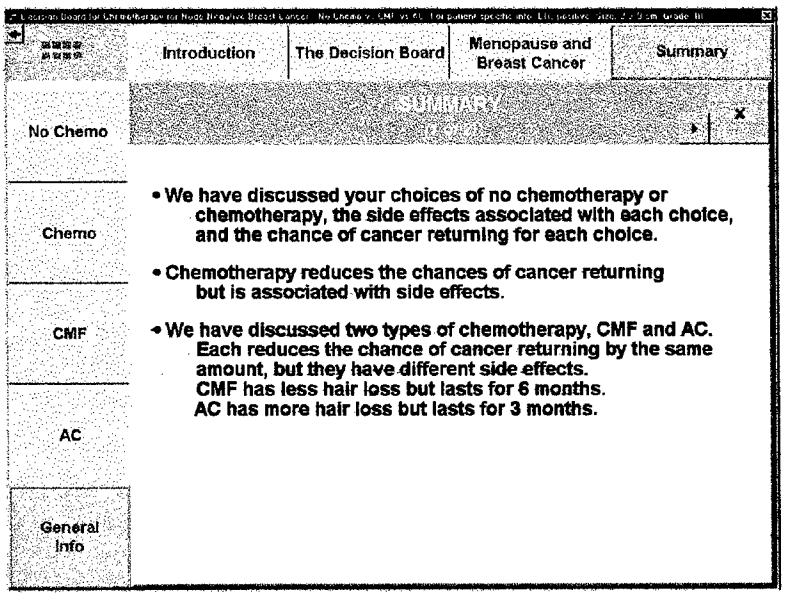
Administration of the Computerized Decision Board (con't)

Step 33:

- Read the information contained in the Summary panel with the patient.

The Summary panel is two pages long.

Ask for and answer any questions the patient may have.



Step 34:

- Provide the patient with the appropriate take home version of the computerized decision board that matches the outcome probabilities presented.
- See the "Matching the Take-home version with the patient's disease characteristics" section below.

Take-home version of the Computerized Decision Board

Take-home version of the Computerized Decision Board	The take-home version of the decision board is an exact replica of the decision board the patient was administered and also includes the information discussed in the optional cards It is very important that the patient receives the correct take-home version of the Decision Board, otherwise they may be very confused if the information they were told by the doctor does not match the information they were given to read.
Who receives the Take-home version of the Computerized Decision Board	All consenting patients who are randomized to the Computerized Decision Board Arm of the Trial will receive a take-home version matching the information they were presented regarding their treatment choice.
Appropriate Take-home version of the Computerized Decision Board	There are five take-home versions of the computerized decision board. There are different versions because they are based on the patient's disease characteristics and whether or not they would be considered for Tamoxifen therapy. The take-home versions of the Computerized Decision Board are colour coded so that they can easily be distinguished from each other. As with the Standard Decision Board take-home versions, the following criteria identify which patients receive which take-home version.

Matching the Take-home version with the patient's disease characteristics

ER Status	Disease Characteristics		Outcome Probabilities		Take-home version colour
	Tumour Size	Tumour Grade	No Chemo	Chemotherapy	
ER -	1 - < 2 cm	GII and GIII	65% Cancer Free 35% Cancer Returns	75% Cancer Free 25% Cancer Returns	1
	≥ 2 cm	GI and GII			
ER -	≥ 2 cm	GIII	50% Cancer Free 50% Cancer Returns	65% Cancer Free 35% Cancer Returns	2
ER +	1 - < 3 cm	GII	85% Cancer Free 15% Cancer Returns	90 % Cancer Free 10% Cancer Returns	3
	2 - < 3 cm	GI			
ER +	1 - < 2 cm	GIII	75% Cancer Free 25% Cancer Returns	85% Cancer Free 15% Cancer Returns	4
	≥ 3 cm	GI and GII			
ER +	≥ 2 cm	GIII	65% Cancer Free 35% Cancer Returns	75% Cancer Free 25% Cancer Returns	5

Appendix E

Take-home version of the Computerized Decision Board

Organizational Structure (con't)

Supportive Cancer Care Research Unit (SCCR Unit)

- The SCCR Unit is located at the Hamilton Regional Cancer Centre in Hamilton, Ontario. The SCCR Unit is responsible for the overall study execution, including case report form development, data collection, review, and analysis; development of a study database and quality assurance.

Steering Committee

- The Steering Committee is the major decision making body for the study.

Steering Committee Members

Tim Whelan	SCCR Unit, Hamilton Regional Cancer Centre, Hamilton, Ontario
Mark Levine	Hamilton Regional Cancer Centre, and McMaster University, Hamilton, Ontario
Amiram Gafni	Centre for Health Economics, McMaster University, Hamilton, Ontario
Jim Julian	Henderson Research Centre, McMaster University, Hamilton, Ontario
Peter Ellis	Hamilton Regional Cancer Centre, Hamilton, Ontario
Richard Tozer	Hamilton Regional Cancer Centre, Hamilton, Ontario
Mary Ann O'Brien	SCCR Unit, Hamilton Regional Cancer Centre, Hamilton, Ontario
Shelley Chambers	SCCR Unit, Hamilton Regional Cancer Centre, Hamilton, Ontario

Adjudication Committee

Adjudication Committee

- The adjudication committee has the primary responsibility of determining the eligibility of patients for this trial. If required, each member of the adjudication committee will review the eligibility criteria of a patient and determine if she actually met the criteria.

Members of the Adjudication Committee

- Still to be determined.

Recruitment / Randomization

Patient Screening

- All patients who meet the inclusion criteria for the trial will be screened for eligibility and recorded on the Eligibility Assessment Case Report Form (CRF).

Inclusion Criteria

*All answers must be **YES** to be recorded on the Eligibility Assessment CRF.*

The patient:

- Is female
- Has histologically documented invasive carcinoma of the breast treated with modified radical mastectomy or lumpectomy.
- Has had an axillary node dissection with all lymph nodes negative for metastatic disease.
- Has chemotherapy alone or in addition to tamoxifen as an appropriate treatment option.

Patient Eligibility

Exclusion Criteria

*All answers must be **NO** for the patient to be eligible.*

The patient:

- Requires further surgical treatment.
- Has an overall tumour size of $\leq$ 5.0 cm in largest dimension.
- Has clinical evidence of metastatic disease.
- Is a candidate for CEF chemotherapy.
- Has serious comorbidity (e.g., cardiovascular disease, renal disease, etc.), that would preclude her from receiving chemotherapy treatment.
- Is unable to speak or read English fluently.
- Is mentally incompetent including any psychiatric or addictive disorder that would preclude shared decision- making.

Informed Consent

Patient Information and Consent

- It is the responsibility of the Investigator to ensure that the patient has been given both written and verbal information regarding the objectives and procedures of the trial. The patient must be informed about their right to withdraw from the trial at any time. If the patient should refuse to participate in the trial, she should be ensured that she will receive optimal and appropriate care and that her decision will not prejudice any further treatment she may receive.
- An explanation of whom to contact with questions or concerns will be given.
- It should be pointed out that any personal identifying information will not be published and will be kept strictly confidential.

Obtaining Informed Consent

- After the Medical Oncologist has informed the patient about the trial, she will be asked if she is willing to participate in the trial.
- The patient must sign and date the Consent Form. A witness (other than the Investigator) must also sign and date the form.

Filing the Consent Form

- A copy of the signed and dated Consent Form must be kept in the patient's chart.

Consent Form

- A copy of the Consent Form is on the next page.

Decision Board for Early Breast Cancer

CONSENT FORM FOR PARTICIPANTS

Why is this study being done?

Research shows that patients have a desire for better communication with their doctors. Women with breast cancer have shown a need for more information about their disease and desire to be more involved in making decisions about their care. The aim of this study is to improve the transfer of information between the doctor and the patient and to improve decision making for women with breast cancer.

What is the study about?

A decision aid, called the *Decision Board,* has been developed to provide information to patients about treatment choices in breast cancer. It also helps patients make decisions about their treatment choices. The information provided on the Decision Board is based on high quality research results. With more treatments becoming available and a desire for detailed information, there is a need to present the various choices to women in different ways. Presently, the standard Decision Board presents written and pictorial information about treatment choices. A computer version of the Decision Board allows information to be personalized for each woman's own needs.

This study will test a computer version of the Decision Board. The computer version will be compared to the standard Decision Board. It will try to answer important questions. How well do patients understand the information? How satisfied are they with the information? How satisfied are they with the way the Decision Board helps them make a decision?

We would like to invite you to take part in this research. At the moment, we do not know if there is a difference between the standard Decision Board or the computer version. The only way to know whether there is a difference between the two presentations is to compare similar groups of patients at the same time. The only fair way to decide which presentation the patient gets is to decide this by chance, a method called randomization (like tossing a coin or picking a

Participant's initials: _____ Witness' initials: _____ Date: _____

number from a hat). This will be done by a computer to ensure that there is an equal chance of each patient receiving a particular presentation. If you agree to take part in this study, the research assistant will find out which presentation you will get by calling the research office. The benefit to taking part in this study is that women will be assured of receiving all information about their breast cancer, outlook and choices for treatment. There is no specific risk associated with participation in the study. Your choice of treatment will take place regardless of which Decision Board version is presented.

What is your involvement in the study?

If you agree to take part in this study, the doctor will explain your treatment choices at your appointment using the standard Decision Board or the computer version. A few days following your visit, you will be contacted by telephone, or at your next scheduled appointment, by the research assistant. You will be asked about your breast cancer and the different treatments available. You will be asked about the benefits and risks or side effects associated with the different treatment choices. You will also be asked about your satisfaction with the information presented and the decision-making process. Some basic information about your personal characteristics will also be collected. This interview will take about 15 minutes. There will not be any more involvement on your part following this interview. There will be no cost to you for participation in the study. You will receive a copy of the consent form.

Participant's agreement to take part in this study:

I have read the information about the Development and Evaluation of Computer-based Versions of the Decision Board for Early Breast Cancer Study.

I agree to take part in this study with the understanding that information will be collected and used for research purposes only and will be treated as confidential. No participant names will be identified in any report of this study. I have been informed about the purpose of the study. I know that I am under no obligation to participate and may withdraw at any time. My present or future medical treatment will not be affected in any way if I choose not to take part in this study.

Representatives from the U.S. Army Medical Research and Materiel Command may inspect the records of the research in their duty to protect human subjects in research.

You should also understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the Principal Investigator before you enrol in this study.

Participant's initials: _____ Witness' initials: _____ Date: _____

If you have any questions about the study, please contact the Principal Investigator, Dr. Tim Whelan at (905) 387-9495, ext. 64501 or the Research Coordinator at (905) 387-9495, ext. 64510.

The name of an individual not directly involved in this study who can provide answers to questions about my rights as a research subject is Leslee Schynal who is located at the Hamilton Health Sciences Corporation, Henderson Hospital, 711 Concession Street, Hamilton, Ontario, telephone number (905) 389-4411, Ext. 42136.

Participant's name: _____ (Please use block letters.)

Participant's address: _____

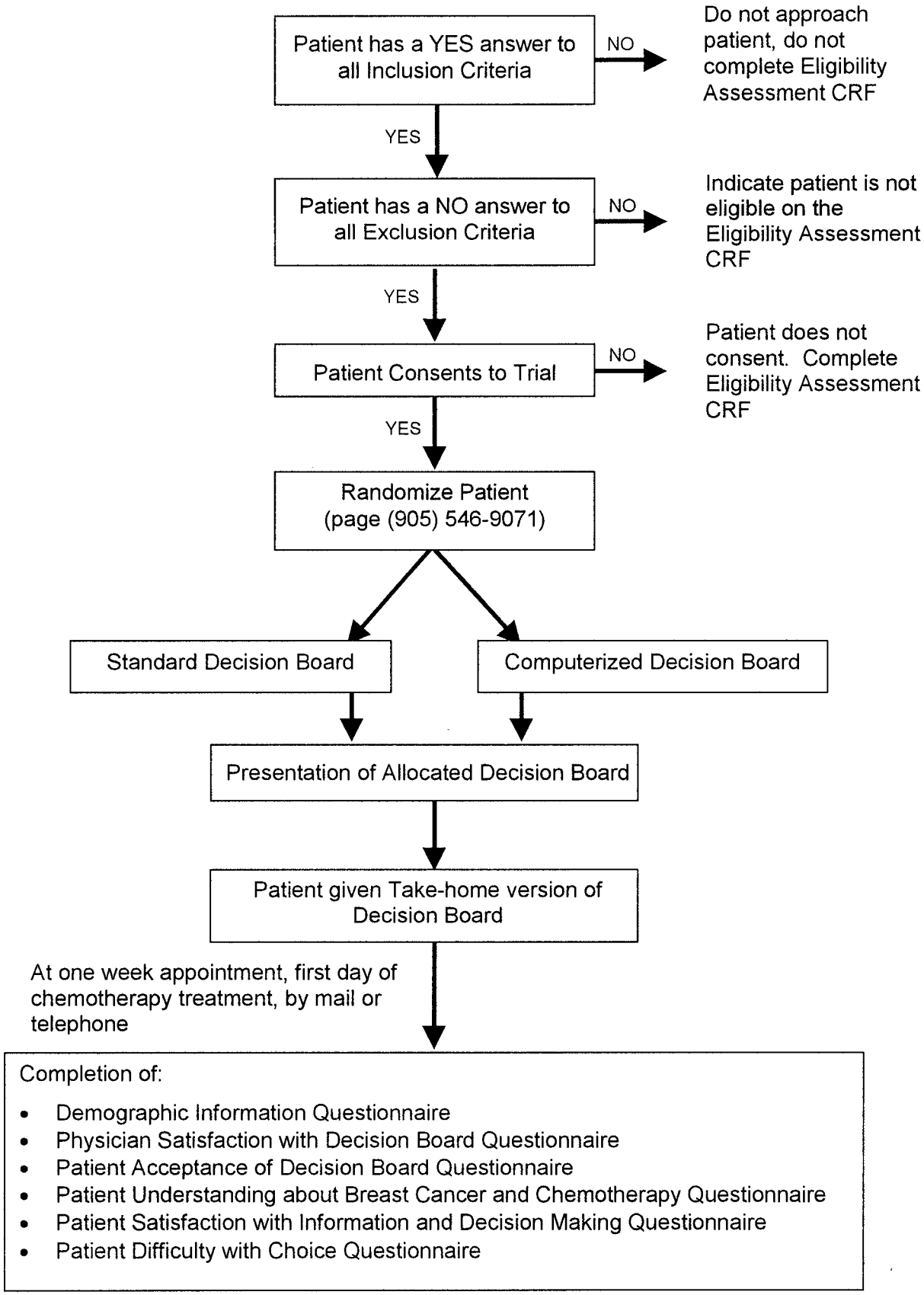
Participant's signature: _____ Date: ___/_____/_____
dd mmm yy

Witness' name: _____ (Please use block letters.)

Witness' signature: _____ Date: ___/_____/_____
dd mmm yy

END OF FORM

Schemata


Patient has a YES answer to all Inclusion Criteria
NO
Do not approach patient, do not complete Eligibility Assessment CRF
YES
Patient has a NO answer to all Exclusion Criteria
NO
Indicate patient is not eligible on the Eligibility Assessment CRF
YES
Patient Consents to Trial
NO
Patient does not consent. Complete Eligibility Assessment CRF
YES
Randomize Patient (page (905) 546-9071)
Standard Decision Board
Computerized Decision Board
Presentation of Allocated Decision Board
Patient given Take-home version of Decision Board
At one week appointment, first day of chemotherapy treatment, by mail or telephone
Completion of:
• Demographic Information Questionnaire
• Physician Satisfaction with Decision Board Questionnaire
• Patient Acceptance of Decision Board Questionnaire
• Patient Understanding about Breast Cancer and Chemotherapy Questionnaire
• Patient Satisfaction with Information and Decision Making Questionnaire
• Patient Difficulty with Choice Questionnaire

Ineligible Patients

- **Patients who do not meet the Inclusion Criteria**

Patients who have a "NO" answer to at least on Inclusion Criteria are not eligible for the trial and should not be approached for informed consent to the trial. An Eligibility Assessment CRF should not be completed for these patients.

- **Patients who meet at least one Exclusion Criteria**

Patients who have a "YES" answer to at least one Exclusion Criteria are not eligible for the trial. An Eligibility Assessment CRF must be completed for these patients, however, these patients should not be approached for informed consent to the trial.

Non-consenting patients

- If a patient is eligible for the trial but does not consent.
  - Complete the Eligibility Assessment CRF.
  - Indicate the reason that the patient did not consent to the trial.
  - Sign and date the Eligibility Assessment CRF.

Patient Randomization

When to Randomize a patient

- Once a patient is determined as eligible to participate in the trial (i.e., met all of the Inclusion Criteria and did not meet any Exclusion Criteria) and has signed and dated the Consent Form, the patient is eligible for randomization.
- The patient must be randomized prior to any discussion regarding adjuvant systemic therapy.

Prior to Randomization

- You will need to have the following information available prior to calling to randomize the patient:
  - The patient chart number
  - The patient initials
  - Name of the Medical Oncologist treating the patient

Who to call for Randomization

The Supportive Cancer Care Research Unit will be responsible for the central randomization of all patients into the trial. Please page:

905-546-9071

key in the telephone number where you can be reached.

If your page is not answered within a few minutes, please call:

905-387-9495 ext. 64510 or 64501

and the SCCR Unit Staff will assist you.

Patient Randomization (con't)

Process of Randomization

Once you have reached an authorized SCCR Unit staff member, you are ready to randomize the patient.

- You will be asked to supply:
  - The patient initials
  - The patient's chart number
  - The patient's Medical Oncologist
  - The date of randomization (today's date)
- You will be given (and must record on the Eligibility Assessment CRF):
  - The Patient Study ID Number (PID)
  - Decision Aid Arm to which the patient will be allocated, either:
    - Standard Decision Board, or
    - Computerized Decision Board

Study ID Number

The Patient Study ID Number is a 4-digit number which incorporates a one-digit Centre ID number and a three-digit sequential patient number and is in the form of:

____ ____ ____ ____

Centre Patient Number

The Patient Study ID Number is to be recorded at the top of every CRF page and on each page of any source document.

Randomization Log

The Randomization Log sheet is found in this binder and is comprised of multiple pages to record all patients randomized to the study. The patient name, study ID and date of randomization are to be recorded in this Log. This Log provides a means for you to connect the Study ID number with the patient name.

Decision Aid Board of the Trial

Standard Decision Board Arm

- The Standard Decision Board is a visual aid with both written and graphical information that is approximately two and one-half feet wide and three feet tall. It has information windows that are initially closed. The windows are systematically opened to present the information on the two treatment options, related side effects and outcome probabilities. When all of the windows are eventually opened it allows the patient to compare the treatment options. The instrument also consists of additional information that is presented to patients on separate information cards.

Computerized Decision Board Arm

- The Computerized Decision Board is similar to the Standard Decision Board except for the fact that the decision board is presented using a laptop computer. Upon opening the decision board program on the laptop, there will be "windows" that have the appearance of being closed. These windows will be systematically opened to present the two treatment options, related side effects and outcome probabilities. When the windows are closed, highlighted bullet points emphasizing the main points in each window will remain on the screen giving the appearance of open windows, similar to the Standard Decision Board.

Sample Size

- There will be 100 patients randomized to the trial, with 50% randomized to the Standard Decision Board Arm and 50% to the Computerized Decision Board Arm.

Schedule of Study Events

	Timing of events			
	Prior to Randomization	**Immediately after Randomization**	**Immediately after Decision Board Presentation**	**1 week after Decision Board Presentation**
Eligibility Assessment	X			
Signing of Consent Form	X			
Presentation of Allocated Decision Board		X		
Baseline Assessment				X
Demographic Information Questionnaire				X
Take-home version of Decision Board given to patient			X	
Physician Satisfaction with Information Transfer and Decision Making Questionnaire				X
Patient Acceptance of Decision Board Questionnaire				X
Patient Understanding about Breast Cancer and Chemotherapy Questionnaire				X
Patient Satisfaction with Information and Decision Making Questionnaire				X
Patient Difficulty with Choice Questionnaire				X

Administration of Standard Decision Board

Before Administering the Standard Decision Board

The Probability Slider

- Is a vertical panel that contains two probability wheels. The top probability wheel reflects the chances of the patient remaining cancer free (pink section) and of the cancer returning (blue section) if the patient chooses not to undergo chemotherapy treatment. The bottom probability wheel reflects that chances of the patient remaining cancer free or having the cancer return if she chooses to undergo chemotherapy treatment.

Choosing the correct probability slider

- There are four different probability sliders, each of which reflect the probabilities based on the patient's disease characteristics. The probability wheel that matches the patient's risk factors should be inserted into the Decision Board prior to administering the board to the patient. Each probability slider is numbered on the back.

- The chances of a patient remaining cancer free or having the cancer return are based on many disease characteristics. The table on the next page indicates the disease characteristics and the probability slider number that correspond to those characteristics. Match the patient's disease characteristics with the characteristics on this table to choose the correct probability slider.

Disease Characteristics and the Probability Slider Number

(Patients with the following combination of characteristics are not found on this table a they generally are not offered chemotherapy: (ER+, < 1cm, any grade) OR (ER+, 1- < 2 cm, grade 1 or 2).

ER Status	Disease Characteristics		Outcome Probabilities		Prob. Slider Number
	Tumour Size	Tumour Grade	No Chemo[1]	Chemotherapy	
ER -	1 - < 2 cm	GI, GII and GIII	65% Cancer Free 35% Cancer Returns	75% Cancer Free 25% Cancer Returns	1
	≥ 2 cm	GI and GII			
ER -	≥ 2 cm	GIII	50% Cancer Free 50% Cancer Returns	65% Cancer Free 35% Cancer Returns	2
ER +	1 - < 3 cm	GII	85% Cancer Free 15% Cancer Returns	90 % Cancer Free 10% Cancer Returns	3
	2 - < 3 cm	GI			
ER +	1 - < 2 cm	GIII	75% Cancer Free 25% Cancer Returns	85% Cancer Free 15% Cancer Returns	4
	≥ 3 cm	GI and GII			
ER +	≥ 2 cm	GIII	65% Cancer Free 35% Cancer Returns	75% Cancer Free 25% Cancer Returns	1

1 For ER + patients, the "Cancer Free" probabilities are for patients receiving tamoxifen but not receiving chemotherapy

Before Administering the Standard Decision Board (con't)

Inserting the Probability Wheel into the Decision Board

- The Probability Wheel slider is inserted vertically into the slot at the top right hand-side of the Decision Board. When inserting the Probability Wheel the wheels should face toward the front of the board. Note that the probability slider number and appropriate take-home decision board colour are indicated on the back of each probability wheel slider.

Familiarize yourself with the Tab numbers on the horizontal sliders

- See the diagram indicating the Tab numbers for each horizontal slider on next page.

Prepare the appropriate Take-home version of the Decision Board

There are five different take-home versions of the Decision Board. The take-home version of the Decision Board that matches the Probability Wheels presented to the patient should be out and ready to hand to the patient after the presentation of the Decision Board. See the Take-home version of the Decision Board section.

Laminated information cards

- The laminated information cards are stored at the back of the Decision Board in a plastic pouch. Pull all of the cards out of the pouch and have them ready and in a convenient location to go over with the patient.
- The Cards that are available are:

  Introduction

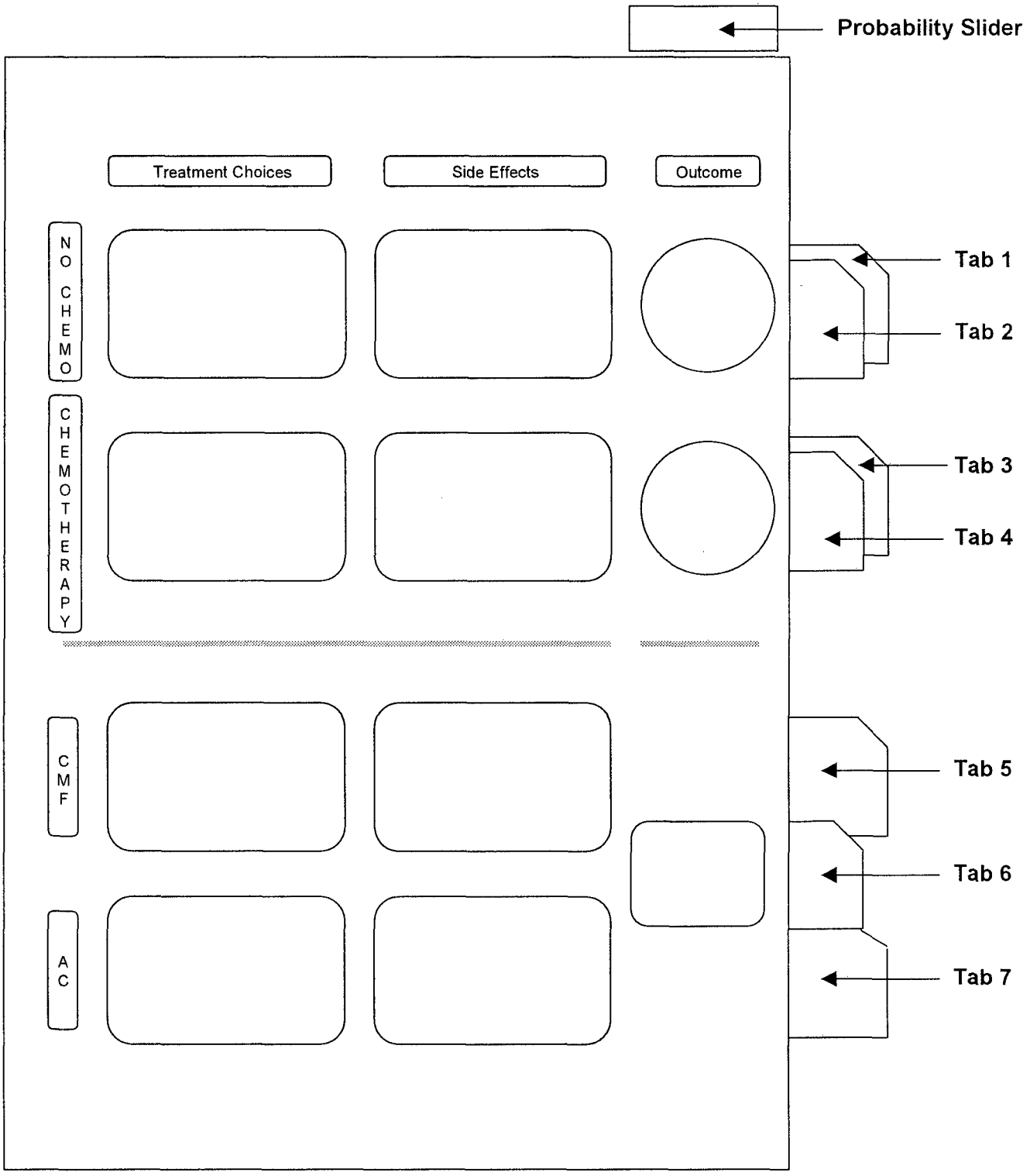
  Decision Board

  Cancer Free / Cancer Returns

  Menopause

  Summary

All Windows Closed

- Ensure that all information windows on the Decision Board are closed before starting the presentation of the Decision Board.

Tab Numbers on the Standard Decision Board