2007

Evaluation of a guided decision aid for treatment selection in follicular non -Hodgkin's lymphoma

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Dissertation submitted to the
Eberly College of Arts and Sciences
at West Virginia University
in partial fulfillment of the requirements
for the degree of

Doctor of Philosophy
in
Psychology

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Keywords: lymphoma, medical decision-making, decision aid, cancer

ABSTRACT

Evaluation of a Guided Decision Aid for Treatment Selection in Follicular non-Hodgkin's Lymphoma

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Decision aids for treatment selection have improved the decision-making process by increasing patient knowledge, decreasing decisional conflict (or uncertainty), increasing strength of preference for an option, and increasing decision satisfaction. Decision aids provide information and assist patients in making informed medical decisions. Guided decision aids help patients weigh pros and cons of options. This study involved the creation and evaluation of a guided decision aid for patients with follicular lymphoma, a disease with multiple complex treatment options. The aid was evaluated in a non-patient sample (30 males and 30 females, aged 40 to 79). Participants received either the guided decision aid or a comparison decision aid. Participants were asked to make a decision as if they were patients with follicular lymphoma by rating preference for each option and rank ordering treatment options before and after reading the materials. Decision satisfaction, decisional conflict, and knowledge of follicular lymphoma were assessed before and after reading the materials. Both groups showed a comparable increase in decision satisfaction, decrease in decisional conflict, and increase in knowledge after reading the materials. Thus, the decision aid was effective in improving the decision-making process. Both groups showed a change in preference for treatment options when rating treatment preference; however, only the comparison group showed a change in treatment preference when treatments were rank-ordered. Preference increased for watch and wait and biologic therapy and decreased for stem cell transplantation. The extent to which age, education, gender, depression, anxiety, need for cognition, and monitory/blunting predicted variability in satisfaction with decision and decisional conflict was examined. There were no significant predictors of residualized change in decision satisfaction; however, age significantly predicted residualized change in decisional conflict, and younger participants showed a decrease in decisional conflict. Analysis of the extent to which reading time and decision-making time predicted residualized change in knowledge suggested that longer reading times showed an increase in knowledge. These findings suggest that receiving information about follicular lymphoma effectively improved the decision-making process for a non-patient sample regardless of whether treatment preference changed. Additionally, the findings suggest that the guided decision aid may be more effective for younger ages.

ACKNOWLEDGEMENTS

There are many people without whom this project would not have been possible. First and foremost, I would like to thank my advisor and dissertation chair, Barry Edelstein, for being a wonderful mentor and friend. Your guidance, patience, humor, and kindness have been invaluable. You are a remarkable individual and an inspiration. There really are not enough words to express the full extent of my gratitude. Thanks for giving me a chance.

I would like to thank my committee members, Stan Cohen, Kevin Larkin, Amy Fiske, and Amy Combs-Lane, for all their advice and helpful comments. Their assistance helped not only shape this project, but also my skills as a researcher. I greatly enjoyed working with each of them.

Thank you to Solveig Ericson, Nathan Vishweshwar, and Aaron Cumpston for giving time in their very hectic schedules to offer their expertise about lymphoma, which was essential to the success of this project. Additionally, I would like to thank the brave patients with lymphoma who contributed tremendously to this project by sharing information about their cancer experience with me. For many, I know it was emotional to discuss.

I would like to acknowledge Mary and Jerry Lowery, Barb Kulas, Ronnie and Jane Dietrich, Jenny and Derik MacAskill, Ellie Griesel, and Elaine Headke for their help in participant recruitment and data collection.

Finally, thank you to my husband, Jon Lowery, for his love and support. Thank you to my mom, Nancy Sweeny, for always believing in me.

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Cancer accounts for 22.8% of all deaths. Out of all deaths, it is the second leading cause of death following heart disease (National Center for Health Statistics, 2004). Of the types of cancer, lung cancer is currently the leading cause of death in both men and women. Breast cancer is currently the most prevalent cancer in women, and prostate cancer is currently the most prevalent cancer in men. Lymphomas (cancers of the lymphatic system) are currently the fifth leading cancer in new cancer cases and the seventh leading cause of cancer-related death. There are two primary types of lymphoma: Hodgkin's lymphoma and non-Hodgkin's lymphoma (NHL). Of the lymphomas, NHL is the most prevalent (American Cancer Society, 2005).

NHL was estimated to account for 56,390 new cancer cases in 2005 and 19,200 deaths (American Cancer Society, 2005). The incidence rate of NHL has doubled since the 1970s. Some symptoms of NHL include fatigue, weight loss, enlarged lymph nodes, itching, night sweats, and fever. Types of NHL can be classified several ways including by stage of the disease (how far the disease has spread from the original site), speed of growth [indolent (slow-growing) versus aggressive (fast growing)], and location [contiguous (affected sites close together) versus non-contiguous (affected sites far apart)]. The most common type of NHL is diffuse large B-cell lymphoma (an aggressive disease), and the second most common is follicular (an indolent disease) (National Cancer Institute, 2005). Treatment for aggressive lymphomas typically involves more aggressive treatment measures with the goal of bringing the disease to remission. However, treatment of indolent lymphomas is more controversial. Patients are often faced with the decision of when to begin treatment of the disease, what type of treatment to use, when and if

to begin more aggressive treatment measures, and what treatment to choose when the disease recurs (Ansell & Armitage, 2005).

Treatment Decisions in Cancer

Patients with cancer often experience difficult decisions in selecting among treatment options. For example, patients with stage II prostate cancer can face several treatment options including surgical removal of the prostate (prostatectomy), watchful waiting, external radiation, or brachytherapy (radiation near the site of the tumor) (Holmes-Rovner et al., 2005). Patients with breast cancer who have had a mastectomy can face the decision of whether to receive additional chemotherapy (Peele et al., 2005).

Patients with follicular lymphoma may be treated with radiation, biologic therapy, combination chemotherapy, watch and wait, or a variety of clinical trials. When the disease relapses, patients have other treatment options from which to choose including bone marrow transplantation (Ansell & Armitage, 2005). Chemotherapy is a treatment in which a drug is transfused into the veins, often when the patient is first diagnosed (Gandhi & Marcus, 2005). This treatment is often well-tolerated in patients. There are several side effects including nausea, hair loss, fatigue, and mouth sores. Drugs are available to help ease side effects such as nausea (Leukemia & Lymphoma Society, 2006). Radiation therapy uses high-energy rays to target cancer cells (Leukemia & Lymphoma Society, 2006). Side effects include fatigue, decreased appetite, skin irritation, and bone marrow suppression; however, these side effects are often short in duration (Holman et al., 2004). Biologic therapy uses antibodies to target the cancer cells directly while leaving other cells alone (American Cancer Society, 2006). This treatment is associated with side effects such as fever, chills, nausea, and headache; however, these are

usually most prominent only during the initial treatment with the drug (Holman et al., 2004). Bone marrow stem cell transplantation is another option for some patients in which high-dose chemotherapy is given to the patient, which destroys much of the bone marrow. Bone marrow stem cells from a donor are then transfused into the blood (Cancer Facts, 2006). Stem cell transplantation offers a relatively safe way to deliver high dose chemotherapy and it can offer a potential cure for lymphoma. However, it is potentially associated with very serious risks. Patients can have a suppressed immune system for a long time, and some patients may develop graft versus host disease, a potentially fatal condition in which the body rejects the donor cells (Holman et al., 2004). Some patients may also explore clinical trials as a treatment option, which are research studies in which new treatment options are being tested. Patients may have access to some highly effective treatments through these studies; however, patients may not have a choice as to which treatment they will receive (Cancer Facts, 2006). Finally, since follicular lymphoma is a slow-growing cancer, patients may also have the choice of watching and waiting until symptoms of the disease become more prominent, without necessarily shortening their survival time. Patients would not need to worry about side effects since they are not actively being treated; however, they will require fairly frequent scans, medical tests, and examinations of the lymph nodes (Holman et al., 2004).

For follicular lymphoma patients, the treatment decision is difficult partly because of the number of treatment options from which patients must choose (Ansell & Armitage, 2005). Additionally, the decision can be difficult because patients are often faced with the choice of when and if to begin more aggressive treatment. When the disease recurs, patients may also be faced with a difficult choice because treatments used before may not work as well again. As

discussed in the last paragraph, the choice of whether to begin treatment may also be difficult because the treatment may not necessarily lengthen the survival time (Holman et al., 2004).

Several factors have been associated with cancer decision making that can make the decision process more difficult. These include a lack of knowledge of treatment options (Schapira et al., 1997) and decisional conflict, which is uncertainty about which option to choose (O'Connor, 1995). Other factors associated with decreased effectiveness in decision making include higher anxiety, inability to receive information, poor health, and fatigue (Saino et al., 2001).

Utility of Decision Aids in Cancer

There is no one accepted definition of a decision aid. For the purpose of this study, decision aid will be defined as any source of information such as pamphlets, audiotapes, counseling sessions, or videos that are designed to offer information to patients about medical disease and/or medical dilemmas to help patients make a medical decision. A guided decision aid will be defined as a source of information such as a pamphlet, audiotape, or video that not only offers information about medical disease and medical dilemmas, but offers exercises to help patients identify their values and deliberate between options according to their values. Guided decision aids are designed to educate patients about medical disorders and options and to assist in making informed, satisfactory decision that are consistent with their values.

Several decision aids have been created to increase patient knowledge about treatment options (Whelan et al., 2001; Whelan et al., 2004), decrease decisional conflict associated with the decision making process (Fiset et al., 2000; Whelan et al., 2004), increase the strength of preference for an option (Brundage et al., 2000), and increase satisfaction with the decision making process (Brundage et al., 2000; Molenaar et al., 2001; Onel et al., 1998; Sepucha et al.,

2000). The use of decision aids in selection of treatment for cancer is a fairly new area of research. These aids have been evaluated in breast cancer, prostate cancer, non-small cell lung cancer, ovarian cancer, and chronic myeloid leukemia. Other aids have been created (e.g., decision aids for leukemias), but have not been empirically evaluated.

There are several formats that have been used to relay treatment information to patients and to help guide the decision process. For example, decision boards have been created that typically utilize a large, blank foam board. Patients are read informational cards by the provider, and the cards are attached to the board with Velcro after they have been read (e.g., Whelan et al., 2004). Decision counseling or interviewing can also be used to help patients make a decision and to generate factors that are important in the decision making process (e.g., Feldman-Stewart et al., 2001; Sepucha et al., 2000). Other methods that have been used to relay information to patients include videotapes (e.g., Schapira et al., 1997), computer software (e.g., Molenaar et al., 2001), booklets (e.g., Fiset et al., 2000), and audiotapes (e.g., Goel et al., 2001).

Several strategies have been used to evaluate decision aids for cancer. Aids have been evaluated as to whether they help patients increase knowledge about the disease and treatment options (e.g., Brundage et al., 2000), decrease decisional conflict (e.g., Fiset et al., 2000), increase decision satisfaction (Whelan et al., 2003), influence quality of life (e.g., Molenaar et al., 2001), and whether they are acceptable (e.g., Levin et al., 1992). Several methods have been used to evaluate these aids including comparing the aids to a standard-of-care control group (e.g., Whelan et al., 2004) or comparing different media formats of the decision aid (e.g., Street et al., 1995). Some studies also have used pre-post measures of the constructs described above (e.g., Chapman et al., 1995). Most of the studies that will be described used patients as participants;

however, some studies used non-patients who made decisions about treatment as if they were patients. The principle purpose of this dissertation was to develop and evaluate a guided decision aid for patients with indolent follicular lymphoma.

Review of the Literature

The following section is an overview of current decision aids for treatment selection in cancer that have been utilized and evaluated. The aids are organized according to the type of cancer including breast cancer, prostate cancer, non-small cell lung cancer, ovarian cancer, and chronic myeloid leukemia. Several methodological criticisms are then offered.

Decision Aids in Breast Cancer

Several studies have examined the use of a decision aid in considering mastectomy versus lumpectomy treatments for breast cancer. Sepucha et al. (2000) conducted a pilot study to examine whether recording of a decision counseling session would increase satisfaction with the consultation and would increase the quality of the treatment decision in 24 patients with early-stage breast cancer. The counseling sessions included a 5-step agenda to prompt patients to provide reasoning for their views. Patient input was not used in the development of the agenda. Decision quality was measured using the Decision Quality Scale, which includes 10 Likert-type items (Howard, 1989). The authors stated that decision quality is based on "six elements;" however, these elements are not identified or defined (Sepucha et al., 2001, p. 1232). The authors found that the counseling group and the standard-of-care control group significantly increased the quality of the decision; however, the counseling group reported significantly higher decision quality. Molenaar et al. (2001) evaluated the extent that an interactive CDROM would impact the treatment decision, quality of life, and patient satisfaction in 180 breast cancer patients. A breast

cancer support group and medical team were involved in the creation of the CDROM. The researchers found that there was no difference between the CDROM group and the standard-of-care control group in the actual decision choice; however, the CDROM group was more satisfied with the decision. The CDROM group also had better quality of life directly following the decision aid, three months later, and nine months later. However, patients were allowed to choose which group in which they wanted to participate; thus, there may have been other characteristics that influenced the quality of life ratings. Street et al. (1995) compared the effects of a computer program to that of a brochure using 60 breast cancer patients. No patients were involved in the development of the computer program. The authors hypothesized that those using the computer program would learn more about breast cancer treatment, express more optimism about the future, and be more involved in decision making as compared to the brochure group. They found that overall knowledge about breast cancer treatment increased in both groups, but there was no significant difference between the two groups in the amount of knowledge gained. In addition, there was no difference between the groups on the amount of optimism expressed or the involvement in the decision. The authors also found that younger and more educated individuals were more involved in the decision-making process. However, the authors did not report findings of whether age or education influenced optimism or knowledge.

Other formats used in mastectomy/lumpectomy decisions have included audiotapes, videotapes, and decision boards. Goel et al. (2001) compared the effects of an audiotape/booklet decision aid to that of a pamphlet using 140 breast cancer patients. Both media contained the same information; however, only the audiotape/booklet contained photographs and values-clarification exercises. Only one patient was involved in the creation of the audiotape/booklet.

The authors hypothesized that use of the decision aid would decrease decisional conflict and increase breast cancer knowledge as compared to the pamphlet group. There was no significant difference found between the two groups. This study gathered some information about patient characteristics such as anxiety and employment status. The authors reported that a "trend" was evident in that those who preferred mastectomy or were undecided showed more of a decrease in decisional conflict after using the decision aid than those who preferred lumpectomy. A concern with this study was that multiple t-tests were conducted without adjusting alpha to control for family-wise Type I error. Chapman et al. (1995) examined whether 48 psychology and 34 nursing undergraduates who viewed a video decision aid would have more knowledge about breast cancer and different treatment preferences than those who used a booklet. The development of the decision aid video was not described. The authors found that for psychology undergraduates, the video decision aid group gained more knowledge as compared to the booklet group. For nursing students, there was no difference in knowledge between the video and the booklet groups. The authors did not assess knowledge of breast cancer before groups were given the materials; thus, it is unclear whether prior knowledge may have influenced the results. For both nursing and psychology undergraduates, the video groups showed greater preference than the booklet groups for lumpectomy. This study did not examine whether individual characteristics may have influenced decision-making. Whelan et al. (2004) compared the effects of a decision board decision aid to that of regular physician consult in 201 breast cancer patients. This decision board was made out of 20x26 inch foam core. Panels of information were covered by sliding doors, and the panels were revealed to the patient in sequence. It was not clear whether patients offered input into the creation of the board. The decision board group showed

higher knowledge of breast cancer treatment, lower decision conflict, and more decision satisfaction than the control group. However, the authors did not measure baseline scores of knowledge, decision conflict, and decision satisfaction, so it is unclear whether these groups may have differed prior to using the decision board.

Decision aids also have been developed to help patients make decisions related to adjuvant therapy, which is chemotherapy used in conjunction with breast removal surgery. Several decision boards have been created for this purpose. Whelan et al. (2003) and Levine et al. (1992) evaluated a decision board to help patients decide whether to use chemotherapy. Levine et al. (1992) examined the test-retest reliability and acceptability of the decision aid in 13 healthy volunteers, and acceptability in 37 breast cancer patients. The design of this board required a physician to read cards with information aloud to the patient. The patient then attached each card to the board after it was read. When finished, all information was on the board in front of the patient. The authors reported that this decision aid was piloted in a group of 6 patients to assess clarity and determine whether the information was related to the patient's prior experience; however, it was not clear how this was done. The authors found that in healthy adults, treatment preferences remained stable over a two week time period, indicating reliability of the aid. The 37 breast cancer patients reported that the aid was understandable and helped them make decisions; however, these results were not statistically analyzed and there was no control group for comparison. Individual patient characteristics were not examined to determine if they influenced the effectiveness of the decision aid. Whelan et al. (2003) studied whether the use of a decision board aid would increase knowledge and decision satisfaction when compared to a control group. The decision board was similar to the board described before in which cards

were read to the patient and then attached to the board. The authors did not discuss how the decision aid was developed. There were 176 breast cancer patients included in the study. The authors found that patients utilizing the decision board showed more knowledge and made more satisfactory decisions than patients who only received a medical consultation. However, knowledge and satisfaction were not assessed before the use of the decision board, so it was not clear whether these improved. Anxiety decreased equally for both groups. Whelan et al. (1995) created a similar decision board to help patients decide whether to use radiation therapy and compared this board to a regular physician consultation. A group of experts designed the aid. This decision board was initially shown to 10 healthy women and 16 patients to assess whether the information was clear and non-threatening. When they tested the aid using 82 patients, they found that the decision board group resulted in greater knowledge on a 10-item true/false quiz than the control group on only one question (i.e., that radiation could not be repeated in the same breast); however, the decision board group felt that they were offered more of a choice in the decision than the control group. Participant characteristics were not evaluated as predictors of effectiveness of the aid. Finally, Irwin et al. (1999) created a decision board to help increase patient comprehension of two chemotherapy regimens in 46 patients. Initially, 4 patients and 7 healthy women were given the aid to verify clarity. No description was offered as to how the aid was developed. The two treatment options were presented to 46 patients in two different orders. After the decision aid was administered, patients showed adequate knowledge of the treatment options. There was no difference in knowledge found between which treatment option was shown first. Knowledge was not assessed prior to the administration of the aid; thus, the initial

level of knowledge was not clear. The authors asked women why they made their respective treatment choices. Most women listed side effects or treatment schedules as reasons.

Decision Aids in Prostate Cancer

Several studies have examined decision aids in choosing prostatectomy surgery, radiation, or watchful waiting as treatments for prostate cancer. Onel et al. (1998) hypothesized that patients' knowledge of prostate cancer would increase following an informational tape in a group of 97 prostate cancer patients. They did not describe how this decision aid was developed. The authors found that that the subjective reports of knowledge about prostate cancer increased after viewing the video; however, no statistics were used to determine the significance of this increase. Additionally, there was no control group for comparison. The authors did not examine personal characteristics as predictors of increase in knowledge. Schapira et al. (1997) also examined the effects of an information video. Thirty-two men without prostate cancer viewed an informational video about prostate cancer and treatment options. Oncologists were involved in the creation of the decision aid. Patient focus groups were also used to determine topics for the decision aid that would be relevant to patients. The results showed that knowledge increased after viewing the videotape; however, there was no control group for comparison. Participant characteristics were not examined as predictors of the increase in knowledge.

Other studies have used an interview format as a decision aid for prostatectomy surgery, radiation, or watchful waiting. Feldman-Stewart et al. (2001) hypothesized that after using an interview decision aid, 69 participants never diagnosed with prostate cancer would identify attributes important in treatment selection and would identify preferred treatment options. They described the decision aid, but did not describe the method used in creating it. The authors found

that the participants were successful at identifying several attributes that were important to them in making a treatment decision and changed treatment preference while using the aid. The authors stated that they found that there were no participant personal characteristics associated with the findings; however, the authors did not clearly identify the characteristics that were analyzed. The authors did not assess the patients prior to use of the aid and did not use a control group for comparison. Davidson and Degner (1997) hypothesized that the use of an interview in decision making would decrease anxiety and depression in 60 men newly diagnosed with prostate cancer. The authors did not describe how this decision aid was developed. A control group of patients was given a pamphlet with comparable information. Neither the use of the decision aid nor the control pamphlet decreased anxiety or depression; however, in the decision aid group, patients reported that a list of questions to ask a physician was helpful in communicating with the physician. Anxiety and depression were not assessed as predictors of effectiveness of the decision aid.

One study used multiple media to create decision aids for choosing prostatectomy surgery, radiation, or watchful waiting. Holmes-Rovner et al. (2005) compared different media formats of a decision aid including an audiotape, a booklet, and the internet. In creating the decision aid, men with prostate cancer were interviewed to determine information important to include. Then, the aid was shown to a focus group to determine whether the information was confusing. The authors examined whether knowledge of prostate cancer differed among 60 men with prostate cancer using each of the three types of aids. No significant difference in knowledge was found between the groups. Those who used the audiotape were much less likely to share the

decision aid with their family. No individual characteristics were examined as predictors of effectiveness of the aid.

Decision Aids in Lung Cancer

Two studies have examined decision aids for the choice between radiation alone or a combination of chemotherapy and radiation in the treatment of non-small cell lung cancer. Brundage et al. (2001) hypothesized that an interview decision aid would increase patient knowledge, strengthen treatment preference, and decrease decisional conflict in a group of 27 patients. The authors did not describe how the decision aid was developed. The aid increased knowledge and decreased decisional conflict. Treatment preference was strengthened only for those that did not have a strong preference before the use of the aid. No control group was used for comparison. Brundage et al. (2000) created a decision board, which was a large board that described treatment choices for lung cancer and offered exercises to aid in treatment choice. The authors did not describe how the decision aid was created. The decision aid was given to a group of 18 patients with lung cancer. Although no hypotheses were stated, the results of the study indicated that use of the aid increased patient knowledge of lung cancer, increased the strength of treatment preference, and decreased decision uncertainty. No control group was used for comparison of these findings. The authors reported patient demographics, but did not examine participant characteristics that influenced effectiveness of the decision aid. Fiset et al. (2000) created a booklet/audiotape decision aid for deciding among radiation, chemotherapy, and supportive care. Oncologist experts were involved in the creation of the decision aid. The aid was then evaluated by 6 patients for content validity and acceptability. The aid was then given to 20 lung cancer patients. This combination of booklet and audiotape aid was expected to decrease

decisional conflict and decrease decision uncertainty. The results of the study supported these hypotheses. The authors also found a greater change in preference for treatment choice in those who were more undecided before using the decision aid. There was no control group used to compare the performance of the intervention group.

Decision Aids in Ovarian Cancer

Elit et al. (1996) created a decision board to help patients decide between chemotherapy options for advanced ovarian cancer. Similar to other decision boards, an oncologist read informational cards aloud to patients and then attached them to the board. In creation of the decision aid, the authors stated they observed patient interactions with oncologists and surveyed oncologists to determine important content. However, patients were not directly involved in the development of the decision aid. The decision board was used with 37 healthy women and 11 ovarian cancer patients. The authors stated that their goal was to examine the feasibility, comprehension, reliability, and validity of the aid. The authors reported that the validity of the aid was supported in that the patients' treatment choices were affected by the information offered on survival. The authors reported that interobserver reliability of the aid was supported in that two different observers achieved 100% agreement. The authors stated that these observers were observing "choice," but they were not clear in describing exactly what this meant. Scores on measures of anxiety did not change during administration of the aid. Participant characteristics were not examined as predictors of effectiveness of the aid.

Decision Aids in Leukemia

Only one published study (Sebban et al., 1995) has examined the effectiveness of a decision aid in the treatment of a blood cancer. A decision board aid was developed to help

patients with chronic myeloid leukemia choose between a bone marrow transplant and additional chemotherapy. The authors did not describe how the decision aid was developed. This aid was administered to 42 non-patients. The authors reported that they attempted to demonstrate construct validity of the aid in several ways. These included demonstration that manipulations of survival probabilities would create predictable changes in treatment choices (testing understanding of information as a determinant of choice), that choices in the decision aid group would differ from choices in the group that used a shorter version of the aid (testing impact of quantity of information on choice), that older individuals would make more conservative choices, and that participants would be more satisfied with their decisions in the decision aid group. All hypotheses were supported except that older individuals did not make more conservative treatment choices. Since the topic of this study is relevant to the current project, this study is described further in the Statement of the Problem section.

Methodological Critique

There are several methodological shortcomings in the research literature on decision aids for selection of cancer treatment. Several studies failed to describe the method used to create the decision aid (Brundage et al., 2001; Chapman et al., 1995; Sepucha et al., 2000; Street et al., 1995). This presents a problem in that it precludes replication and an examination of adequacy of content. Other studies did not utilize patient input in determining the content of the decision aid (Brundage et al., 2000; Davidson & Degner, 1997; Elit et al., 1996; Feldman-Stewart et al., 2001; Levine et al., 1992; Molenaar et al., 2004; Onel et al., 1998; Whelan et al., 1995; Whelan et al., 2003). This presents a problem in that the authors may have missed content that could have been useful for patients who were attempting to make a treatment selection. There were also

several studies that did not examine participant characteristics that may have influenced the effectiveness of the decision aid (Brundage et al., 2000; Brundage et al., 2001; Elit et al., 1996; Fiset et al., 2000; Holmes-Rovner et al., 2005; Onel et al., 1998; Schapira et al., 1997; Sebban et al., 1995). This presents a problem in this literature because participant characteristics may help determine for whom the aid would be most useful, and may also help in modifying the aids to benefit all types of patients. Finally, several studies failed to use a control group as a comparison, which precludes examination of whether the effects of the decision aid differ from or was superior to the effects of the regular standard-of-care (Elit et al., 1996; Feldman-Stewart et al., 2001; Holmes-Rovner et al., 2005; Irwin et al., 1999; Levine et al., 1992; Onel et al., 1998; Schapira et al., 1997).

Statement of the problem

Patients with cancer often experience difficult decisions in selecting among treatment options. For example, patients with breast cancer who have had a mastectomy can face the decision of whether to receive additional chemotherapy (Peele et al., 2005). Several factors have been associated with cancer decision making such as knowledge of treatment options (Shapira et al., 1997) and decisional conflict (i.e., uncertainty about which option to choose; O'Connor, 1995). Other factors associated with decreased effectiveness in participation in decision making include higher anxiety, inability to receive information, poor health, and fatigue (Saino et al., 2001).

Decision aids in cancer treatment selection have improved the decision making process by increasing patient knowledge about treatment options (e.g., Brundage et al., 2000; Brundage et al., 2001), decreasing decisional conflict associated with the decision making process (e.g.,

Brundage et al., 2000; Fiset et al., 2000), increasing the strength of preference for an option (e.g., Brundage et al., 2001), and increasing satisfaction with the decision making process (e.g., Brundage et al., 2000; Molenaar et al., 2001; Onel et al., 1998; Sepucha et al., 2000). However, as discussed previously , flaws were evident in several of these studies. Several studies failed to describe the method used to create the decision aid (e.g., Brundage et al., 2001; Sepucha et al., 2000), failed to utilize patient input in determining the content of the decision aid (e.g., Brundage et al., 2000; Molenaar et al., 2004; Onel et al., 1998), failed to examine participant characteristics that may have influenced the effectiveness of the decision aid (e.g., Brundage et al., 2000; Brundage et al., 2001; Onel et al., 1998), and failed to use comparison group (e.g., Onel et al., 1998). Thus, the results that support these decision aids are open to question.

Only one published study (Sebban et al., 1995) has examined the effectiveness of a decision aid in the treatment of a blood cancer. A decision board aid was developed to help patients with chronic myeloid leukemia choose between a bone marrow transplant and additional chemotherapy. The aid described scenarios of how BMT and chemotherapy were performed. Potential quality of life during each treatment and potential outcome of each treatment (i.e., morbidity and mortality) were also described. Forty-two participants (ranging in age from 23 to 61 years) that had never been diagnosed with leukemia were included in the evaluation of the aid. Participants were randomly assigned to a decision board group or a group that was given a shorter version of the information that had been offered in the decision aid. The latter group was considered a control group. A foam board was used to present the scenario cards. The cards were attached to the board once they were read by the patient. The first hypothesis was that manipulations of survival probabilities would create predictable changes in treatment choices

(testing understanding of information as a determinant of choice). This first hypothesis was examined in 16 of the participants; however, the authors failed to state their reasoning for using a smaller portion of their sample. The second hypothesis was that choices in the decision aid group would differ from choices in the group that used the shorter version (testing impact of quantity of information on choice). This hypothesis was supported. The third hypothesis, that older individuals would make more conservative choices, was not supported. The final hypothesis, that participants would be more satisfied with their decisions in the decision aid group, was supported.

It is unfortunate that there is only one published aid that has been evaluated for use in a blood cancer, as there are other blood cancers that involve difficult treatment decisions. The present study involved the creation of a guided decision aid for patients with follicular lymphoma. Follicular non-Hodgkin's lymphoma was previously discussed as a disease with multiple complex treatment options from which patients must choose (Ansell & Armitage, 2005). Patients often must make the decision of when to begin aggressive treatment and these patients must often choose among several options including radiation, biologic therapy, combination chemotherapy, watch and wait, or a variety of clinical trials. However, an empirically validated aid has not yet been created for this disorder. The purpose of this study was to create a guided decision aid for follicular NHL using the Ottawa Decision Support Framework (O'Connor et al., 1998). The format of this framework includes offering information about the disease, information about treatment options, and providing a method for patients to weigh options according to their specific values. Decision aids that have employed this framework have been empirically supported in several areas of medical decision making, including autologous blood

donation before surgery (Grant et al., 2001), discontinuation of cardiac arrest resuscitation (van Walraven et al., 2001), antithrombotic therapy for patients with atrial fibrillation (Man-Son-Hing et al., 2000), breast cancer prevention (Stacey et al., 2002), intubation in chronic obstructive pulmonary disease (Wilson et al., 2005), tube feeding (Mitchell et al., 2001), and treatment of lung cancer (Fiset et al., 2000). These aids have been empirically supported in that they have been shown to decrease decisional conflict, increase satisfaction with decision, and increase knowledge. Not only have decision aids created using this framework been empirically supported, this framework is also unique in that it describes a detailed method for creating a decision aid that will be useful to patients. The framework encourages the inclusion of experts and patients in the creation of the decision aid to ensure that the information will be accurate and relevant to patient needs. Additionally, this framework encourages patients to examine the available options according to their own values, which ensures that patients are making a choice that will be most suitable for them. Finally, the creators of the Ottawa Framework also evaluated the psychometric properties of measures used to evaluate the decision aid in terms of decision satisfaction and decisional conflict (Holmes-Rovner et al., 1996; O'Connor et al., 1995).

The goal of the present study was to develop and evaluate a guided decision aid for treatment selection in follicular lymphoma, which is the most common non-Hodgkin's lymphoma that has the highest potential for conflict among treatment options. Information for the decision aid was collected from a literature review of current treatment options, input from lymphoma patients, and input from oncologists that specialize in hematological malignancies.

The guided decision aid was evaluated in a non-patient sample, and participants were asked to make a decision about treatment as if they were a patient with NHL. Most of the studies

discussed earlier used patient samples to evaluate a decision aid. A few studies used non-patients with successful results. Chapman et al. (1995) found that psychology undergraduate students scored higher on measures of knowledge after watching a video than after reading a booklet; however, baseline knowledge was not assessed. Schapira et al. (1997) demonstrated that an aid increased knowledge of the disease and the treatment options, but did not utilize a comparison group. Feldman-Stewart et al. (2001) demonstrated that participants could identify attributes important to them after using the aid and treatment choice changed over the course of using the aid; however, there was no assessment at baseline and no comparison group was utilized. Additionally, the authors did not describe the method used in creating the decision aid. Elit et al. (1996) indicated that comprehension was high following use of the decision aid; however, baseline comprehension was not assessed and no statistics were utilized. Finally, Sebban et al. (1995) demonstrated that the treatment selection differed between groups that received a decision aid or a shortened version of the decision aid; however, the difference between the materials was not clear. There were several benefits to using a non-patient sample in this study. Since none of the patients in this study had been diagnosed with cancer, it omitted potential problems associated with any direct prior experience with cancer treatment. Additionally, since patients made decisions about treatment using a standard patient description, this allowed for control over the situation in which the decision was made.

Participant characteristics that may influence the effectiveness of decision aids were also explored. These factors had been largely ignored in the literature. A few studies examined how personal characteristics affected the decision-making process. Street et al. (1995) found that younger and more educated individuals were more actively involved in the decision-making

process. Goel et al. (2001) and Brundage et al. (2001) found that those who were initially undecided had a greater increase in treatment preference after using a decision aid. Sebban et al. (1995) found that older adults were not more likely to make conservative treatment selections. Other studies examined how the decision aid affected personal characteristics. Whelan et al. (2003) found that patient anxiety decreased over the course of using a decision aid; while Davidson and Dengler (1997) and Elit et al. (1996) found that anxiety and depression did not decrease over the course of using a decision aid. However, none of the studies examined participant characteristics as a predictor of effectiveness of decision aids.

Information about participant characteristics may be valuable in determining the characteristics of individuals for whom the aid would be most useful. This information also may be useful for modifying the proposed aid to maximize its effectiveness for the greatest number of potential users. The present study examined participant characteristics that could account for some of the variance in changes in ratings on decision satisfaction and decisional conflict. We were interested in the extent to which age, gender, education, trait anxiety, depression, monitoring/blunting, and need for cognition would be predictive of decision satisfaction and decisional conflict. Older patients prefer to receive less medical information and to take less of an active role in the decision-making process (Pinquart & Duberstein, 2004); thus, older individuals may be less satisfied and feel more uncertain about their decision. Those with higher education have tended to desire being more involved in the decision-making process (Funk, 2004), and may be more satisfied and less conflicted with their decisions after using the decision aid. Anxiety and depression are common psychological responses to cancer diagnoses (Block, 2006) that have been shown to have a negative effect on one's ability to participate effectively in

medical decisions (Saino et al., 2001; Thomas et al., 1999). Thus, it might be expected that those with higher anxiety and higher depression may experience less satisfaction and more decisional conflict than those with lower scores. Need for cognition is an "individual's tendency to engage in and enjoy effortful cognitive endeavors" (Cacioppo et al., 1984, p. 3). Individuals high in this characteristic may enjoy the acquisition of knowledge, the weighing of values, and the decision-making process more than those who are low in need for cognition. Finally, styles of coping including blunting (preference for distraction from stressful information) and monitoring (preference for attending to stressful information) may also be related to the effectiveness of the aid in that those who have a higher preference for distraction from stressful information may experience less satisfaction and more decisional conflict following exposure to potentially stressful information in the decision aid. Additionally, since the decision aid offers information about follicular lymphoma and its treatment options along with exercises to help participants make a decision, those with a higher desire for cognitive activity (higher scores on the Need for Cognition Scale) and those with a higher preference for information relating to a stressful situation (higher scores on the Miller Behavioral Style Scale) were expected to experience greater decision satisfaction and lower decisional conflict as a result of using the decision aid, as these groups are more likely to have a positive experience in dealing with the information included in the aid. We also examined how reading time and the time spent making the decision influenced knowledge gained from the decision aid. It was thought that those who spent more time reading the materials and deliberating about the decision might gain more knowledge about follicular lymphoma.

As discussed previously, blood cancers have been largely ignored in the decision aid literature. The focus of this study was to create and evaluate a decision aid for treatment selection in follicular NHL, a disease with multiple complex treatment options. This study is unique in comparison to the discussed literature in several other respects. Many of the described studies opted to use either a pre/post design or compared results of an experimental to a control or comparison group. These approaches enable one to not only examine whether variables change after use of the decision aid, but also how this change compares to that of a comparison group. The current study utilized both approaches. For the comparison group, this study used a shortened version of the guided decision aid, which was labeled a comparison decision aid. To create this pamphlet, portions of the guided decision aid were removed that were unique to the Ottawa Framework (e.g., weighing of pros and cons). This made the comparison decision aid more similar to a standard brochure. As discussed previously, our use of a non-patient sample allowed us to control for several factors including prior experience with treatment and the situation in which the decision was made. This study is also unique in our use of patient input into the creation of the decision aid. Several studies either asked patients what to include or asked patients to evaluate the content of the aid. We chose to do both, which ensured that we were getting optimum patient contribution to the creation of the decision aid. Finally, for the reasons described above, we chose to evaluate participant characteristics as predictors of effectiveness of the decision aid.

As discussed previously, decision aids in cancer treatment selection have improved the decision making process by increasing patient knowledge about treatment options (e.g., Brundage et al., 2000), decreasing decisional conflict (e.g., Brundage et al., 2000), increasing the

strength of preference for an option (e.g., Brundage et al., 2001), and increasing satisfaction with the decision (e.g., Brundage et al., 2000). However, results of some these studies arequestionable due to several flaws such as failing to describe the method used to create the decision aid (e.g., Brundage et al., 2001), failing to utilize patient input in content of the decision aid (e.g., Brundage et al., 2000), failing to examine participant characteristics that may have influenced the effectiveness of the decision aid (e.g., Brundage et al., 2000), and failing to use comparison group (e.g., Onel et al., 1998). Thus, the results that support these decision aids are open to question. Additionally, only one decision aid has been evaluated for treatment selection in a blood cancer (leukemia). The aim of the current study was to create and evaluate a guided decision aid for follicular NHL in a non-patient sample, while correcting for some common flaws in previous studies.

Hypotheses

Based upon the above discussion, the following hypotheses were examined in this study.

1. Total scores on the satisfaction with decision scale would increase in the guided decision aid group following use of the aid, more than the comparison group scores would increase following use of the pamphlet. This was hypothesized because several studies have demonstrated that use of decision aids increased scores on measures of decision satisfaction (e.g., Sepucha et al., 2000; Whelan et al., 2003; Whelan et al., 2004).
2. The guided decision aid group scores would decrease on the decisional conflict scale following use of the aid, more than the comparison group scores would decrease following use of the pamphlet. This was hypothesized because several studies have

demonstrated that use of decision aids decreased scores on measures of decisional conflict (e.g., Brundage et al., 2000; Brundage et al., 2000; Fiset et al., 2000; Whelan et al., 2004).

3. Total scores on the knowledge scale would increase following use of the guided decision aid more than the comparison group scores would increase following use of the pamphlet. This was hypothesized because several studies have demonstrated that use of decision aids increased scores on measures of knowledge (e.g., Brundage et al., 2000; Brundage et al., 2000; Schapira et al., 1997; Whelan et al., 2003; Whelan et al., 2004). Additionally, it was thought that since the guided decision aid group would also be completing written exercises to help make a decision, they would be spending more time reading and thinking about the materials, and would therefore likely retain more information.

Exploratory Questions of Changes in Treatment Preference.

1. Will there be an interaction between treatment options, time, and groups for ratings of preference? In other words, will ratings of preference for treatment options change across time for the guided decision aid group and/or the comparison group? It was expected that a significant interaction would indicate that preference for the treatment options changed more over time for the guided decision aid group than the comparison group. The direction of change in preference for each treatment could not be predicted because no other study has examined the effect of an aid on treatment preference in NHL. However, it was possible that initially patients would show higher preference for common cancer treatments such as chemotherapy and radiation, simply because these

treatments are more familiar. Then, after use of the decision aid, we expected that preference for familiar treatments would decrease, while preference for less familiar treatments such as biologic therapy would increase. We expected that the decision aid group would show a greater change in treatment preference than the comparison group because other studies have found significant changes in treatment preferences following the use of an aid (e.g., Feldman-Stewart et al., 2001; Sebban et al., 1995).

2. In addition to examining ratings of treatment preference, participants were also asked to rank the treatment options in order of preference. Ratings of treatment preference would show how strongly participants preferred each option, while rankings of treatment preference would reveal which treatments the participants would choose when selecting between the treatment options. The second exploratory question was as follows: Will there be an interaction between treatment options, time, and groups for rankings of preference? In other words, will rankings of preference for treatment options change across time for the guided decision aid group and/or the comparison group? It was expected that a significant interaction would indicate that preference for the treatment options changed over time for the guided decision aid group more than the comparison group. The direction of change in ranking for each treatment could not be predicted because no other study has examined the effect of an aid on treatment preference in NHL. However, as discussed above, it is possible that initially patients would rank common cancer treatments higher. Then, after use of the decision aid, we would see rankings for familiar treatments decrease, while preference for less familiar treatments such as biologic therapy increase. We expect that the guided decision aid

group would show a greater change in rankings than the comparison group because other studies have found significant changes in ranking of treatment following the use of an aid (e.g., Feldman-Stewart, 2001).

Exploratory Predictor Analyses. To extend knowledge of participant characteristics that may predict changes in decision satisfaction and decisional conflict scores following use of decision aids, an exploratory analysis was conducted. Participant characteristics that could account for some of the variability in change in total scores following use of the guided decision aid were examined as predictor variables including age, gender, education, anxiety, depression, need for cognition, and monitoring/blunting. We were also interested in exploring how much variability in knowledge gained from the guided decision aid that was accounted for by the time spent reading the decision aid and time spent making the decision. The following exploratory questions were examined in the guided decision aid group.

1. How much of the variance for change in satisfaction with decision was accounted for by each of the following: age, gender, education, anxiety, depression, need for cognition, and monitoring?
2. How much of the variance for change in decisional conflict was accounted for by each of the following: age, gender, education, anxiety, depression, need for cognition, and monitoring?
3. How much of the variance for change in knowledge was accounted for by each of the following: reading time and time spent making decision?

Method

The study was conducted in two phases. The first phase included the development of the guided decision aid and the second phase included the evaluation of the decision aid.

Phase I: Development

Participants

Fifty-one patients (26 males and 25 females) aged 18 and older who had experienced treatment for follicular NHL were asked to participate in the study. Twenty participants (10 males and 10 females) agreed to participate. These participants were recruited from a list of patients from the Hemotology/Oncology program at the Mary Babb Randolph Cancer Center in Morgantown, WV. Participants were randomly assigned to one of three groups: a decision aid input group, decision aid evaluation, and a scenario evaluation group. See Table 1 for a list of participants in each group. All participants were able to read.

Table 1

Number of Patient Participants per Groups

Group	Number of Participants	Males	Females
Decision aid input	9	4	5
Decision aid evaluation	6	3	3
Scenario evaluation	5	3	2

Measures

Guided Decision Aid. The decision aid was developed for patients with indolent follicular lymphoma who have experienced a recurrence of their disease and are now attempting to determine which treatment to use to bring the disease into remission and/or to prolong life (See Appendix A for a copy of the Guided Decision Aid). The decision aid was created based on the previously described Ottawa Decision Framework (O'Connor et al., 1998). First, the decision aid described the purpose of the aid. Then, information was included about the lymphatic system, Lymphomas, and follicular Lymphoma. Next, information about the treatment options for follicular NHL was described along with lists of the risks and benefits of the treatment options. The next section included questions to ask a physician about which treatments were available to the patient. An example of a patient making a decision about treatment was then described. Sources for additional information were then listed. The final section of the aid included value clarification exercises based on worksheets created by O'Connor and Jacobsen (2004). The exercises contained questions that helped patients explore values that were important to them in treatment selection and exercises to help patients weigh the pros and cons of each option. The format of the aid was a booklet.

Semi-Structured Interview. This was a five-item measure that was administered over the telephone. It included open-ended questions that assessed what information content was important to include in the content of each section of the decision aid and the content that was important to include in a scenario of a patient with follicular lymphoma (See Appendix B for questions included in this interview). This interview took about 15 minutes to administer.

Decision Aid Evaluation Questionnaire. This measure included Likert-type ratings and open-ended questions for each section of the decision aid that participants used to evaluate the content of the decision aid for the utility of each section of the decision aid (See Appendix C for this questionnaire). Utility was defined as the extent to which the patient believed that the informational content offered would be helpful in making a treatment decision. Sections of the decision aid that were created included the lymphatic system, lymphomas and follicular lymphoma, chemotherapy, radiation, biologic therapy, stem cell transplantation, watch and wait, and clinical trials. Likert-type questions were listed for each section related to usefulness, relevance, clarity, understandability, and applicability. Each item was rated from 1 (disagree) to 4 (agree). The scale also included open-ended questions for each section of the decision aid regarding items participants thought should be added, deleted, or modified.

Patient Demographic Questionnaire. This questionnaire was a measure created by the investigator to gather information on sociodemographic characteristics including age, gender, race, and education (See Appendix D for a copy of this scale).

Patient Scenario. This was a description of a patient with recurrent follicular lymphoma who needed to make a decision about treatment (See Appendix E for a copy of this scenario). The scenario described the patient's age, gender, type of lymphoma, length of time in remission, marital status, children, and the current treatment options that the patient was considering.

Patient Scenario Evaluation Questionnaire. This questionnaire was designed by the investigator to request patient input about the previously described patient scenario (See Appendix F for a copy of this questionnaire). Patients were asked to rate the believability of the patient scenario on

a scale of 1 (not very believable) to 4 (very believable). Patients were also asked open-ended questions about what aspects of the scenario they felt should be added, deleted, or modified.

Procedures

The development of the guided decision aid involved several steps. First, thirteen patients (7 males and 6 females) were mailed a consent form, the patient demographic questionnaire, a form for the patient to fill in his or her name and convenient times to be telephoned, and a stamped envelope with the researcher's address. Patients were requested to complete and mail all materials to the researcher if interested in participating the study. If the researcher did not receive materials within one week, patients were telephoned by the researcher to ask if they had questions about the study. Nine patients (4 males and 5 females) agreed to participate and were administered the semi-structured interview by the investigator over the telephone. Once important information to include in the aid was determined through these interviews, literature on available treatments for the recurrence of NHL was reviewed. Then, the decision aid was created using the information from the interviews and the literature review according to the format described above.

After the guided decision aid was created, it was evaluated for face validity and content validity by two oncologists and one pharmacist who specialized in hematological malignancy. The content of the decision aid was then altered according to their recommendations.

Next, the decision aid, patient demographic questionnaire, and the decision aid evaluation questionnaire were mailed to 28 patients (15 males and 13 females) who had not yet participated in the study. These participants were asked to evaluate the utility of the decision aid based on the questions on the decision aid evaluation questionnaire. Participants were asked to return the

patient demographic questionnaire and the decision aid evaluation questionnaire to the investigator in a self-addressed stamped envelope. If materials were not received from the participants within one week after mailing, the investigator telephoned the patients to determine if they had questions about the materials. Six participants (3 males and 3 females) returned the questionnaires. Comments from the patients on the decision aid evaluation questionnaire were used to modify the decision aid accordingly.

Finally, a scenario of a patient who was attempting to make a decision about treatment for recurrent follicular lymphoma was created based upon information obtained in a literature review, input from an oncologist specializing in the study of hematological malignancies, and input from patients in the semi-structured interview. This scenario was used in the second phase of the study as a basis for treatment decisions. The scenario described the patient's age, gender, type of lymphoma, length of time in remission, marital status, children, socioeconomic status, and the current treatment options that the patients was considering. This scenario was mailed to 10 patients (4 males and 6 females) who had not yet participated in the study along with the patient demographic questionnaire and patient scenario evaluation questionnaire. Participants were asked to complete and return the patient demographic questionnaire and the patient scenario evaluation questionnaire to the investigator in a self-addressed stamped envelope. If materials were not received from the participants within one week after mailing, the investigator telephoned the patients to determine if they had questions about the materials. Five participants (3 males and 2 females) returned the questionnaires. Comments from the patients on the patient scenario evaluation questionnaire were used to modify the patient scenario accordingly.

Phase II: Non-patient Evaluation

Participants

Seventy-two community-dwelling adults (38 males and 34 females) aged 40 to 80 years who had never been diagnosed with cancer were asked to participate in this study. This age group was chosen because the incidence for NHL is highest during this age period (National Cancer Institute, 2002). Sixty participants (30 males and 30 females) ages forty to seventy-nine agreed to participate in the study. As discussed previously, the reason that participants were chosen who had never been diagnosed with cancer was that this allowed for some control over variability contributed by participant knowledge of NHL and emotional responses to the cancer diagnosis. All participants were able to read and write. Participants were assigned randomly to either an experimental group that received the guided decision aid created in Phase I, or a comparison group that received the comparison decision aid.

Measures

Comparison Decision Aid. The comparison decision aid was designed to be similar to the "standard of care" brochure that patients might receive in a hospital. No brochures were available specifically for follicular lymphoma; thus, the guided decision aid was pared down to include information that one might find in such a brochure (See Appendix G for a copy of the Comparison Decision Aid). The comparison decision aid has the same structure as the decision aid with several sections removed. The comparison decision aid does not include the purpose of the aid, lists of the risks and benefits of the treatment options, questions to ask a physician, an example of a patient making a decision about treatment, or value clarification exercises.

Decisional Conflict Scale. The Decision Conflict Scale is a nine item rating scale of decision uncertainty (O'Connor, 1995). According to the creators of this scale, decisional conflict is "a state of uncertainty about the course of action to take" (O'Connor, 1995, p. 25). The rating scale consists of three sections: decision uncertainty, factors contributing to uncertainty, and perceived effective decision making. Each item is rated on a scale from 1 (strongly agree) to 5 (strongly disagree) and negative items are reverse scored. Higher scores indicate greater decisional conflict. When completing the scale, participants were asked to reflect on the decision they just made. This scale has been psychometrically evaluated in patients making decisions about breast cancer screening and influenza immunization (O'Connor, 1995). In this evaluation, the decision conflict scale was shown to have adequate test-retest reliability ($r = 0.81$), internal consistency for the total scale (alpha ranged from 0.78 to 0.92), and internal consistency for the subscales (alpha ranged from 0.58 to 0.92). The authors also reported that the scale had high discriminant validity in that scores were significantly higher on most subscales for individuals who were unsure of their decision than individuals who had accepted or rejected the influenza immunization or cancer screening. This instrument was chosen because it has been frequently used within the cancer decision aid literature to measure for treatment decision uncertainty and because it has been shown to have psychometrically sound properties (O'Connor, 1995).

The Satisfaction with Decision Scale. This scale was designed as a global measure of satisfaction with a decision (Holmes-Rovner et al., 1996). The Satisfaction with Decision Scale is a 6 item measure that asks participants to rate each item on a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). Higher scores indicate higher satisfaction with the decision. This scale was evaluated for discriminant validity in women considering hormone replacement

therapy (Holmes-Rovner et al., 1996). The authors examined the relation between the scale and seven measures of decision uncertainty, provider satisfaction, decision confidence, and knowledge. The authors found that the scale scores correlated poorly with scores of scales measuring knowledge (r = 0.22) and provider satisfaction (r = 0.2). The scale was moderately inversely related to the decisional conflict scale scores (r = -0.54) and was moderately related to decision confidence (r = 0.64). The authors determined that the Satisfaction with Decision Scale measured a unique construct in decision making because the scale items showed much higher correlations among themselves as compared to items from other measures of decision making. This scale was chosen to measure how satisfied participants were with their treatment selection and because there is evidence to support its validity (Holmes-Rovner et al., 1996).

Ratings and Rankings of Treatment Preference. This scale was created by the investigator (See Appendix H for a copy of this scale). This scale listed each of the treatment options mentioned in the decision aid and asked the participants to rate each treatment on a 4-point Likert-type scale. The ratings were anchored thusly: 1 = would not prefer, to 4 = would definitely prefer. This scale was used as a measure of the strength of preference for each treatment option. The scale then asks participants to rank the treatment options in order from 1 = best to 6 = worst.

Knowledge Test. This test was created by the investigator to evaluate knowledge of the content of the guided decision aid and comparison decision aid (See Appendix I for a copy of this questionnaire). The test consisted of twenty multiple choice questions based on each informational content area of the guided decision aid and comparison decision aid. This measure did not include questions related to lists of risks and benefits, questions to ask the doctor, resources, or the patient example. The test was evaluated by two oncologists and one pharmacist

to determine whether the information in the questionnaire was representative of the information presented in the guided decision aid and comparison decision aid. Before administration to participants, this test was evaluated with ten psychology graduate students. The graduate students scored an average of 10.2 (SD = 3.55) before reading the decision aid and an average of 15.8 (SD = 2.44) after reading the decision aid. There was a significant increase in scores (t = -4.36, p < .05), which indicated that the knowledge test was an adequate measure of knowledge gained following reading of the decision aid.

Sociodemographic Questionnaire. This questionnaire was a measure created by the investigator to gather information on sociodemographic characteristics including age, gender, race, and education (See Appendix J for a copy of this scale). The questionnaire also asked participants whether they know someone with cancer, know someone with lymphoma, or have helped someone make a decision about treatment for cancer.

Spielberger Trait Anxiety Inventory (STAI-Trait). This inventory is a measure of trait anxiety, which is the individual's general level of anxiety in response to stressful situations (Spielberger, 1983). The scale includes 20 items on which patients are asked to rate their "general feeling" on a 4 point Likert-type scale from 1 (almost never) to 4 (almost always). Higher scores indicate greater trait anxiety. This scale was evaluated for internal consistency in 391 college students (Tanaka-Matsumi & Kameoka, 1986). The scale showed adequate internal consistency with a Cronbach's alpha value of .90. The authors also found that total scores on this scale correlated with total scores on other measures of anxiety (r = .38 to .72). The total scale score was also shown to correlate with total scores on other measures of anxiety in a sample of older adults (r = .43 to .57; Stanley et al., 1996). This scale also showed high test-retest reliability in this sample

(r = .84). This scale was chosen because it is a widely used measure of trait anxiety and because it has been shown to have psychometrically sound properties.

Center for Epidemiologic Studies Depression Scale (CES-D). This scale is a measure of general depression (Radloff, 1977). The CES-D is a 20-item measure in which participants indicated on a Likert-type scale how often they experienced symptoms within the last week from 0 ("rarely or none of the time") to 3 ("most or all of the time"). Four of the items are reversed scored. Higher scores indicate more depressive symptoms. This scale was evaluated for internal consistency in 117 cancer patients and 62 healthy adults (Hann et al., 1999). The scale showed internal consistency with a Cronbach's alpha of 0.89 in patients and 0.87 in healthy adults. Test-retest reliability over 2.5 weeks was also adequate (r = 0.57 in patients and r = 0.51 in healthy adults). The authors also found that the CES-D correlated negatively with a measure of mental health functioning (r = -.065 for patients and r = -.67 for healthy adults). This measure was chosen because it is a widely used measure of depression and because of its sound psychometric properties.

Need for Cognition (short form). This scale was designed to measure an individual's desire to engage in effortful cognitive activity (Cacioppo et al., 1996). The scale is an 18-item measure on which participants are asked to rate statements of desire for cognitive activities on a 5-point Likert-type scale from 1 (extremely uncharacteristic) to 5 (extremely characteristic). Nine of the items are reversed scored. Higher scores indicate greater need for cognition. Internal consistency values for this scale range from a Cronbach's alpha of .65 to .97 (Cacioppo et al., 1996). The scale has also been examined for discriminant validity and has been shown to correlate poorly with measures of other constructs (values of r ranging from -.45 to -.08). Also, this scale has

been shown to correlate with other measures of cognitive motivation (r = .20 to .51). This scale was chosen because it is a widely used measure of desire for cognitive activity and because there is some evidence of its psychometric properties.

Miller Behavioral Style Scale (MBSS). This scale was designed to measure two styles of coping with stressful information including blunting (preference for distraction from stressful information) and monitoring (preference for attending to stressful information) (Miller, 1987). Participants were asked to imagine four stressful scenes. Following each scene, participants were asked (yes/no) whether they would respond in the manner indicated in each of eight statements (4 monitoring statements and 4 blunting statements). The scale results in two subscale scores, one of monitoring and one of blunting. Higher scores on each subscale indicate higher levels of each coping style. A total score can then be calculated by subtracting the blunting subscale score from the monitoring subscale score. Higher total scores indicate more monitoring behavior. This scale showed adequate test-retest reliability over a 4 month time period (r = .72 for the monitoring subscale and r = .75 for the blunting subscale; Miller, 1987). This scale has also been shown to correlate moderately with a measure of a similar construct (r = .32; Ludwick-Rosenthal et al., 1993). This scale has also been shown to correlate poorly to moderately with measures of other constructs (r = -.28 to .2). The authors suggest using the monitoring subscale in research involved with this questionnaire, as this has shown the best predictive ability; thus, the monitoring subscale was used in analyses in the current study. This scale was chosen because it is a widely used measure of stressful information coping style and because there is some evidence of its psychometric properties.

Opinion of the Decision Aid. This questionnaire was designed by the investigator to determine what aspects of the decision aid were most and least helpful to the decision-making process. See Appendix K for a copy of this questionnaire. This questionnaire included two open-ended questions that asked participants to report the aspects they felt were most and least helpful.

Procedure

Participants were recruited from churches, clubs, and by word of mouth in Winona, MN. Data collection took place at churches or homes, depending upon what was convenient for each participant. Directly before data collection, the study protocol was described to the participants by the investigator and written informed consent was gathered at that time. Participants were asked to fill out the study materials described below after the protocol had been described to them by the investigator. The investigator was nearby to answer any questions.

First, the participants were instructed to complete the sociodemographic questionnaire, State Trait Anxiety Inventory, Need for Cognition Scale, Center for Epidemiologic Studies Depression Scale, and Miller Behavioral Style Scale. Then, the participants were instructed to read the patient scenario (as described in Phase I). They were asked to make a treatment selection as though they were the person described in the scenario. Participants completed the first set of questionnaires, which included the knowledge test, ratings and rankings of treatment preference, satisfaction with decision scale, and the decisional conflict scale. Once these materials were completed, they were collected from each participant. Then, the participants were given and instructed to either read and complete the guided decision aid or the comparison decision aid depending upon group. Participants were asked to record the time they began to read the materials and the time they stopped reading the materials. Those in the guided decision aid

group were also instructed to complete the value clarification exercises at the end of the aid. Once the participants had finished with the guided decision aid or the comparison decision aid, these items were collected from them. Finally, the participants were given and asked to complete the second set of questionnaires, which included the ratings and rankings of treatment preference, knowledge test, satisfaction with decision scale, and the decisional conflict scale. Participants were asked to record the time that they finished the ratings and rankings of treatment preference. For the pre and post decision aid questionnaires, the order of the satisfaction with decision scale and the decisional conflict scale were randomized to preclude order effects. Participants in the decision aid group were also asked to complete the opinion of the decision aid questionnaire.

Participants were offered the opportunity to fill out a raffle ticket for a drawing that took place once all data were collected. The participants had the opportunity to win either a one-hundred dollar check or a twenty-five dollar gift certificate to Culver's restaurant. Once data collection was completed, winning raffle tickets were drawn randomly and winners were notified via telephone. Each participant was offered a wristband from the Leukemia and Lymphoma Society.

Design, Analysis, and Data Management

A pre/post design was used to detect change in scores on measures of decisional conflict, decision satisfaction, and knowledge. Total scores on the first three measures before and after using the guided decision aid or comparison decision aid were compared. A mixed 2 (group) X 2 (time) ANOVA was used to detect these changes. For each ANOVA, time was the within subject variable (pre-post), while group was the between group variables (decision aid and pamphlet).

Additionally, the treatment preference ratings for each of the six treatment options before and after using the decision aid or pamphlet were compared. Treatment preference rankings for each of the six treatment options before and after using the decision aid or pamphlet were also compared. A mixed 2 (group/between) X 2 (time/within) X 6 (treatment options/within) ANOVA was used to detect these changes.

To determine the sample size for these analyses, a power analysis was performed for repeated-measures ANOVA. This analysis revealed that the current sample size was sufficient for a power of 80% ($p = .05$) and an effect size of $f = .40$ (as used by Goel et al., 2001).

To extend knowledge of participant characteristics that may predict changes in scores following use of decision aids, exploratory analyses were conducted. Participant characteristics that could account for some of the variability in change in total scores following use of the guided decision aid were examined as predictor variables in a stepwise multiple regression analysis. Age, gender, and total scores on the STAI-Trait, CES-D, Need for Cognition Scale, and monitoring subscale of the MBSS were used as predictors. Scores on the decisional conflict scale and the satisfaction with decision scale served as criterion variables in two multiple regression analyses. Time spent reading the guided decision aid and time spend making the decision were also examined as potential predictors in a third stepwise multiple regression analysis. Total scores on the knowledge questionnaire served as the criterion variable in this analysis. Raw change scores as well as residualized change scores served as criterion variables in the multiple regression analyses.

Out of 60 participants in Phase II, only two participants had missing data. Both participants were from the guided decision aid group. One participant did not answer one

question on the CES-D; while the other did not answer one question on the CES-D and one question on the STAI-Trait. It appeared that these items were accidentally missed. For these participants, missing scores were replaced with the mean score for the items on the respective measure.

Results

The results of this study are divided into two phases. Phase I includes information related to the patient participation in the development of the guided decision aid. Phase II includes results of the evaluation of the guided decision aid in a non-patient sample.

Phase I

Phase I is divided into four sections. First, demographic information of the participating patients is described. Then, results of interviews with participants regarding material to include in the decision aid is then presented. Next, participants' evaluations of the patient vignette are described. Finally, participants' evaluations of the guided decision aid are presented.

Demographic Information for Patient Participants

Participants included 20 adults, 10 males and 10 females, who had been diagnosed with follicular lymphoma (*M* age = 61.85, SD = 8.399; please see Table 2 for participant demographic information). All participants were Caucasian. Most participants were moderately educated with either a high school degree (30%) or some college education (30%). Many participants had not graduated high school (25%). Several participants were highly educated and either graduated college (5%) or attended graduate school (10%).

Table 2

Demographic characteristic of Patient Participants

Variable	
Number of patients	20
Age [*Mean* (*SD*)]	61.85 (8.39)
Gender	
Male	10
Female	10
Ethnicity	
Caucasian	100%
Education	
Some high school	25%
High school grad	30%
Some college	30%
College grad	5%
Graduate school	10%

Interviews with Participants Regarding Content of Decision Aid

Before the decision aid was written, participants were telephoned and interviewed to discuss content they felt was important to include in the decision aid. Nine participants (4 males and 5 females) participated in telephone interviews. Participant responses to the interview questions are listed in Appendix L. Generally, participants offered a variety of opinions related to their individual situations. Regarding information participants believed was important to include about the disease, common responses included information about symptoms of the disease and how quickly the disease spreads. Several common responses regarding information about

treatment options included information about side effects, lengths of procedures, and both risks and benefits of treatments. Participants offered a variety of questions that one might consider asking a physician. Several common themes for questions included side effects of treatments, procedure of treatments, and effects of the treatments on the body. Regarding format of the decision aid, most participants felt that pictures and patient examples would be helpful. Most felt that there should be a combination of listed and paragraph information. There was a range of preferred lengths of the decision aid, which ranged from four pages to twenty pages. Common participant suggestions were considered in development of the decision aid.

Participants were also interviewed regarding information they thought would be helpful to include in a patient vignette. Again, a variety of information was suggested. Common themes suggested by participants included describing family information, extent of patient disease, and treatments available. These suggestions were incorporated into the creation of the patient vignette.

Evaluation of Patient Vignette

Five patient participants (3 males and 2 females) responded to a questionnaire requesting feedback on the accuracy and believability of the patient vignette. Patients were asked to report how believable they found the patient vignette, using a 4-point rating scale, where 1= not very believable and 4= very believable. The mean rating of believability was 3.8 (SD = .45), which indicates that most participants felt the patient vignette was very believable. Participants were also asked to provide feedback regarding changes that should be made to the vignette to make it more believable. Participant feedback is found in Appendix M. The most common suggestion given by participants was to include more information about treatment options; however, this

information was purposefully excluded from the patient vignette because this information was presented in the decision aid and comparison group pamphlet. Other information suggested was incorporated in the patient vignette such as whether insurance would cover options.

Evaluation of Decision Aid

Six patient participants (3 males and 3 females) responded to a questionnaire evaluating the accuracy and utility of the decision aid. Participants rated how much they agreed with statements about the sections of the decision aid on a 4-point scale, where 1= disagree and 4= agree. The sections were the lymphatic system, lymphoma and follicular lymphoma, chemotherapy, radiation, biologic therapy, stem cell transplant, watch and wait, and clinical trial. Each section had a highest possible score of twenty. Overall, participants gave high ratings for all sections of the decision aid, indicating that patients felt the sections were useful and accurate (see Table 3). Suggestions made by participants regarding the content of the decision aid are listed in Appendix N. Several participants did not make suggestions for changes to the decision aid. A common suggestion was to make the lymphatic system diagram larger, and thus a larger diagram was incorporated in the decision aid. Other responses were quite varied and appeared to represent specific preferences of each rater. All responses were considered in the final Decision Aid product.

Table 3

Mean Ratings of Accuracy and Utility of Decision Aid Organized by Section of the Decision Aid

Section	Mean Rating (SD)
Lymphatic System	19.17 (.98)
Lymphoma and Follicular Lymphoma	19.50 (.84)
Chemotherapy	19.60 (.89)
Radiation	19.40 (1.34)
Biologic Therapy	19.33 (1.03)
Stem Cell Transplant	19.80 (.45)
Watch and Wait	18.33 (4.08)
Clinical Trial	18.00 (2.00)

Phase II

Phase II addresses results related to the evaluation of the guided decision aid and is divided into several sections. The first section addresses demographic information related to the non-patient sample. Next, results related to three hypotheses evaluating change in Satisfaction with Decision, Decisional Conflict, and Knowledge of Follicular Lymphoma are described. Results related to exploratory analyses are then described that evaluate change in Ratings of Preference for Treatment Options and Ranking of Preference for Treatment Options across time and between the decision aid and comparison groups. Results related to exploratory analyses of predictors of changes in Satisfaction with Decision scores and Decisional Conflict scores are then presented. Finally, results of exploratory analyses of reading time and decision time as potential predictors of change in knowledge scores are then described. Alpha was set at the .05 level for all analyses.

Demographics

Participants included 60 adults (30 males and 30 females) aged 40 to 79 years (M = 55.35, SD = 9.19; see Table 4 for participant demographic information). All participants were Caucasian. The participants were highly educated, and all participants received at least a high school diploma. Most of the participants had obtained at least some college education (23.3% had attended some college and 26.7% were college graduates). The largest percentage of participants had attended graduate school (38.3%). A small percentage had received only a high school diploma (11.7%). All participants had some prior experience with cancer in that all participants knew someone with cancer. Forty percent of participants knew someone with lymphoma, and 30% had helped someone make a decision about treatment for cancer.

Table 4

Demographic characteristics, Participant experience with cancer

Variable	Decision Aid Group	Comparison Group	All
N	30	30	60
Age [*M* (*SD*)] [a]	59.03 (9.14)	55.67 (9.09)	57.35 (9.19)
Male	15	15	30
Female	15	15	30
Ethnicity			
Caucasian	100%	100%	100%
Education[b]			
Some high school	0	0	0
High school grad	10%	13.3%	11.7%
Some college	23.3%	23.3%	23.3%
College grad	26.7%	26.7%	26.7%
Graduate school	40%	36.7%	38.3%
Knew someone with cancer			
Yes	100%	100%	100%
No	0%	0%	0%
Helped make cancer[b] treatment decision			
Yes	23.3%	36.7%	30%
No	76.7%	63.3%	70%
Knew someone[b] with lymphoma			
Yes	33.3%	46.7%	40%
No	66.7%	53.3%	60%

[a] A two-tailed t-test revealed no significant age differences between groups ($t = 1.43$, $p = .158$). [b]A chi-square test revealed no significant differences between groups regarding education [$\chi^2(3) = .186$, $p = .98$], number who helped make a cancer decision [$\chi^2(1) = .1.27$, $p = .26$] , and number who knew someone with lymphoma [$\chi^2(1) = 1.11$, $p = .29$].

Hypothesis 1: There will be a significant interaction between groups and time for satisfaction with decision. The guided decision aid group was hypothesized to have a greater increase in satisfaction with decision than the comparison group.

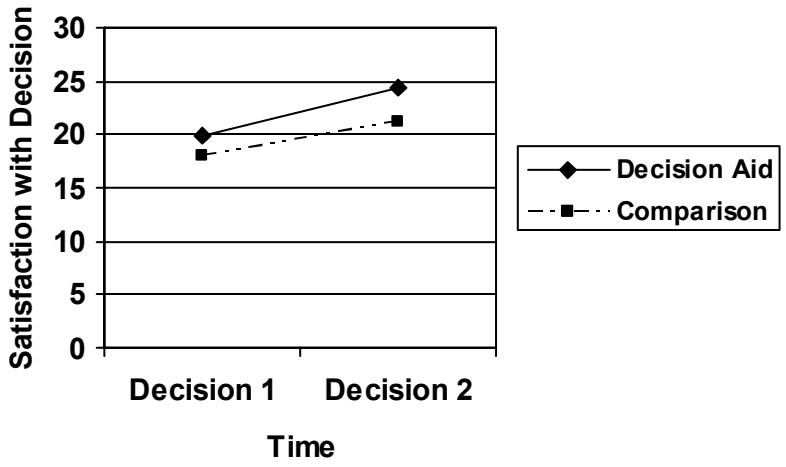
The results of a Mixed 2 (groups) x 2 (time) ANOVA revealed increases in satisfaction with decisions for both the guided decision aid and comparison groups [F (1, 58) = 51.2, p < .001; see Table 5 for results]. However, hypothesis 1 failed to be supported. No interaction was found. Thus, increase in satisfaction with decision for the guided decision aid group was no greater than that of the comparison group [F (1, 58) = 1.78, p = 0.187]. Means for Satisfaction with Decision are displayed in Figure 1. There was a significant main effect for group [F (1, 58) = 5.71, p < .05].

Table 5

Mixed ANOVA, Satisfaction with decision difference between decision aid and comparison groups across time

Source	*df*	*F*	η^2	*p*
		Within Subjects		
Time	1	51.2	0.47	<.001
Time*Group	1	1.78	0.03	0.187
Within Error	58	*MS* = 9.06		
		Between Subjects		
Group	1	5.71	0.09	0.02
Between Error	58	*MS* = 32.8		

Figure 1. Satisfaction with Decision for Decision Aid and Control Groups across Time



Hypothesis 2: There will be a significant interaction between groups and time for decisional conflict. The guided decision aid group was hypothesized to have a greater decrease in decisional conflict than the comparison group.

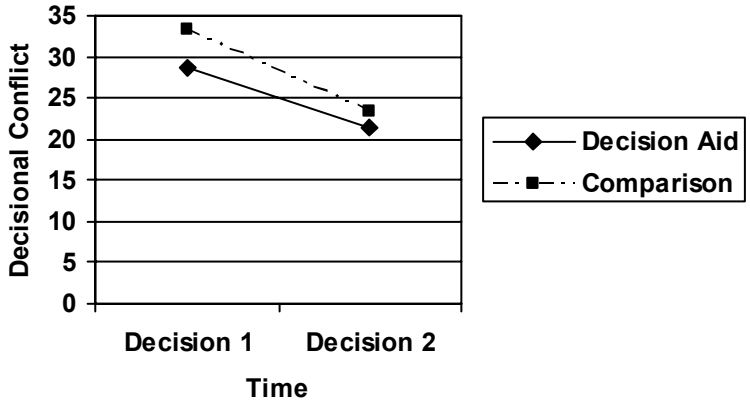
The results of a Mixed 2 (groups) x 2 (time) ANOVA revealed a main effect for time [F (1, 58) = 96.9, $p < .001$; see Table 6 for results]. Decisional conflict decreased significantly for both groups. However, hypothesis 2 was not supported. No interaction was found between the groups and time. Thus, decisional conflict did not decrease significantly more for the guided decision aid group than the comparison group [F (1, 58) = 1.84, $p = 0.18$]. Means for decisional conflict across time for both groups are presented in Figure 2. There was a significant main effect for group [F (1, 58) = 5.05, $p < .05$].

Table 6

Mixed ANOVA, Decisional Conflict difference between guided decision aid and comparison groups across time

Source	*df*	*F*	η^2	*p*
		Within Subjects		
Time	1	96.9	0.63	<.001
Time*Group	1	1.84	0.03	0.18
Within Error	58	*MS* = 22.82		
		Between Subjects		
Group	1	5.05	0.08	0.028
Between Error	58	*MS* = 65.39		

Figure 2. Decisional Conflict for Decision Aid and Control Groups across Time



Hypothesis 3: There will be an interaction between groups and time for knowledge. The guided decision aid group would have a greater increase in knowledge than the comparison group.

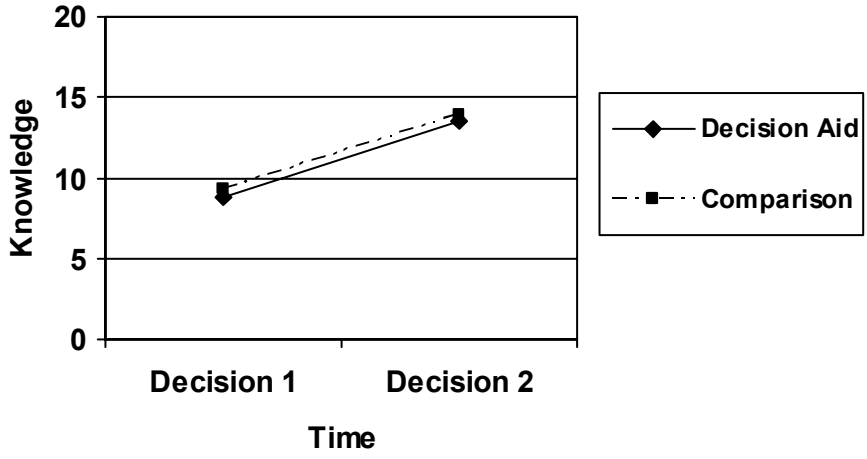
A Mixed 2 (groups) x 2 (time) ANOVA yielded a main effect for time [F (1, 58) = 143.46, $p < .001$; see Table 7 for results]. Thus, knowledge increased significantly after reading the guided decision aid or comparison group pamphlet. However, hypothesis 3 was not supported. No interaction was found between time and groups, suggesting that knowledge did not increase more for the guided decision aid than the comparison group [F (1, 58) = 0.03, p = 0.87]. Means for knowledge across time for both groups are presented in Figure 3.

Table 7

Mixed ANOVA, Knowledge difference between guided decision aid and comparison groups across time

Source	*df*	*F*	η^2	*p*
		Within Subjects		
Time	1	143.46	0.71	<.001
Time*Group	1	0.03	0.00	0.87
Within Error	58	*MS* = 9.06		
		Between Subjects		
Group	1	0.34	0.006	0.56
Between Error	58	*MS* = 14.2		

Figure 3. Knowledge for Decision Aid and Control Groups across Time



Exploratory Treatment Preference Analysis 1: Will there be an interaction between treatment options, time, and groups for ratings of treatment preference? In other words, will ratings of preference for treatment options change across time for the guided decision aid group and/or the comparison group?

Participants were asked to rate their preference for each of the six treatment options on a 4-point scale (1 = would not prefer and 4 = would definitely prefer). Participants were asked to rate the treatments before and after reading either the guided decision aid or comparison decision aid. Analyses examined whether the guided decision aid group would have more changes in ratings of preference across time for the treatment options than the comparison group. This question was examined using a Mixed 2 (group) X 2 (time) X 6 (treatment options) ANOVA. Mauchly's test of sphericity revealed that the assumption of sphericity was violated for the main effects of Treatment Options [$\chi^2(14) = 58.3$, $p < .001$] and Treatment Options x Time [χ^2 (14) =

67.9, $p < .001$]. Degrees of freedom were corrected using the Greenhouse-Geisser correction ($\varepsilon = 3.55$ for Treatment Options and 3.37 for Treatment Options x Time). Mean ratings for each treatment option for each group are presented in Figures 4 and 5.

There was a significant main effect for treatment options [$F(3.55, 205.6) = 4.75$, $p < .01$]; full results are presented in Table 8]. That is, ratings of preference for treatment options differed. However, there was not a significant interaction between treatment options and groups [$F(3.55, 205.6) = .16$, $p = .948$]. Thus, the guided decision aid group did not rate the treatment options significantly different from the comparison group.

Additionally, there was a significant main effect for time [$F(1, 58) = 5.8$, $p < .05$]. Ratings of treatment options were significantly higher during the second rating than the first rating. However, there was not a significant interaction effect for time and groups [$F(1, 58) = 3.22$, $p = .078$]. That is, the guided decision aid group did not rate the treatment as significantly different from the comparison group across time. A significant interaction was found between treatments options and time [$F(3.37, 195.2) = 3.01$, $p < .05$]. Thus, ratings of treatment options changed across time.

There was not a significant three-way interaction between treatment options, time, and groups [$F(3.37, 195.2) = 1.94$, $p = .12$]. That is, there was not a significant difference between groups in ratings of treatment options across time. Since there was not a significant three-way-interaction as suggested in the exploratory question, follow-up analyses of the simple effects of the highest order interaction, treatment options and time, were conducted. Analyses of simple simple effects were conducted to follow this significant interaction using Least Significant Difference test with a Bonferroni adjustment for alpha. For the groups combined, ratings of

biologic therapy increased following use of the guided decision aid or comparison decision aid ($p < .01$). See Table 9 for estimated marginal means for the groups combined. Ratings of watch and wait also increased ($p < .05$). Thus, it appears that although we did not see a difference between groups, both groups rated biologic therapy, and watch and wait, as more preferable following use of the reading materials. No differences were observed from Time 1 to Time 2 for chemotherapy, radiation, stem cell transplantation, or clinical trials.

Table 8

Mixed 2 (groups) x 2 (time) x 6 (treatment options) ANOVA, Treatment Ratings for groups across time

Source	*df*	*F*	*p*
		Within	
Treatment Options[1]	3.545	4.75	<.01
Treatment Options*Group[1]	3.545	.16	.948
Error (Treatment) [1]	205.6	*MS* = 1.94	
Time	1	5.81	<.05
Time*Group	1	3.22	.078
Error (Time)	58	*MS* = .528	
Treatment Options*Time[1]	3.365	3.01	<.05
Treatment Options*Time*Group[1]	3.365	1.94	.12
Error (Treatment Options*Time) [1]	195.17	*MS* = .817	
		Between	
Group	1	.013	.909
Error (Group)	58	MS = .079	

[1] Greenhouse-Geisser correction used

Table 9

Estimated marginal means for treatment ratings for groups combined

Treatment option	Time	Estimated Marginal Mean Rating
Chemotherapy	Time 1	2.47
	Time 2	2.70
Radiation	Time 1	2.82
	Time 2	2.80
Biologic therapy*	Time 1	2.70
	Time 2	3.10
Stem Cell Transplant	Time 1	2.45
	Time 2	2.42
Watch and Wait*	Time 1	2.23
	Time 2	2.60
Clinical Trial	Time 1	2.40
	Time 2	2.23

Figure 4. Ratings of treatment preference across time for the guided decision aid group

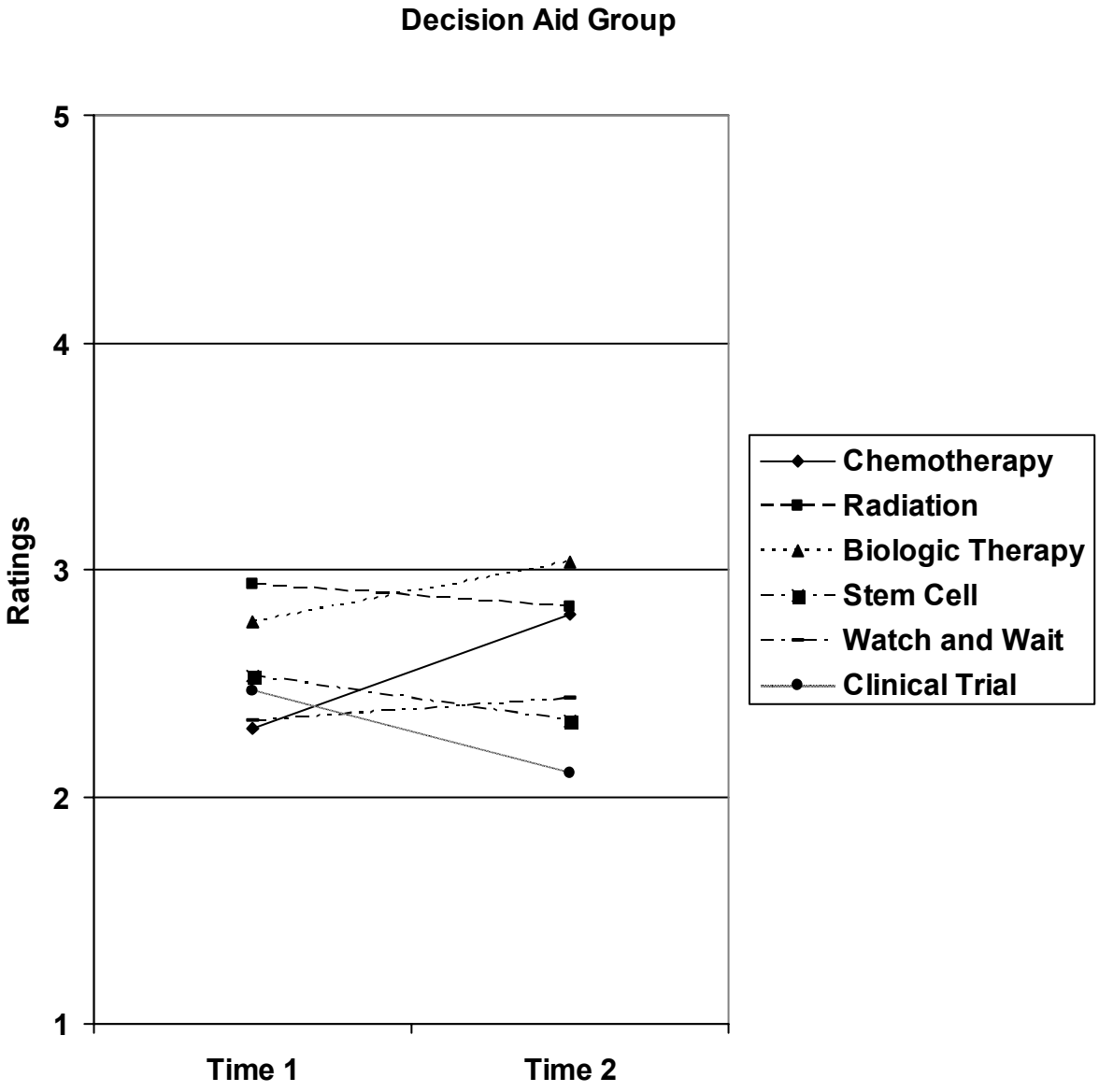
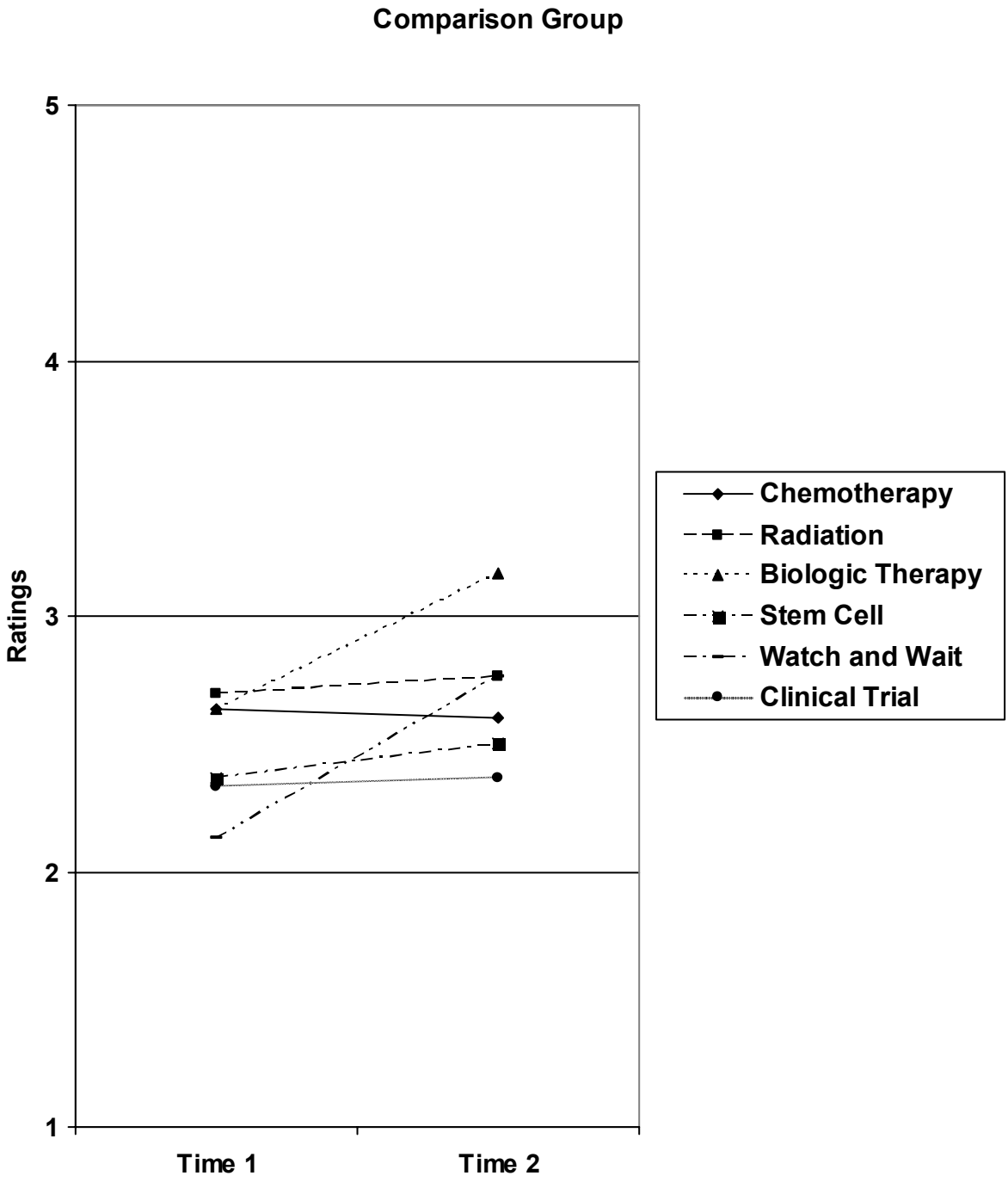


Figure 5. Ratings of treatment preference across time for the comparison group



Exploratory Treatment Preference Analysis 2: Will there be an interaction between treatment options, time, and groups for rankings of preference? In other words, will rankings of preference for treatment options change across time for the guided decision aid group and/or the comparison group?

Participants were asked to rank order the six treatment options from 1 to 6 (1 = best treatment option and 6 = worst treatment option) before and after reading either the guided decision aid or comparison decision aid. The question was whether the guided decision aid and comparison decision aid would influence the ranking of treatment options across time. We examined this using a Mixed 2 (groups) X 2 (time) X 6 (treatment options) ANOVA (full results presented in Table 10). Mauchly's test of sphericity revealed that the assumption of sphericity was violated for the main effects of Treatment Options [$\chi^2(14) = 57.0, p < .001$] and Treatment Options x Time [χ^2 (14) = 46.4, $p < .001$]. Degrees of freedom were corrected using the Greenhouse-Geisser correction ($\varepsilon = 3.55$ for Treatment Options and 3.76 for Treatment Options x Time). Means for rankings of treatments for each group are presented in Figures 6 and 7.

There was a significant main effect for treatment options, [$F(3.55, 206.1) = 11.3, p < .001$; Table 10], suggesting that the treatment options differed in how highly they were ranked. However, there was not a significant interaction between treatment options and groups [$F(3.55, 206.1) = .16, p = .94$]. This suggested that groups did not differ in overall rankings of treatments. Also, there was not a significant main effect for time [$F(1, 58) = 1.0, p = .32$], and there was not a significant interaction between time and groups [$F(1, 58) = 1.0, p = .32$]. Thus, rankings of treatment options did not differ across time, and groups did not differ across time. However, a

significant interaction was found between treatment options and time [$F(3.76, 218.2) = 5.32$, $p < .01$]. Thus, treatments options were ranked differently across time.

There was a significant three-way interaction between treatment options, time, and groups [$F(3.76, 218.2) = 4.11$, $p < .05$]. Thus, groups differed in rankings of treatment options across time. Analyses of simple interactions and simple main effects were conducted to further explore this interaction. Keppel (1991) suggests conducting analyses that are most consistent with the questions one is interested in answering with the data. The research questions focused on whether rankings of treatment options changed across time for each group; thus, separate repeated-measure ANOVAs were conducted to analyze simple interactions for each group. A significant interaction was not found between time and treatment options for the guided decision aid group [$F(3.86, 111.79) = 2.099$, $p = .088$, $\eta^2 = .067$]. Thus, there was no change in rankings of treatment options across time for the guided decision aid group. However, there was a significant interaction between time and treatment options for the comparison group [$F(3.23, 93.68) = 7.59$, $p < .001$, $\eta^2 = .207$]. This indicates that rankings of treatment options changed across time for the comparison group. Analyses of simple simple effects were conducted to follow this significant interaction using Least Significant Difference test with a Bonferroni adjustment for alpha (Keppel, 1991). For the comparison group, rankings for preference of biologic therapy decreased following use of the comparison decision aid ($p < .05$). See Table 11 for estimated marginal means for both groups. Rankings of stem cell transplant increased ($p < .01$). Rankings of watch and wait decreased ($p < .001$). Since lower rankings indicate higher preference for the treatment options, preference for biologic therapy and watch and wait

increased; whereas, preference for stem cell transplant decreased for the comparison group following use of the comparison decision aid.

Table 10

Mixed 2 (groups) x 2 (time) x 2 (treatment options) ANOVA, Treatment Rankings for groups across time

Source	*df*	*F*	*p*
Treatment Options[1]	3.55	11.26	<.001
Treatment Options*Group[1]	3.55	.162	.944
Error (Treatment) [1]	206.1	*MS* = 6.11	
Time	1	1.00	.321
Time*Group	1	1.00	.321
Error (Time)	58	*MS* = .022	
Treatment Options*Time[1]	3.76	5.32	<.01
Treatment Options*Time*Group[1]	3.76	4.11	<.05
Error (Treatment Options*Time) [1]	218.15	*MS* = 2.31	
	Between		
Group	1	1.00	.321
Error (Group)	58	MS = .004	

[1] Greenhouse-Geisser correction used

Table 11

Estimated marginal means for treatment rankings for each group

Group	Treatment option	Time	Estimated Marginal Mean Rank
Decision Aid Group	Chemotherapy	Time 1	3.40
		Time 2	2.63
	Radiation	Time 1	2.90
		Time 2	2.87
	Biologic therapy	Time 1	3.17
		Time 2	2.83
	Stem Cell Transplant	Time 1	3.33
		Time 2	3.87
	Watch and Wait	Time 1	4.07
		Time 2	4.13
	Clinical Trial	Time 1	4.13
		Time 2	4.67
Comparison Group	Chemotherapy	Time 1	2.73
		Time 2	3.33
	Radiation	Time 1	2.93
		Time 2	3.10
	Biologic therapy*	Time 1	3.17
		Time 2	2.50
	Stem Cell Transplant*	Time 1	3.20
		Time 2	4.13
	Watch and Wait*	Time 1	4.63
		Time 2	3.10
	Clinical Trial	Time 1	4.33
		Time 2	4.70

Figure 6. Rankings of treatment preference across time for the guided decision aid group

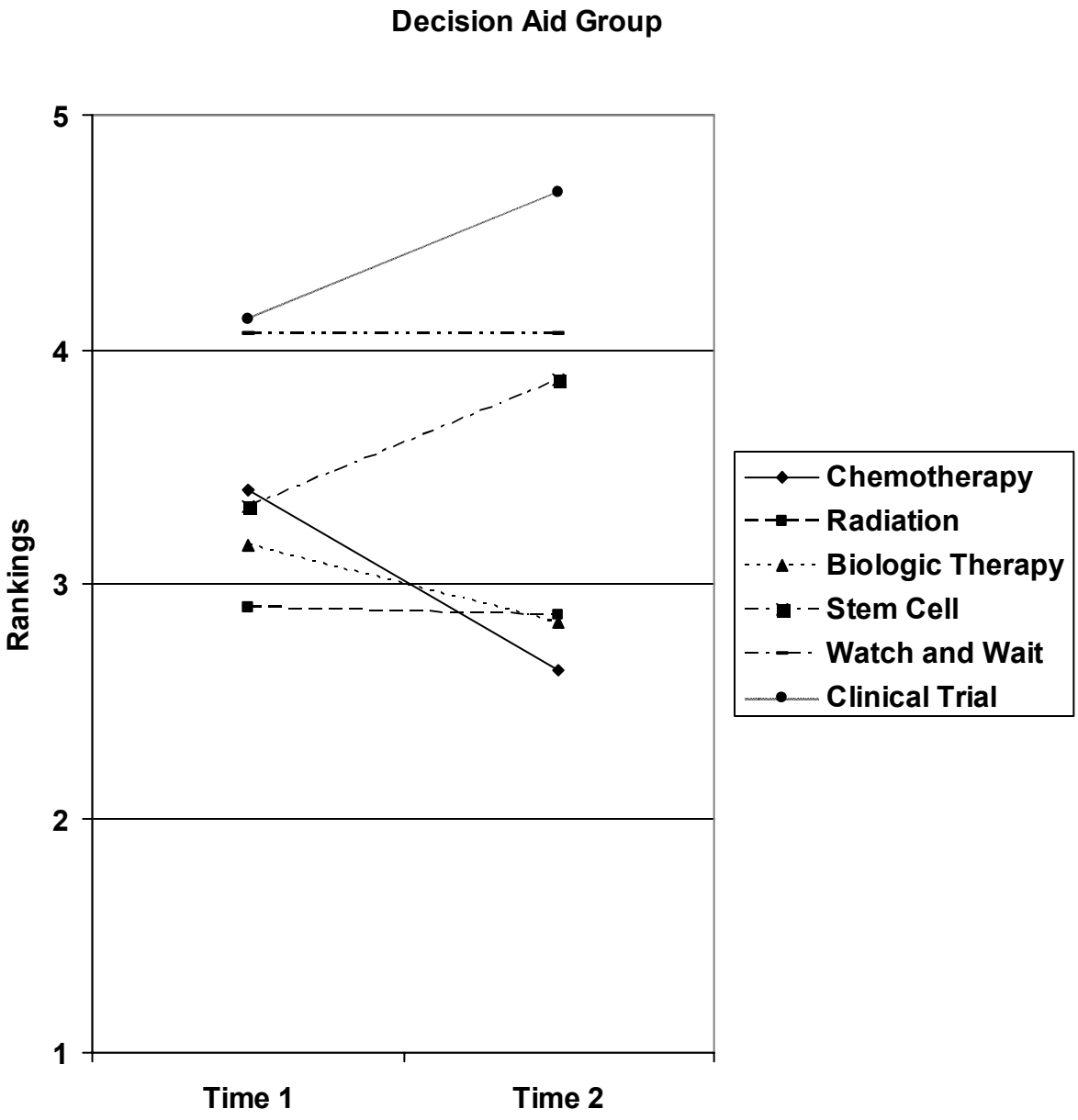
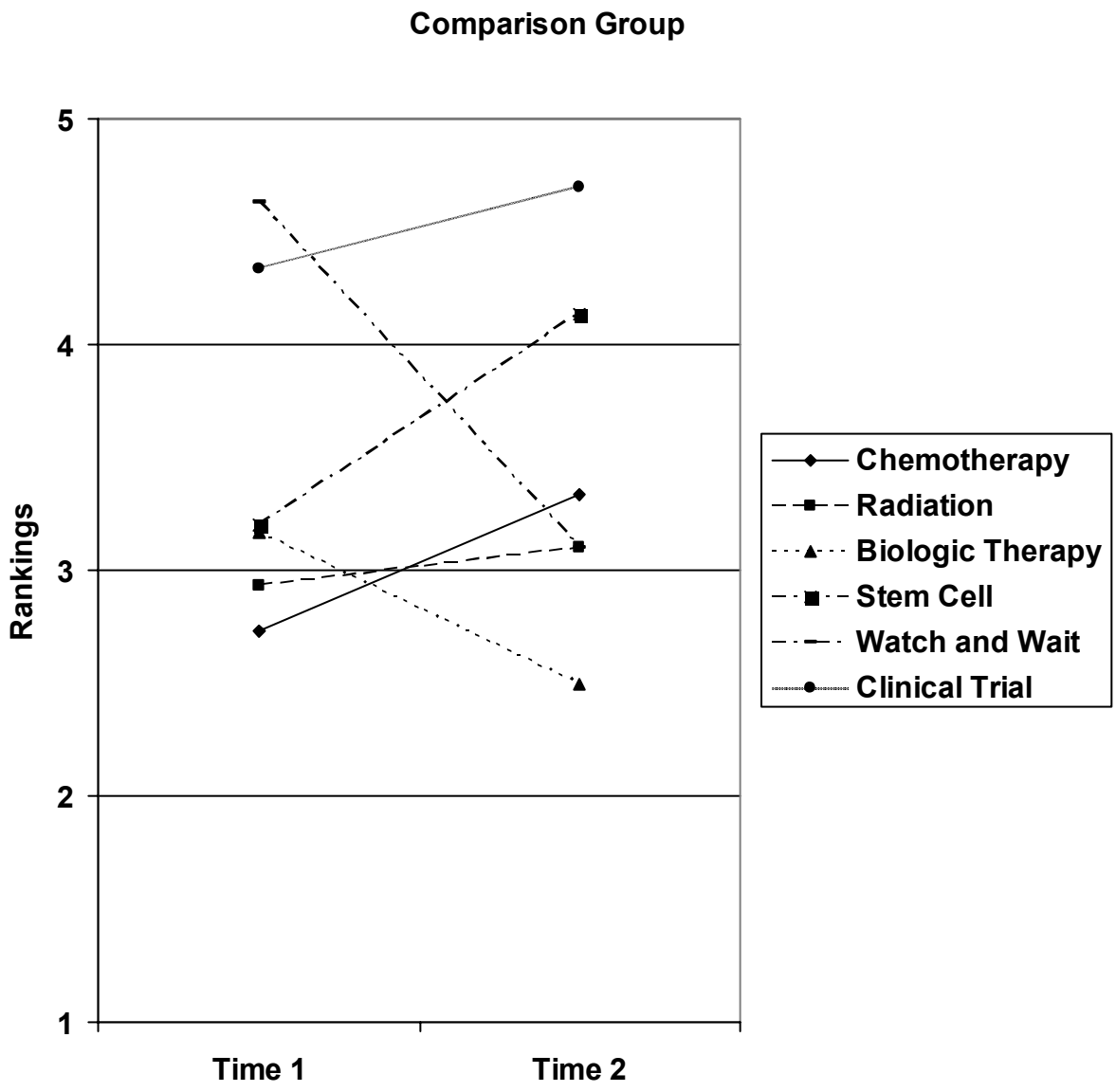


Figure 7. Rankings of treatment preference across time for the comparison group



Exploratory Predictor Question 1: How much variance can be accounted for in predicting change in satisfaction with decision using the following predictor variables: age, gender, education, anxiety, depression, need for cognition, and monitoring?

In this section, we explored individual variables that could potentially predict change in satisfaction with decision in the guided decision aid group while controlling for shared variance between predictors. A Stepwise Multiple Regression analysis revealed that for the decision aid group, age was the only significant predictor of change in Satisfaction with Decision (β = -.299, R^2 = .089, $p < .05$; Table 12). A Multiple Regression analysis was also conducted to predict residualized change scores for Satisfaction with Decision to control for the initial satisfaction values. None of the variables were significant predictors of change in Satisfaction with Decision (see Table 13). This suggests that although age was a predictor of raw change in Satisfaction with Decision, this finding may have been influenced by the initial satisfaction score.[1] Pearson Product Moment Correlation coefficients for predictor and criterion variables are presented in Appendix O. Mean values of continuous predictor variables are presented in Appendix P.

Table 12

Stepwise multiple regression, predictors of change in Satisfaction with Decision

	β	*t score*	*p*
Constant B = 11.922 (SE = 3.4)		3.52	.001
	Variables Entered		
Age	-.299	-2.386	<.05*
R^2 = .089, p < .05*			
	Excluded Variables		
Need for Cognition	-.062	-.487	.628
Monitoring/Blunting	.107	.825	.413
STAI	-.052	-.398	.692
CES-D	-.125	-1.00	.321
Gender	-.155	-1.213	.230
Education	-.023	-.180	.024

Table 13

Stepwise multiple regression, predictors of residualized change in Satisfaction with Decision

	β	*t score*	*p*
Constant B = .356 (SE = 1.856)		.192	.849
Age	-.020	-.113	.895
Need for Cognition	-.073	-.481	.633
Monitoring/Blunting	.041	.285	.776
STAI	-.118	-.610	.545
CES-D	.193	1.03	.306
Gender	-.080	-.486	.629
Education	.106	.772	.444

R^2 = .053, p = .888

Exploratory Predictor Question 2: How much variance can be accounted for in predicting change in decisional conflict using the following predictor variables: age, gender, education, anxiety, depression, need for cognition, and monitoring?

In this section, we explored individual variables that could potentially predict change in decisional conflict in the guided decision aid group while controlling for shared variance between predictors. A Stepwise Multiple Regression analysis revealed that for the decision aid group, age was the only significant predictor of change in Decisional Conflict ($\beta = .529$, $R^2 = .280$, $p < .001$; Table 14). When a Stepwise Multiple Regression analysis was conducted using residualized change scores for Decisional Conflict as the criterion variable, age was a significant predictor ($\beta = .377$, $R^2 = .142$, $p < .01$; Table 15). Thus, it appears that age accounted for a moderate amount of variance in predicting change in decisional conflict. Pearson Product Moment Correlation coefficients for predictor and criterion variables are presented in Appendix O. Mean values of continuous predictor variables are presented in Appendix P.

Table 14

Stepwise multiple regression, predictors of change in Decisional Conflict

	β	*t score*	*p*
Constant B = -31.004 (SE = 4.79)		-6.478	<.001
	Variables Entered		
Age	.529	4.743	<.001*
R^2 = .280, p < .001*			
	Excluded Variables		
Need for Cognition	-.088	-.784	.436
Monitoring/Blunting	-.211	-1.876	.066
STAI	-.075	-.649	.519
CES-D	.070	.622	.537
Gender	.040	.344	.732
Education	-.020	-.179	-.024

Table 15

Stepwise multiple regression, predictors of residualized change in Decisional Conflict

	β	*t score*	*p*
Constant B = -2.331 (SE = .761)		-3.063	.003
	Variables Entered		
Age	.377	3.102	<.01
R^2 = .142, p < .01*			
	Excluded Variables		
Need for Cognition	.009	.076	.940
Monitoring/Blunting	-.168	-1.354	.181
STAI	-.050	-.395	.695
CES-D	-.140	-1.151	.255
Gender	.006	.049	.961
Education	-.162	-1.345	.184

Exploratory Predictor Question 3: How much variance can be accounted for in predicting change in knowledge using the following predictor variables: reading time and time spent making decision?

We also explored the extent to which reading time and time until the decision predicted knowledge gained about follicular lymphoma. A Stepwise Multiple Regression analysis revealed that time spent reading the guided decision aid was the only significant predictor of change in Knowledge for the decision aid group ($\beta = .424$, $R^2 = .072$, $p < .05$; Table 16).[2] Mean values and Pearson Product Moment Correlation coefficients for predictor and criterion variables are presented in Appendix Q.

Table 16

Stepwise multiple regression, predictors of change in Knowledge

	β	*t score*	*p*
Constant (B = 2.57, SE = 1.09)		2.36	.022
	Variable Entered		
Time reading materials	.269	2.13	<.05*
$R^2 = .072$, $p < .05$*			
	Variable Removed		
Time until decision	-.113	-.777	.440

What was most/least helpful about the decision aid?

After the study, participants in the guided decision aid group were asked to complete the Opinion of the Decision Aid questionnaire to determine what information they felt was most important in making their decision. Participants' answers to this questionnaire are listed in Appendix R. Many participants felt that the most helpful parts of the decision aid were the descriptions of treatments and the lists of pros and cons. There was no evident frequent response when asked what was least helpful about the decision aid. A few people mentioned that the reference section was the least helpful. Others offered suggestions for more information to include such as more information about survival time.

Discussion

The following section describes the goals of the current study, discusses the findings, and relates the findings to the relevant literature. The implications of this study as well as the limitations and future directions for this research are also discussed.

Several studies have demonstrated that the use of a decision aid in medical decision-making for cancer can improve satisfaction with decision, decrease decisional conflict, and increase knowledge about the medical condition and treatment options (e.g., Brundage, 2001; Street et al., 1995; Whelan et al., 2003). The goal of the present study was to create and evaluate a guided decision aid for treatment selection in follicular non-Hodgkin's Lymphoma, which is a form of cancer with multiple complex treatment options (Ansell & Armitage, 2005).

This study was conducted in two phases. The first phase involved the creation of the guided decision aid. Patients were asked to identify information they felt would be important to include and to evaluate and revise the final draft of the decision aid according to their preferences. Then, the guided decision aid, and comparison decision aid, were evaluated and compared using a non-patient sample. The participants were asked to make a decision about treatment as if they were a patient, before and after reading the guided decision aid or comparison decision aid. Changes in satisfaction with decision, decisional conflict, knowledge, ratings of treatment preferences, and rankings of treatment preferences were evaluated at the time of each decision. We expected satisfaction with decision would increase, decisional conflict would decrease, and knowledge would increase following use of the decision aid, and that these changes would be greater for the guided decision aid than the comparison decision aid. We also expected that ratings and rankings of treatment preference would change more for the guided

decision aid group than for the comparison group. Several individual difference variables were explored as predictors of decision aid effectiveness. Thus, exploratory analyses were performed with the decision aid group to examine the extent to which age, gender, depression, anxiety, monitoring/blunting, need for cognition, and education would predict a change in decisional conflict or satisfaction with decision. Additionally, we explored whether time spent reading the decision aid, or time spent making the decision would predict change in knowledge in the guided decision aid group.

The following section is a review of the findings from this study and a discussion of implications of these findings in light of the relevant literature.

Satisfaction with Decision, The primary hypotheses driving this research related to the effectiveness of the guided decision aid for follicular Lymphoma. The first hypothesis, that following use of the materials, satisfaction with decision would increase more for the guided decision aid group than for the comparison group, was not supported. The results showed that satisfaction with decision increased following use of the guided decision aid. However, contrary to previous findings (Molenaar et al., 2001; Sebban et al., 1995; Whelan et al., 2003; Whelan et al., 2004), the results revealed no difference in the change in satisfaction between the decision aid and comparison groups. Thus, it appears that both the guided decision aid and comparison decision aid were equally effective in increasing satisfaction with decision.

There are several possible reasons why no difference in results was found between the guided decision aid group and comparison group. Few studies in the cancer decision aid literature have examined satisfaction with decision. Several of the previous studies compared a decision aid to medical consultations without giving participants additional reading materials

(Molenaar et al., 2001; Whelan et al., 2003; Whelan et al., 2004). The authors did not clearly state how much information was conveyed to the participants during these consultations. Only one study compared a decision aid group to a group that received a pamphlet (Sebban et al., 1995). These authors also found that the decision aid group had significantly higher satisfaction with decision than the comparison group. The authors stated that the pamphlet was a shortened version of the decision aid, but they did not clearly state how much information was included in the pamphlet. If the pamphlet included very minimal information, this could have accounted for the difference in satisfaction between groups.

Additionally, several of the previous studies in the cancer decision aid literature used patient samples (Molenaar et al., 2001; Whelan et al., 2003; Whelan et al., 2004). It is possible that no difference was found between the two groups because non-patients were used in the current study. Since patients assisted in the creation of the guided decision aid for the present study, the decision aid contained information identified as important to a patient sample. For our non-patient sample, the information offered in the comparison decision aid may have been seen as sufficient for making a decision about treatment in the patient vignette, whereas patients may have found the additional information and exercises of the guided decision aid more helpful than the comparison decision aid. Patients may have found the decisional context more salient and the information in the aid more personally relevant and important. Thus, patients may have been more satisfied with their decisions due to the more comprehensive and personally relevant information in the guided decision aid. Only one study in the cancer decision aid literature used a non-patient sample to examine satisfaction with decision (Sebban et al.,, 1995). It is difficult to compare the Sebban et al. (1995) sample to the sample in the current study, since the authors in

the previous study did not list many demographic variables. The Sebban et al. (1995) sample included younger participants than the current study, but it is unclear whether this might account for the different findings between this and the current study.

The comparison decision aid was created using less information to make it similar to a pamphlet that a patient might find in the physician's office; however, the same material was used in the creation of the pamphlet. This method was used because there was no pamphlet available for follicular lymphoma that we could use for comparison. If there had been a pamphlet available for use for the comparison group, there may have been a difference between the groups, as the pamphlet would have likely offered somewhat different information than that presented in the decision aid. A review of other pamphlets for lymphomas revealed that most pamphlets offered different information, different explanations of treatments, and different material.

Decision Conflict. The second hypothesis, that following use of the materials, decisional conflict would decrease more for the guided decision aid group than for the comparison group, was not supported. Few studies have examined decisional conflict among users of cancer decision aids. The present results showed that decisional conflict decreased following use of the guided decision aid, which was similar to findings in previous studies of cancer decision aids (Brundage et al., 2000; Brundage et al., 2001; Fiset et al., 2000). However, there was no difference in decisional conflict decrease between the guided decision aid and comparison groups. This finding is contrary to results of Whelan et al. (2004), but supports the findings of Goel et al. (2001) in that there was not a significant difference in decisional conflict between the decision aid group and a group that received a pamphlet. The Whelan et al. (2004) study used a decision aid in comparison to medical consultations and found that the decision aid group had

less decisional conflict than medical consultation groups. Whelan et al. (2004) did not clearly describe the nature and amount of information conveyed during the medical consultations. If the information during these consultations was minimal, this may have accounted for differences in decisional conflict between groups.

Another potential reason for the difference in findings between the Whelan et al. (2004) study and the present study is that the Whelan et al. study asked participants to choose between two treatment options, while the current study asked participants to choose between six. Previous research suggests having many options results in more difficulty making selections (Iyengar & Lepper, 2000). Thus, participants in the current study may have been overwhelmed with the number of options in the decision aid, which may have prevented a larger decrease in decisional conflict.

A possible reason for the difference in findings between the current study and Whelan et al. (2004) is that the Whelan et al. study used a patient sample, while the present study used a non-patient sample. Again, patients may have found the decisional context more salient and the information in the aid more personally relevant and important. Thus, patients may have experienced less decisional conflict due to the more comprehensive and personally relevant information in the decision aid.

Knowledge. The third hypothesis, that knowledge would increase more for the guided decision aid group than for the comparison group following use of the materials, was not supported. The results showed that knowledge increased for both groups following use of the decision aid, which is consistent with previous studies (Brundage et al., 2000; Brundage et al., 2001; Schapira et al., 1997). However, knowledge did not increase more for the guided decision

aid group than the comparison group, which is contrary to some previous findings in the cancer decision aid literature (Whelan et al., 2003; Whelan et al., 2004), but confirms findings from other studies in the cancer decision aid literature (Chapman et al., 1995; Goel et al., 2001; Holmes-Rovner et al., 2005; Street et al., 1995).

One possible reason for the inconsistency in the previous studies of knowledge acquisition is that several previous studies did not assess baseline knowledge (Chapman et al., 1995; Goel et al., 2001; Holmes-Rovner et al., 2005; Whelan et al., 2003; Whelan et al., 2004). Thus, it is not known how well the groups would have performed on the knowledge measure before using the decision aid or reading the pamphlet, and it is not known whether knowledge increased due to the materials. The present study assessed baseline knowledge to ensure an accurate measure of knowledge acquired from the materials.

Some of the previous studies (Whelan et al., 2003; Whelan et al., 2004) compared knowledge gained after using a decision aid to knowledge gained in medical consultations. These studies found that the decision aid group retained more knowledge than the medical consultation groups. Previous studies that did not find a difference between the decision aid and comparison group, used a pamphlet as a comparison (Chapman et al., 1995; Goel et al., 2001; Holmes-Rovner et al., 2005). Studies that used medical consultations as the comparison group did not clearly describe the quantity of information conveyed during the medical consultations. If the information during these consultations was minimal, this may have accounted for differences in knowledge acquisition between groups.

Treatment Preferences. In addition to examining effectiveness of the decision aid, we were also interested in whether the decision aid might affect preference for the treatment options.

The current study explored the question of whether use of the guided decision aid or comparison decision aid would result in changes in ratings of treatment preference in the non-patient sample. The results revealed that pre-post ratings of treatment preference changed across time for both groups and differed between treatment options for both groups; however, the groups did not rate the treatment preferences differently. The results confirm the findings of Molenaar et al. (2001), who found that treatment choices did not differ between a decision aid group and comparison group. However, the results conflict with the findings of Sebban et al. (1995). Sebban et al. found that treatment choices differed in a non-patient sample between the decision aid group and a group that received a shorter version of the decision aid. As discussed above, it is possible that the reason we did not see a difference between groups was that we did not use a patient sample. Participants in the present study were asked to make a decision about treatment relatively soon after using the guided decision aid and comparison decision aid. It is likely that patients who are not making decisions in the context of an experiment may take more time to deliberate over the treatment options and weigh the risks and benefits over a much longer period of time. It is possible that the risks and benefits presented in the decision aid might have yielded a greater change in treatment preference over time. Molenaar et al. (2001) utilized a patient sample and physician consults for the comparison group. The current study is most similar to the Sebban et al. (1995) study because of the use of a non-patient sample, and a pamphlet for the comparison group. Thus, it is curious that the findings of this study were not consistent with Sebban et al. (1995).

The nature of the interaction between treatment options and time was examined, revealing that preference ratings of biologic therapy, and watch and wait, increased over time.

This was consistent with the expectations in that ratings of these lesser-known treatment options were expected to increase following use of the informational materials. Preference for the lesser-known treatment options likely increased because patients rated them lower at first due to unfamiliarity, and then rated them higher after reading the information and learning about the benefits of these treatment options. Although the information presented in the guided decision aid and comparison decision aid was objective, it is also possible that biologic therapy and watch and wait were perceived as more preferable following use of the materials. The materials may have discussed positive aspects of these options that were not considered by the participants before reading the materials.

Rankings of Treatment Preference. The question of whether use of the guided decision aid or comparison decision aid would result in changes in rankings of treatment preference in the non-patient sample was explored. The results were consistent with Sebban et al. (1995) in that the groups differed in treatment preferences. However, contrary to expectations, only the comparison group showed significantly different rankings for treatment options across time. It is unclear why there was more change in rankings in the comparison group.

One speculation about why there was not a change in treatment rankings across time for the decision aid group was that these participants might have been presented with more information than was possible to process, or that they were willing to process, in a short period of time. Although knowledge of the materials increased following use of the guided decision aid, this does not necessarily mean that participants were able or willing to process the information well enough to incorporate it into a final decision in which they felt confident. Previous research suggests that when faced with many options from which to choose, people have more difficulty

making selections (Iyengar & Lepper, 2000). Since these participants made decisions about treatment options in only a few minutes, the detailed information about risks and benefits presented in the decision aid may have been too much information about too many treatment options in such a short period of time. Thus, participants may have been more likely to choose the same treatments after reading the decision aid that they chose before because the information about the treatment options was too much to process. Those in the comparison group read less information about the treatment options, and thus changed their treatment selection after processing the information. Perhaps the amount of information presented in the guided decision aid was too much or too tedious to process in a short period of time.

When the nature of the change in rankings of preference for treatment options across time was examined for the comparison group, preference for biologic therapy increased, stem cell transplantation decreased, and watch and rate increased. Since lower rankings indicate higher preference, preference increased for biologic therapy, and watch and wait, while preference decreased for stem cell transplantation. Although we did not see a change in rankings of treatment options across time for the guided decision aid group, the results from the comparison group were consistent with our expectations in that lesser-known treatments were ranked as more preferable following use of the reading material. However, stem cell transplantation, which could be considered a less well-known treatment option, was ranked less preferable following use of the comparison decision aid. A conversation with one of the participants following this study may shed some light on this finding. This participant told the researcher that several years before this study, a teenager in Winona, MN, the town from where participants were drawn, was diagnosed with Hodgkin's Lymphoma, and the town conducted a fundraiser to raise money for

an autologous stem cell transplant for him. Hodgkin's disease can often be put into remission with a stem cell transplant (Evens et al., 2007), and as such, this patient was in remission following the transplant. Thus, since Winona is a small town, many of the participants likely knew about this success story, and rated stem cell transplant highly before reading the materials. After reading the comparison decision aid, participants may have realized that stem cell transplantation has many risks associated with it, and then rated it lower. Thus, participants less familiar with stem cell transplantation success might have shown results more consistent with our expectation of lower initial ratings and higher ratings after reading the information.

Although there was not a difference between groups in treatment preference that we had expected, both groups showed an increase in satisfaction, a decrease in decisional conflict, and an increase in knowledge following use of the guided decision aid and comparison decision aid. Thus, our findings suggest that regardless of whether use of the reading materials resulted in a change in the treatment decision, they increased the satisfaction with decision, decreased decisional conflict, and increased knowledge.

Individual Predictors of Change in Satisfaction with Decision. One of the goals of this study was to discover whether individual characteristics predicted effectiveness of the guided decision aid. The exploration revealed no significant predictors of change in satisfaction. The finding that age did not emerge as a predictor is similar to a finding by Berry et al. (2006), who also found that age was not a significant predictor of satisfaction with decision. Anxiety and depression may not have emerged as significant predictors because the mean anxiety and depression scores in this sample were low and had a restricted range. Cancer patients are more likely to experience anxiety and depression (Bock, 2006); therefore, the wider range of anxiety

and depression symptoms in a patient sample might have contributed to the prediction of change in satisfaction with decision. It was expected that those high in need for cognition, monitoring, and education would be associated with an increase in satisfaction with decision. It is unclear why need for cognition, monitoring/blunting, and education did not emerge as predictors of change in satisfaction with decision.

Individual Predictors of Change in Decisional Conflict. The same individual difference variables that were explored as predictors of satisfaction were also explored as predictors of decisional conflict. Age contributed to the prediction of change in decisional conflict. As age decreased, decisional conflict decreased. Thus, it appeared that the decision aid may have been less effective for older individuals. Unfortunately, the relation between age and decisional conflict has not been examined in previous studies. One speculation for the current finding is that older adults have more difficulty processing the complex information presented in the decision aid. Previous research suggests that older adults have more difficulty with decision-making and make more inconsistent decisions when information related to the decision is complex (Finucane & Mertz, 2005). If older adults experienced more difficulty processing the information, they likely did not feel confident in the choice they made following use of the materials. Thus, the older adults did not show a decrease in decisional conflict.

Another possible explanation for the current finding is that older adults preferred to be more passive in the decision-making process and preferred to receive less information (Cassileth et al., 1980; Pinquart & Duberstein, 2004). Thus, older adults may not have shown a decrease in decisional conflict because they would have preferred to be less involved in the decision-making process. It is possible that despite the fact that they were making more informed decisions after

using the decision aid, older adults may have felt more uncomfortable with making a decision about treatment. Thus, when they made a decision in this study, they still felt uncertain about their decision after reading the decision aid.

Once again, anxiety and depression may not have emerged as significant predictors of change in satisfaction with decision because the mean anxiety and depression scores were in this sample were low and had a restricted range. As discussed previously, cancer patients are more likely to experience anxiety and depression (Bock, 2006); therefore, the wider range of anxiety and depression symptoms in a patient sample might have predicted change in decisional conflict. It was also thought that those high in need for cognition and monitoring would be associated with an increase in satisfaction with decision. It is unclear why need for cognition and monitoring/blunting did not emerge as predictors of change in satisfaction with decision.

Individual Predictors of Change in Knowledge. The extent to which the amount of time the individuals spent with the decision aid might predict the amount of knowledge gained was examined. Time spent reading the decision aid predicted knowledge acquired. The results suggest that those who took more time and care in reading the decision aid gained more knowledge. This finding suggests that it may be beneficial for patients to read slowly and thoroughly to gain the most knowledge about the information.

Most Helpful/Least Helpful Aspects of the Decision Aid. Participants reported that the most helpful aspects of the guided decision aid were the descriptions of treatment options and the list of pros and cons. There was no apparent "least helpful" aspect of the decision aid.

Overall, it appeared that the guided decision aid was well-received by participants and the most helpful sections identified were the lists of risks and benefits and treatment descriptions.

The item seen as least helpful was the reference section, which was a necessary part to include credit to sources, but was not necessary for the decision-making process. However, this section might be more helpful to patients who wish to seek other sources of information. When examining the answers given by participants, it is not evident that changes need to be made to the guided decision aid at this time.

Limitations

As discussed previously, the aim of this study was to add to the cancer decision aid literature by adjusting for some of the methodological flaws in previous literature as well as to develop a decision aid for the largely ignored and very difficult treatment selection in follicular NHL. However, the current study was not without its own areas in need of improvement.

There were some drawbacks to using a non-patient sample. Using a non-patient sample did not allow evaluation of all of the potential benefits of the guided decision aid. Since patients assisted in the development of the decision aid, the contents were likely more beneficial for a patient sample, and may have explained why we did not see a difference in effectiveness between the guided decision aid group and the comparison group. Additionally, there were components of the guided decision aid that were designed to facilitate the physician/patient relationship (i.e., questions to ask your doctor and sources for further information). Evaluating the decision aid in a non-patient sample did not allow us to evaluate the effectiveness of these portions of the decision aid. Finally, participants in this study were asked to make a treatment decision in a very short period of time. Patients would likely take hours or days to make such a decision. Thus, generalizability of the present findings to cancer patients may be questionable.

The sample used for this study was not representative of the general population. All of the participants were Caucasian, which means that we cannot necessarily extend the results of this study to other races. The patients in this sample also had low scores on the measures of depression and anxiety, which likely decreased our ability to evaluate the effectiveness of this decision aid in more depressed and anxious individuals. The restricted range in these measures would have decreased our ability to predict change in decisional conflict and satisfaction with decision. Cancer patients often experience symptoms of depression and anxiety (Block, 2006), and we cannot generalize the effectiveness of the decision aid to these individuals.

Sample size may have been a limiting factor in power for the multiple regression analyses conducted for the prediction of decision aid effectiveness. Since the pre-post analyses of decision aid effectiveness were considered the primary hypotheses, the sample size was based on adequate power for those analyses. Multiple regression analyses require 10 to 15 participants per predictor (Field, 2000). Our analyses included only about 4-5 participants per predictor. Thus, more significant predictors of effectiveness may have emerged with a larger sample size.

Future Directions

There are several possible directions in which to take this area of research. A logical next-step for the current study would be to evaluate the guided decision aid in a patient sample. As discussed above, since patients contributed to the creation of the guided decision aid, patients may have found the guided decision aid to be more effective than the comparison decision aid. Since the guided decision aid was designed for use by patients, a patient sample would give a better indication of the benefit of the decision aid.

There are some other possible variations that could be of use in examining the effectiveness of this aid. For example, the current study evaluated the guided decision aid against a shortened version of the guided decision aid. A future study could add another comparison group that would receive irrelevant information (e.g., a decision aid targeted toward a different medical dilemma). This group would offer a comparison to see whether simply making the decision about treatment twice would result in higher satisfaction with decision and lower decisional conflict after the second decision.

A future study could examine changes in treatment selection over time. Participants in this study made a decision about treatment in a few minutes; however, patients would likely deliberate over treatment selection for several days. Thus, patients using the decision aid over time would likely add to the lists of risks and benefits and change treatment preference over time as they incorporate information from oncologists and significant others. This would support findings by Feldman-Stewart et al. (2001) that revealed several changes in treatment preference while using a decision aid.

Additionally, it may be beneficial to examine whether individual characteristics influence the effectiveness of the decision aid in a patient sample. A patient sample would likely be more representative of the patient population and would likely have higher scores in characteristics such as depression and anxiety, as cancer patients commonly experience anxious and depressive symptoms (Block, 2006). It could also be beneficial to evaluate whether other characteristics (e.g., race, SES) may be predictive of effectiveness of the decision aid to continue to examine types of individuals for which the decision aid would be most effective.

As Kennedy (2003) has suggested, future studies should focus on whether decision aids help participants in making decisions consistent with their values. This has been largely neglected in the literature. The decision aid in the current study led patients through value clarification exercises to assist in the decision-making process. A future study could focus on whether the decisions made by patients are consistent with their values.

Finally, there are several areas within medical decision-making for which decision aids have not yet been created and/or evaluated. There is need for more decision aids within the blood cancers. For example, a decision aid has not yet been created for patients with acute myelogenous leukemia, who must decide whether to undergo a stem cell transplant after a relapse of the disease (Mathews & DiPersio, 2004). There is also a need for decision aids outside the cancer literature. For instance, a decision aid has not yet been created to help patients decide whether to undergo bariatric surgery for obesity (Brethauer et al, 2006).

Conclusions

The goal of the current study was to create and evaluate a guided decision aid for treatment selection in follicular non-Hodgkin's lymphoma. Additionally, we examined whether individual characteristics predicted the effectiveness of the decision aid. This study involved patients in the creation of the guided decision aid and in evaluation of the utility of the final guided decision aid product.

The results of this study showed that in a non-patient sample, the guided decision aid was effective in improving satisfaction with decision, decisional conflict, and knowledge; however, the guided decision aid was not more effective than a comparison decision aid. The decision aid appeared to be more effective for younger adults. Although some evidence of effectiveness of

the decision aid was apparent in this study, there were some drawbacks to using a non-patient sample that may have prevented the examination of the full potential of the guided decision aid. Further studies should focus on the evaluation of this guided decision aid in a follicular NHL patient sample, examination of other potential individual characteristics to predict effectiveness of decision aids, and evaluation of decision aids for other areas of difficulty in medical decision-making.

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Footnotes

[1] Analyses of normality revealed that monitoring/blunting and CES-D were both positively skewed. The same multiple regression analyses were conducted using log transformations of monitoring/blunting and CES-D, which corrected the positive skew. These analyses revealed the same results as those presented.

[2] The multiple regression was also conducted using the residualized change score for knowledge. The results of this analysis were the same as those presented.

Appendix A

Guided Decision Aid

A Guided Decision Aid for Patients with Indolent Follicular non-Hodgkin's Lymphoma

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This decision aid was designed based upon the framework created by Ottawa Decision Aids, Inc.[1]

Table of Contents

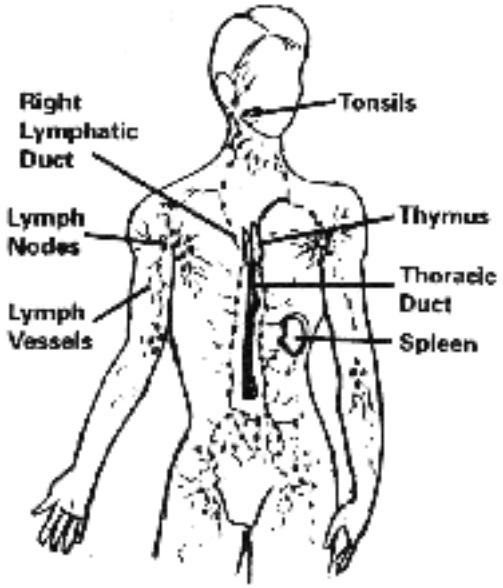
Purpose of the Decision Aid

One purpose of this decision aid is to offer information about the lymphatic system, Follicular non-Hodgkin's Lymphoma, and treatment options for Follicular non-Hodgkin's Lymphoma. Another purpose of this decision aid is to help patients make decisions about which treatment options may be best for them.

What You Will Learn

- The anatomy and function of the lymphatic system.
- Symptoms of Follicular non-Hodgkin's Lymphoma.
- Procedures of treatment options for Follicular non-Hodgkin's Lymphoma.
- Risks and benefits of treatment options.

The Lymphatic System



The lymphatic system consists of several body parts including:

- spleen
- thymus
- tonsils
- bone marrow
- lymph nodes (These are the size of a bean and are distributed throughout the body. Clusters of lymph nodes are found in the armpits, abdomen, groin, pelvis, collarbone area, and neck.)[3,4]

The Lymphatic System

What does the lymphatic system do?

- The lymphatic system includes vessels that transport fluids throughout the body. A fluid called 'lymph' is circulated throughout the lymphatic system. This fluid contains white blood cells, which are also called 'lymphocytes.' These lymphocytes are created in the bone marrow and mature in the thymus. They are important in the body's ability to fight infection.
- The spleen and the lymph nodes are filters of the lymph fluid.
- When your body is fighting an infection such as from bacteria or viruses, the lymph nodes will swell with lymphocytes that will target and destroy these unwanted organisms in the body.[3,4,5]

The Lymphomas

Almost all cells in the human body have the ability to divide to produce new cells that can replace the cells that die. However, cancer results from a defect within a cell that causes the cell to continue to divide faster than the rate of cell death. These cancerous cells inhibit the growth and survival of normal cells.[6]

The lymphomas are cancers of the lymphocytes. Lymphomas are divided into Hodgkin's Lymphoma and non-Hodgkin's Lymphoma. Non-Hodgkin's Lymphoma is the most common type of lymphoma.

Non-Hodgkin's Lymphoma can be categorized in several ways:[2,7,8]

By grade:

Indolent or Low Grade (slow growing)
Intermediate Grade (moderate growth rate)
Aggressive or High Grade (fast growing)

By stage:

Stage I: lymphoma detected in one lymph node

Stage II: lymphoma detected in two or more lymph nodes near each other

Stage III: lymphoma detected in several lymph nodes far apart

Stage IV: widespread involvement of lymph nodes as well as organs such as liver, lungs, or bone

What is Follicular non-Hodgkin's Lymphoma?

Follicular Lymphoma is an Indolent (Low Grade) lymphoma. It is the second most common type of non- Hodgkin's lymphoma.[9]

Follicular Lymphoma is a slow-growing cancer of specific kinds of lymphocytes called B-cells.[10] These cancer cells are grouped in clusters, which are called follicles, in the lymph nodes.

For patients diagnosed with Follicular Lymphoma, especially those in which the disease is more widespread than Stage I, the disease may be considered "incurable." This means that even after treatment, the disease can be expected to remain dormant in the body and may recur. More aggressive treatment may lengthen the amount of time between recurrences.[9,11]

With new and better treatment options available, the length of survival for patients with follicular lymphoma has been increasing over the years.[12]

Symptoms of follicular lymphoma can be difficult to identify and thus, most patients present with advanced-stage disease.[10]

Possible symptoms include:

- Fever
- Fatigue
- Itchy skin
- Drenching night sweats
- Unexplained weight loss
- Pain in chest, bones, or abdomen
- Painless swelling of lymph nodes

Treatments for Follicular non-Hodgkin's Lymphoma

Treatments available to each patient will depend upon several factors including stage of disease, whether organs outside of lymph nodes are affected, the lymphoma's cell type, patient age, and current symptoms.[2]

Current treatment options for follicular lymphoma include:[2,13]

Chemotherapy

Radiation

Biologic Therapy

Stem Cell Transplantation

Watch and Wait

Clinical Trial

As of today, there is no consensus among oncologists about which treatment option is the best.[14]

Chemotherapy

Chemotherapy is commonly used when a patient is first diagnosed, but is also used when the disease recurs.[10]

Chemotherapy is a drug that is either injected into the veins or swallowed orally. Once the drug enters the body, it is carried by the blood stream to areas throughout the body. These drugs are designed to either kill the cancer cells or to stop their ability to multiply.[7]

Chemotherapy drugs can be used alone, in combination with other chemotherapy drugs, or in combination with some of the treatments mentioned in the next few sections (e.g., radiation, biologic therapy, or stem cell transplantation).[2,15] Chemotherapy may also be combined with steroids. Most chemotherapy treatment will require more than one session of treatment. The number of sessions will depend on your specific case. Each type of chemotherapy can have its own different possible risks and benefits.

Examples of common chemotherapy regimens:

- CHOP: Cyclophosphamide, Doxorubicin, Vincristine, Prednisone
- CVP: Cyclophosphamide, Vincristine, Prednisone

Chemotherapy

Benefits 

- Often well-tolerated by patients
- There are drugs available to counteract some side effects such as nausea and low red blood cell count
- Most side effects will end soon after treatment is finished
- Chemotherapy is the most commonly used treatment and its effects have been well-researched [2,15]

Risks 

- Side effects can include:
  - Hair loss
  - Fatigue
  - Loss of appetite
  - Nausea and vomiting
  - Mouth sores
  - Decreased bone marrow cells
  - Numbness, tingling, burning, or weakness in limbs
- May have allergic reaction to drugs such as fevers or skin rash
- Reduced lymphocytes from chemotherapy can create increased risk for infection
- Some chemotherapy drugs may damage the heart, bladder, or reproductive organs, which could be fatal if these organs are already compromised
- Repeated use of chemotherapy may decrease its effectiveness
- Use of some chemotherapies may increase the risk of other cancers in the future [16]
- Use of chemotherapy may not lengthen patient survival
- Patients with large amounts of cancerous tissue must be monitored carefully because toxic chemicals may be released when cancer cells are killed, which can be fatal [2,3,15]

Radiation

Radiation is a treatment that kills lymphoma cells in a specific area using high-energy rays.[2] The rays work to damage the DNA in the lymphoma cells, which can cause death of the cancerous cells.[15]

Before administering radiation, scans will be used to map out a specific area on the body for administration of the radiation to limit the number of healthy cells that are damaged. Treatment usually takes several sessions. These sessions typically last about 15 minutes, with repeated sessions for several weeks.[15]

Radiation can be used when the patient has a large area of lymphoma cells within a small area of the body, or when enlarged lymph nodes are interfering with other organs.[2] Radiation can be used alone, or it is often used in combination with chemotherapy.

Radiation

Benefits 

- Treatments are short in duration
- Most side effects will end soon after treatment is finished
- Will possibly work to quickly control lymphoma at a specific site
- If used with chemotherapy, can reduce the number of cycles of chemotherapy required [2,15,17]

Risks 

- Side effects often include:
  - Fatigue
  - Decreased appetite
  - Skin irritation near the treated area
  - Bone marrow suppression
- May have allergic reaction to radiation such as fevers or skin rash
- Reduced lymphocytes from radiation can create increased risk for infection
- Radiation may damage organs near the site of treatment
- This treatment option may not be available for cancer that is widespread
- Radiation may increase the risk of other cancers in the future [2,15,17]

Biologic Therapy

In the human body, antibodies are produced by the immune system to help the body know which substances are foreign and should be destroyed. Biologic Therapy involves treatments that use antibodies to fight the lymphoma.[18]

Monoclonal Antibody Therapy is a type of biologic therapy in which an antibody is injected into the blood. When a Monoclonal Antibody is circulated throughout the system, it seeks out and destroys lymphoma cells. Monoclonal Antibody Therapy is often used in conjunction with chemotherapy.[2,17]

Radioimmunotherapy is a form of biologic therapy that uses a radioactive substance, which is carried to the lymphoma cells by monoclonal antibodies. This treatment targets the lymphoma cells directly and leaves normal cells intact.[2]

Examples of Biologic Therapy:[17]

- Rituxan: This monoclonal antibody treatment is usually injected into the veins every week for about four weeks. Each treatment can take anywhere from 4 to 8 hours, with the first treatments typically taking the longest.
- Zevalin or Bexxar: These radioimmunotherapies are actually a form of radiation and are given along with Rituxan. It takes seven to nine days to administer. Over the course of therapy, body scans are conducted to determine how the radiation has distributed throughout the body. Radiation is delivered directly to the lymphoma cells, which helps to protect normal cells.

Biologic Therapy

Benefits 

- Medications are available to reduce some side effects such as fever and chills
- Side effects are often most prominent during first administration of the drug
- Side effects are fewer than chemotherapy
- Rituxan used with chemotherapy may be more effective than chemotherapy alone [2,15,17,19]

Risks 

- Side effects often include:
  - Fever and chills (especially with first administration)
  - Nausea
  - Headache
  - Weakness
- Must be used with caution in those with cardiovascular disease
- Not clear whether biologic therapy lengthens survival
- Biologic therapy not as well studied as chemotherapy
- Patients with large amounts of cancerous tissue must be monitored carefully because cellular contents may be released when cancer cells are killed, which can be fatal [2,15,17,20]

Stem Cell Transplantation

In Stem Cell Transplantation, the patient is first given high dose chemotherapy to destroy the lymphoma cells. When this high dose chemotherapy is given, it can destroy much of the bone marrow tissue making it necessary to replace the tissue that has been destroyed. In a Stem Cell Transplant, bone marrow stem cells are infused into the blood stream following chemotherapy. These stem cells will make their way to the bone marrow, where they will grow and create new blood cells.

Stem cells used for transplant must be obtained from a donor. There are two types of donors:

- Autologous: The patient acts as his or her own donor. During a time of remission, the patient is given a drug that will increase the number of stem cells in the blood stream. The stem cells are collected through a machine and the rest of the blood is infused back into the patient. The stem cells are saved and infused into the patient's blood stream after chemotherapy.
- Allogeneic: Stem cells from a sibling or other donor who genetically meets criteria are used. The stem cells are collected from the donor in a similar procedure to the autologous transplant. These stem cells are infused into the patient's blood stream following chemotherapy.

During and following the transplant, patients are hospitalized for several weeks to several months. Since much of the bone marrow has been destroyed and thus the bone marrow is not producing new blood cells, patients often need blood cell replacements during this time.

A common complication that can occur with an allogeneic donor is Graft Versus Host Disease. This occurs when the donor's bone marrow cells recognize the patient's original cells as foreign and begin to work against them. This disease can affect the skin, liver, gastrointestinal tract, eyes, and lung. It can last from several weeks to years, and can sometimes be fatal.[15]

Stem Cell Transplantation

Benefits 

- Offers a safer way to deliver higher doses of chemotherapy
- Autologous transplants have no risk for Graft Versus Host Disease
- There is potential for a cure with this treatment, or at least a lengthened amount of time before the disease recurs [2,15,17]

Risks 

- Since transplants begin with chemotherapy, side effects related to chemotherapy will often occur
- Can take several months to years for the immune system to fully rebuild itself, so there will be an increased risk for infections during that time
- Need for blood and platelet transfusions until the bone marrow starts producing cells
- Long hospitalization following transplant and continual monitoring and possible re-hospitalizations after transplant
- Possible Graft Versus Host Disease in allogeneic transplants
- May increase the risk of developing other cancers in the future [2,15,17]

Watch and Wait

In Watch and Wait, although active sites of disease are present, if there are no symptoms of lymphoma, treatment is withheld until deemed necessary. Treatment is often withheld until symptoms of the disease are present. (Possible symptoms are listed on page 5).

During this period, the patient is closely followed by their oncologist with frequent radiological scans, medical tests, and examinations of lymph nodes.

The reason that Watch and Wait can be used with Indolent Follicular Lymphoma, is that because the disease is slow-growing, so patients can often survive for very long periods of time without any treatment.[15,17]

Watch and Wait

Benefits 

- Since no treatment is being given, there are no side effects of Watch and Wait
- Although aggressive chemotherapy may lengthen periods in which patients are without symptoms, these treatments do not necessarily prolong survival. Watch and Wait allows the patient to avoid side effects and complications often associated with treatments without necessarily shortening survival time.[2,15]

Risks 

- Anxiety related to not actively treating the lymphoma
- Patient may have some symptoms of Follicular Lymphoma if they are present, or symptoms may occur
- Frequent checkups with oncologist, which include radiological scans and other diagnostic tests [2,15]

Clinical Trials

Clinical trials are controlled research studies in which new drugs or new devices are tested in patients to determine their effectiveness. New combinations of currently used treatments may also be tested.

All studies must be approved by an Institutional Review Board and the patient's signature must be obtained before the patient can participate. The risks and benefits of participating in a study are explained to the patient beforehand.

One thing to keep in mind is that because different treatments are often compared in these studies, patients may be randomly assigned to treatments.[15]

Information about current clinical trials can be obtained from:

- ✓ Asking your oncologist about available options
- ✓ National Cancer Institute: www.cancer.gov/clinicaltrials or 1-800-4CANCER
- ✓ American Cancer Society: www.cancer.org or 1-800-ACS-2345
- ✓ Lymphomation: www.lymphomation.org

Clinical Trials

Benefits 

- Might have access to highly effective treatments that are currently being studied
- Will contribute to further understanding of treatment for lymphoma
- May receive treatment without monetary cost[2,15]

Risks 

- May not have choice about which treatments you receive
- Treatment may not result in improved outcome
- Anxiety related to being randomly assigned to treatment groups or not knowing what effect the treatment may have[2,15]

Questions to Ask Your Doctor

Here is a list of questions that might be useful to discuss with your doctor:

What side effects from these treatments are likely to affect me?

Which treatments would you recommend? Why?

How many treatments will I have to take?

What is the survival rate with these treatments for patients with disease similar to mine?

What is the average length of time for remission with these treatments for patients with disease similar to mine?

What will these treatments do to my body?

What can I do to help prevent or minimize side effects from these treatments?

What are my options for emotional support during these treatments?

Patient Decision Example: Catherine's Situation[a]

Below is an example of a patient going through steps to make a decision about treatment.

What is the decision you need to make?

Which treatment to choose for my follicular lymphoma

Do you know what options you have?

Yes

Do you know the good and bad points about each option?

Yes

What are the factors most important to you in determining your decision?

Avoiding spending too much time as a patient in the hospital
Don't want to be nauseated
Minimizing side effects from treatments
Staying in remission for as long as possible and surviving as long as possible

[a] Worksheet adapted from the Ottawa Personal Decision Guide[21]

Catherine's Situation[a]

1. Please list and review only the options you are considering. You do not have to fill in all of the spaces provided for options.
2. List the pros and cons of each option for you.
3. Show how important each pro or con is to you by placing one star (*) to five stars (*****) beside each item.

	Pros	Personal Importance to me (*)	Cons	Personal Importance to me (*)
Option 1 is: *Chemo-therapy*	-Probably won't have to stay in hospital -Have drugs for nausea	***** ***** ***	-Might get nauseated -Don't know if it will increase my survival	***** ***** *****
Option 2 is: *Biologic therapy*	-Probably won't have to stay in hospital -Have drugs for nausea -Side effects won't last long	***** ***** ***	-Might get nauseous -Don't know if it will increase my survival	***** *****
Option 3 is: *A clinical trial*	-Will help the doctors learn about treatments	**	-Probably won't get to choose	****

[a] Worksheet adapted from the Ottawa Personal Decision Guide[21]

Catherine's Situation

	Pros	Personal Importance to me (*)	Cons	Personal Importance to me (*)
Option 4 is: *Watch and wait*	-Probably won't have to stay in hospital -Won't have side effects -May not decrease my survival	***** ***** *****	-Will worry about how long I will be in remission -Will get frequent medical tests	**** **
Option 5 is:				
Option 6 is:				

For Additional Information

Websites

- ✓ National Cancer Institute: www.cancer.gov
- ✓ American Cancer Society: www.cancer.org
- ✓ Lymphomation: www.lymphomation.org
- ✓ Leukemia and Lymphoma Society: www.lls.org

Books

- ✓ Holman, P., Garrett, J., & Jansen, W. (2004). *100 Questions and Answers about Lymphoma.* Sudbury, MA: Jones and Bartlett Publishers.
- ✓ Johnston, L. (1999). *Non-Hodgkin's Lymphomas: Making sense of diagnosis, treatment, and options.* Sebastopol, CA: O'Reilly.

Telephone Numbers

- ✓ National Cancer Institute: 1-800-4CANCER
- ✓ American Cancer Society: 1-800-ACS-2345

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20 Wake, B., Hyde, C. Bryan, S., Barton, P., Song, F., Fry-Smith, A., et al. (2002). Rituximab as third-line treatment for refractory or recurrent Stage III or IV follicular non-Hodgkin's lymphoma: A systematic review and economic evaluation. *Health Technology Assessment, 6,* 1-83.

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Please complete the two pages of this “My Situation” form as if you were trying to make a decision about treatment as the patient in “Max’s Situation.” Feel free to review the information in the decision aid that you just read.

My Situation[a]

What is the decision you need to make?

Do you feel you know what options you have?

Do you feel you know the good and bad points about each option?

What are the factors most important to you in determining your decision?

[a] Worksheet adapted from the Ottawa Personal Decision Guide[21]

My Situation[a]

1 Please list and review the options you are considering. You do not need to list all possible options. List only those you are considering.
2 List the pros and cons of each option for you.
3 Show how important each pro or con is to you by placing one star (*) to five stars (*****) beside each item.

	Pros	Personal Importance to me (*)	Cons	Personal Importance to me (*)
Option 1 is:				
Option 2 is:				
Option 3 is:				
Option 4 is:				
Option 5 is:				
Option 6 is:				

[a] Worksheet adapted from the Ottawa Personal Decision Guide[21]

Appendix B

Semi-Structured Interview

What information about the disease is important in evaluating treatment options?

What information about treatment is important in evaluating treatment options?

What questions should a patient ask a physician about treatment options?

What format would you prefer in a decision aid (e.g., picture illustrations, amount of information per page, overall length of aid, bullet points vs. paragraphs)?

What information do you think would be important to include in a treatment decision scenario for a patient who is attempting to choose among treatment options for recurrent follicular lymphoma?

Appendix C

Decision Aid Evaluation Questionnaire

Please answer each question after reading the decision aid. You will be asked questions about each section of the decision aid.

The Lymphatic System: Circle the number that best represents how much you agree with each statement (1=disagree, 2=somewhat disagree, 3= somewhat agree, 4=agree).

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
The information about the lymphatic system was useful	1	2	3	4
The information about the lymphatic system was relevant to me	1	2	3	4
The information about the lymphatic system was clear	1	2	3	4
The information about the lymphatic system was understandable	1	2	3	4
The information about the lymphatic system was applicable to my situation	1	2	3	4

What information would you like to see added to the information about the lymphatic system?

What information would you like to see deleted from the information about the lymphatic system?

What other modifications would like to see made to the information about the lymphatic system?

The Lymphomas and Follicular Lymphoma: Circle the number that best represents how much you agree with each statement (1=disagree, 2=somewhat disagree, 3= somewhat agree, 4=agree).

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
The information about the lymphomas and follicular lymphoma was useful	1	2	3	4
The information about the lymphomas and follicular lymphoma was relevant to me	1	2	3	4
The information about the lymphomas and follicular lymphoma was clear	1	2	3	4
The information about the lymphomas and follicular lymphoma was understandable	1	2	3	4
The information about the lymphomas and follicular lymphoma was applicable to my situation	1	2	3	4

What information would you like to see added to the information about the lymphomas and follicular lymphoma?

What information would you like to see deleted from the information about the lymphomas and follicular lymphoma?

What other modifications would like to see made to the information about the lymphomas and follicular lymphoma?

Chemotherapy: Circle the number that best represents how much you agree with each statement (1=disagree, 2=somewhat disagree, 3= somewhat agree, 4=agree).

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
The information about chemotherapy was useful	1	2	3	4
The information about chemotherapy was relevant to me	1	2	3	4
The information about chemotherapy was clear	1	2	3	4
The information about chemotherapy was understandable	1	2	3	4
The information about chemotherapy was applicable to my situation	1	2	3	4

What information would you like to see added to the information about chemotherapy?

What information would you like to see deleted from the information about chemotherapy?

What other modifications would like to see made to the information about chemotherapy?

Radiation: Circle the number that best represents how much you agree with each statement (1=disagree, 2=somewhat disagree, 3= somewhat agree, 4=agree).

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
The information about radiation was useful	1	2	3	4
The information about radiation was relevant to me	1	2	3	4
The information about radiation was clear	1	2	3	4
The information about radiation was understandable	1	2	3	4
The information about radiation was applicable to my situation	1	2	3	4

What information would you like to see added to the information about radiation?

What information would you like to see deleted from the information about radiation?

What other modifications would like to see made to the information about radiation?

Biologic Therapy: Circle the number that best represents how much you agree with each statement (1=disagree, 2=somewhat disagree, 3= somewhat agree, 4=agree).

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
The information about biologic therapy was useful	1	2	3	4
The information about biologic therapy was relevant to me	1	2	3	4
The information about biologic therapy was clear	1	2	3	4
The information about biologic therapy was understandable	1	2	3	4
The information about biologic therapy was applicable to my situation	1	2	3	4

What information would you like to see added to the information about biologic therapy?

What information would you like to see deleted from the information about biologic therapy?

What other modifications would like to see made to the information about biologic therapy?

Stem Cell Transplantation: Circle the number that best represents how much you agree with each statement (1=disagree, 2=somewhat disagree, 3= somewhat agree, 4=agree).

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
The information about stem cell transplantation was useful	1	2	3	4
The information about stem cell transplantation was relevant to me	1	2	3	4
The information about stem cell transplantation was clear	1	2	3	4
The information about stem cell transplantation was understandable	1	2	3	4
The information about stem cell transplantation was applicable to my situation	1	2	3	4

What information would you like to see added to the information about stem cell transplantation?

What information would you like to see deleted from the information about stem cell transplantation?

What other modifications would like to see made to the information about stem cell transplantation?

Watch and Wait: Circle the number that best represents how much you agree with each statement (1=disagree, 2=somewhat disagree, 3= somewhat agree, 4=agree).

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
The information about watch and wait was useful	1	2	3	4
The information about watch and wait was relevant to me	1	2	3	4
The information about watch and wait was clear	1	2	3	4
The information about watch and wait was understandable	1	2	3	4
The information about watch and wait was applicable to my situation	1	2	3	4

What information would you like to see added to the information about watch and wait?

What information would you like to see deleted from the information about watch and wait?

What other modifications would like to see made to the information about watch and wait?

Clinical Trials: Circle the number that best represents how much you agree with each statement (1=disagree, 2=somewhat disagree, 3= somewhat agree, 4=agree).

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
The information about clinical trials was useful	1	2	3	4
The information about clinical trials was relevant to me	1	2	3	4
The information about clinical trials was clear	1	2	3	4
The information about clinical trials was understandable	1	2	3	4
The information about clinical trials was applicable to my situation	1	2	3	4

What information would you like to see added to the information about clinical trials?

What information would you like to see deleted from the information about clinical trials?

What other modifications would like to see made to the information about clinical trials?

Appendix D

Patient Demographic Questionnaire

Please answer the following questions.

Date of Birth_____

Gender: (circle) Male Female

Ethnicity: (circle) Caucasian/White
African American/Black
Hispanic/Latino
Other_____

Education: (circle one) 12th grade or below
High School Graduate
Some college
College Graduate
Graduate School

Appendix E

Patient Scenario

Max's Situation

Please read the following patient situation:

Max is a 48-year-old Caucasian male from Morgantown, West Virginia. He has been married to Susan for 23 years. They have two children, Sam (age 19) and Steve (age 21). Both of his children are currently students at West Virginia University. Max has been employed as a construction worker for the last 18 years.

Max was diagnosed with Stage III indolent follicular non-Hodgkin's lymphoma nine months ago. Since his diagnosis, he has undergone treatment with six cycles of chemotherapy. Now that the chemotherapy has finished, his oncologist has conducted some tests and has discovered that he still has some slow-growing active disease in several lymph nodes in his abdomen. Max must decide which type of treatment he should pursue. His oncologist has told him that his options are very open at this point. He may choose to undergo more *chemotherapy* or to begin one of several other therapies (e.g., *radiation*, *biologic therapy*, or a *stem cell transplant*). He also may explore available *clinical trials*. Since the only symptom he is currently experiencing is occasional night sweats, his oncologist has also given him the option to *watch and wait* before beginning active treatment.

Before receiving the diagnosis of follicular lymphoma, Max did not have a history of major medical problems. His only history of illness included developing a cold about once per year.

Max would be able to receive any of these treatments at his local hospital. His insurance has agreed to cover any of these options, and his current boss is willing to give him as much unpaid time off as he needs to recover from treatment.

Appendix F

Patient Scenario Evaluation Questionnaire

Please answer these questions after reading “Max’s Situation.”

	Not very Believable			Very Believable
How believable is Max’s situation? (circle one number of the scale)	1	2	3	4

Please answer the following questions:

What information do you think should be added to the information presented in Max’s situation that might influence his decision about treatment?

What information do you think should be deleted from the information presented in Max’s situation that would be irrelevant or unimportant in his decision about treatment?

What other modifications do you think should be made to Max’s situation that might influence his decision about treatment?

Appendix G

Comparison Decision Aid

A Decision Aid for Patients with Indolent Follicular non-Hodgkin's Lymphoma

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This decision aid was designed based upon the framework created by Ottawa Decision Aids, Inc.[1]

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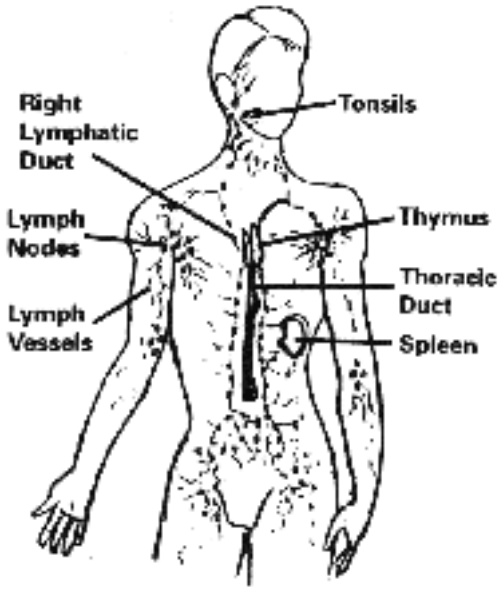
The Lymphatic System



The lymphatic system consists of several body parts including:

- spleen
- thymus
- tonsils
- bone marrow
- lymph nodes (These are the size of a bean and are distributed throughout the body. Clusters of lymph nodes are found in the armpits, abdomen, groin, pelvis, collarbone area, and neck.)[3,4]

The Lymphatic System

What does the lymphatic system do?

- The lymphatic system includes vessels that transport fluids throughout the body. A fluid called 'lymph' is circulated throughout the lymphatic system. This fluid contains white blood cells, which are also called 'lymphocytes.' These lymphocytes are created in the bone marrow and mature in the thymus. They are important in the body's ability to fight infection.

- The spleen and the lymph nodes are filters of the lymph fluid.

- When your body is fighting an infection such as from bacteria or viruses, the lymph nodes will swell with lymphocytes that will target and destroy these unwanted organisms in the body.[3,4,5]

The Lymphomas

Almost all cells in the human body have the ability to divide to produce new cells that can replace the cells that die. However, cancer results from a defect within a cell that causes the cell to continue to divide faster than the rate of cell death. These cancerous cells inhibit the growth and survival of normal cells.[6]

The lymphomas are cancers of the lymphocytes. Lymphomas are divided into Hodgkin's Lymphoma and non-Hodgkin's Lymphoma. Non-Hodgkin's Lymphoma is the most common type of lymphoma.

Non-Hodgkin's Lymphoma can be categorized in several ways:[2,7,8]

By grade:

Indolent or Low Grade (slow growing)
Intermediate Grade (moderate growth rate)
Aggressive or High Grade (fast growing)

By stage:

Stage I: lymphoma detected in one lymph node

Stage II: lymphoma detected in two or more lymph nodes near each other

Stage III: lymphoma detected in several lymph nodes far apart

Stage IV: widespread involvement of lymph nodes as well as organs such as liver, lungs, or bone

What is Follicular non-Hodgkin's Lymphoma?

Follicular Lymphoma is an Indolent (Low Grade) lymphoma. It is the second most common type of non- Hodgkin's lymphoma.[9]

Follicular Lymphoma is a slow-growing cancer of specific kinds of lymphocytes called B-cells.[10] These cancer cells are grouped in clusters, which are called follicles, in the lymph nodes.

For patients diagnosed with Follicular Lymphoma, especially those in which the disease is more widespread than Stage I, the disease may be considered "incurable." This means that even after treatment, the disease can be expected to remain dormant in the body and may recur. More aggressive treatment may lengthen the amount of time between recurrences.[9,11]

With new and better treatment options available, the length of survival for patients with follicular lymphoma has been increasing over the years.[12]

Symptoms of follicular lymphoma can be difficult to identify and thus, most patients present with advanced-stage disease.[10]

Possible symptoms include:

- Fever
- Fatigue
- Itchy skin
- Drenching night sweats
- Unexplained weight loss
- Pain in chest, bones, or abdomen
- Painless swelling of lymph nodes

Treatments for Follicular non-Hodgkin's Lymphoma

Treatments available to each patient will depend upon several factors including stage of disease, whether organs outside of lymph nodes are affected, the lymphoma's cell type, patient age, and current symptoms.[2]

Current treatment options for follicular lymphoma include:[2,13]

- Chemotherapy
- Radiation
- Biologic Therapy
- Stem Cell Transplantation
- Watch and Wait
- Clinical Trial

As of today, there is no consensus among oncologists about which treatment option is the best.[14]

Chemotherapy

Chemotherapy is commonly used when a patient is first diagnosed, but is also used when the disease recurs.[10]

Chemotherapy is a drug that is either injected into the veins or swallowed orally. Once the drug enters the body, it is carried by the blood stream to areas throughout the body. These drugs are designed to either kill the cancer cells or to stop their ability to multiply.[7]

Chemotherapy drugs can be used alone, in combination with other chemotherapy drugs, or in combination with some of the treatments mentioned in the next few sections (e.g., radiation, biologic therapy, or stem cell transplantation).[2,15] Chemotherapy may also be combined with steroids. Most chemotherapy treatment will require more than one session of treatment. The number of sessions will depend on your specific case. Each type of chemotherapy can have its own different possible risks and benefits.

Examples of common chemotherapy regimens:

- CHOP: Cyclophosphamide, Doxorubicin, Vincristine, Prednisone
- CVP: Cyclophosphamide, Vincristine, Prednisone

Radiation

Radiation is a treatment that kills lymphoma cells in a specific area using high-energy rays.[2] The rays work to damage the DNA in the lymphoma cells, which can cause death of the cancerous cells.[15]

Before administering radiation, scans will be used to map out a specific area on the body for administration of the radiation to limit the number of healthy cells that are damaged. Treatment usually takes several sessions. These sessions typically last about 15 minutes, with repeated sessions for several weeks.[15]

Radiation can be used when the patient has a large area of lymphoma cells within a small area of the body, or when enlarged lymph nodes are interfering with other organs.[2] Radiation can be used alone, or it is often used in combination with chemotherapy.

Biologic Therapy

In the human body, antibodies are produced by the immune system to help the body know which substances are foreign and should be destroyed. Biologic Therapy involves treatments that use antibodies to fight the lymphoma.[18]

Monoclonal Antibody Therapy is a type of biologic therapy in which an antibody is injected into the blood. When a Monoclonal Antibody is circulated throughout the system, it seeks out and destroys lymphoma cells. Monoclonal Antibody Therapy is often used in conjunction with chemotherapy.[2,17]

Radioimmunotherapy is a form of biologic therapy that uses a radioactive substance, which is carried to the lymphoma cells by monoclonal antibodies. This treatment targets the lymphoma cells directly and leaves normal cells intact.[2]

Examples of Biologic Therapy:[17]

- Rituxan: This monoclonal antibody treatment is usually injected into the veins every week for about four weeks. Each treatment can take anywhere from 4 to 8 hours, with the first treatments typically taking the longest.
- Zevalin or Bexxar: These radioimmunotherapies are actually a form of radiation and are given along with Rituxan. It takes seven to nine days to administer. Over the course of therapy, body scans are conducted to determine how the radiation has distributed throughout the body. Radiation is delivered directly to the lymphoma cells, which helps to protect normal cells.

Stem Cell Transplantation

In Stem Cell Transplantation, the patient is first given high dose chemotherapy to destroy the lymphoma cells. When this high dose chemotherapy is given, it can destroy much of the bone marrow tissue making it necessary to replace the tissue that has been destroyed. In a Stem Cell Transplant, bone marrow stem cells are infused into the blood stream following chemotherapy. These stem cells will make their way to the bone marrow, where they will grow and create new blood cells.

Stem cells used for transplant must be obtained from a donor. There are two types of donors:

- Autologous: The patient acts as his or her own donor. During a time of remission, the patient is given a drug that will increase the number of stem cells in the blood stream. The stem cells are collected through a machine and the rest of the blood is infused back into the patient. The stem cells are saved and infused into the patient's blood stream after chemotherapy.
- Allogeneic: Stem cells from a sibling or other donor who genetically meets criteria are used. The stem cells are collected from the donor in a similar procedure to the autologous transplant. These stem cells are infused into the patient's blood stream following chemotherapy.

During and following the transplant, patients are hospitalized for several weeks to several months. Since much of the bone marrow has been destroyed and thus the bone marrow is not producing new blood cells, patients often need blood cell replacements during this time.

A common complication that can occur with an allogeneic donor is Graft Versus Host Disease. This occurs when the donor's bone marrow cells recognize the patient's original cells as foreign and begin to work against them. This disease can affect the skin, liver, gastrointestinal tract, eyes, and lung. It can last from several weeks to years, and can sometimes be fatal.[15]

Watch and Wait

In Watch and Wait, although active sites of disease are present, if there are no symptoms of lymphoma, treatment is withheld until deemed necessary. Treatment is often withheld until symptoms of the disease are present. (Possible symptoms are listed on page 4).

During this period, the patient is closely followed by their oncologist with frequent radiological scans, medical tests, and examinations of lymph nodes.

The reason that Watch and Wait can be used with Indolent Follicular Lymphoma, is that because the disease is slow-growing, so patients can often survive for very long periods of time without any treatment.[15,17]

Clinical Trials

Clinical trials are controlled research studies in which new drugs or new devices are tested in patients to determine their effectiveness. New combinations of currently used treatments may also be tested.

All studies must be approved by an Institutional Review Board and the patient's signature must be obtained before the patient can participate. The risks and benefits of participating in a study are explained to the patient beforehand.

One thing to keep in mind is that because different treatments are often compared in these studies, patients may be randomly assigned to treatments.[15]

Information about current clinical trials can be obtained from:

- ✓ Asking your oncologist about available options
- ✓ National Cancer Institute: www.cancer.gov/clinicaltrials or 1-800-4CANCER
- ✓ American Cancer Society: www.cancer.org or 1-800-ACS-2345
- ✓ Lymphomation: www.lymphomation.org

For Additional Information

Websites

- ✓ National Cancer Institute: www.cancer.gov
- ✓ American Cancer Society: www.cancer.org
- ✓ Lymphomation: www.lymphomation.org
- ✓ Leukemia and Lymphoma Society: www.lls.org

Books

- ✓ Holman, P., Garrett, J., & Jansen, W. (2004). *100 Questions and Answers about Lymphoma.* Sudbury, MA: Jones and Bartlett Publishers.
- ✓ Johnston, L. (1999). *Non-Hodgkin's Lymphomas: Making sense of diagnosis, treatment, and options.* Sebastopol, CA: O'Reilly.

Telephone Numbers

- ✓ National Cancer Institute: 1-800-4CANCER
- ✓ American Cancer Society: 1-800-ACS-2345

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Appendix H

Ratings and Rankings of Treatment Preference

If you were in Max's situation, please circle the number that most corresponds with how much you would prefer to receive each treatment (4=would definitely prefer to 1=would definitely not prefer)

	Would Not Prefer			Would Definitely Prefer
Chemotherapy	1	2	3	4
Radiation	1	2	3	4
Biologic Therapy	1	2	3	4
Stem Cell Transplant	1	2	3	4
Watch and Wait	1	2	3	4
Clinical Trial	1	2	3	4

Please rank order the treatments from 1 to 6 in order of what you feel is the best treatment option, with 1=the best treatment option and 6=the worst treatment option.

____Chemotherapy

____Radiation

____Biologic Therapy

____Stem Cell Transplant

____Watch and Wait

____Clinical Trial

Appendix I

Knowledge Test

Please read each question and circle the best possible answer.

1. Stage II lymphoma is defined as:
    a. Lymphoma detected in blood vessels
    b. Lymphoma detected in several lymph nodes far apart
    c. Lymphoma detected in two or more lymph nodes close together
    d. Lymphoma detected in one lymph node

2. Which of the following lists include only organs that are part of the lymphatic system?
    a. Spleen, thymus, heart, bone marrow
    b. Spleen, pancreas, thymus, bone marrow
    c. Spleen, thymus, bone marrow, tonsils
    d. Thymus, pancreas, lymph nodes, bone marrow

3. Which is the most common type of lymphoma?
    a. Hodgkin's lymphoma
    b. Non-Hodgkin's lymphoma
    c. Burkitt's lymphoma
    d. Follicular lymphoma

4. Which grade of cancer is follicular lymphoma?
    a. Irregular
    b. Aggressive or High Grade
    c. Intermediate
    d. Indolent or Low Grade

5. All of the following are common possible symptoms of follicular lymphoma EXCEPT:
    a. Blurred vision
    b. Night sweats
    c. Itchy skin
    d. Fatigue

6. All of the following are possible treatments for follicular lymphoma EXCEPT:
    a. Radiation
    b. Laser therapy
    c. Biologic therapy
    d. Stem cell transplants

7. Advanced stage lymphoma is likely to occur:
    a. Only in the neck and abdomen
    b. In organs
    c. Only in the lymph nodes
    d. In hair and nail tissue

8. Which of the following is a risk of using chemotherapy?
    a. Most side effects continue after treatment is finished
    b. The wrong chemotherapy may increase the severity of the cancer
    c. Chemotherapy is typically not well-tolerated in patients
    d. Chemotherapy may damage other organs

9. Chemotherapy is used for follicular lymphoma:
    a. When the disease is first diagnosed
    b. When the disease has recurred
    c. When the disease is first diagnosed or has recurred
    d. After all other forms of treatment have been exhausted

10. Radiation for follicular lymphoma:
    a. Uses high-energy rays to kill cancer cells
    b. Is introduced with a radioactive pill that is swallowed
    c. Both a and b
    d. None of the above

11. All of the following are relative benefits of using radiation to treat lymphoma EXCEPT:
    a. Most side effects end soon after treatment is finished
    b. Can be used for disease that has spread throughout the body
    c. Can reduce the number of chemotherapy cycles needed
    d. Treatments are short in duration

12. Radioimmunotherapy is a form of:
    a. Bone Marrow Transplantation
    b. Chemotherapy
    c. Antibiotic therapy
    d. Biologic therapy

13. Monoclonal Antibody Therapy:
    a. Seeks out cancer cells
    b. Cannot be used with chemotherapy
    c. Is a form of chemotherapy
    d. Is a form of antibiotic therapy

14. In which type of transplant are stem cells donated from the patients themselves:
    a. Allogeneic
    b. Autologous
    c. Autonomic
    d. Autoimmune

15. What type of cells can be transplanted in a stem cell transplant for follicular lymphoma patients?
    a. Bone marrow
    b. Liver
    c. Spinal
    d. Lymph

16. The side effect called *graft versus host disease*:
    a. Does not occur in an autologous transplant
    b. Does not occur in an allogeneic transplant
    c. Has no symptoms
    d. Results from too much chemotherapy

17. A watch and wait approach is used primarily when:
    a. There is no disease present in the patient
    b. All treatment options have already been pursued
    c. The patient is waiting for a stem cell transplant
    d. The patient does not have active symptoms

18. Which of the following is NOT a risk of watch and wait:
    a. Requires frequent physician check-ups
    b. Patient may experience anxiety
    c. May shorten length of survival
    d. Patient may have some symptoms

19. A clinical trial is:
    a. A research study testing new treatment options
    b. A research study testing the effects of cancer on patients
    c. A research study in which patients choose which treatment options to pursue
    d. A research study that tests effects of hospital stays on cancer patients

20. Clinical trials involve:
    a. Not informing patient of the risks of the study
    b. Approval from an Institutional Review Board
    c. Approval from a Congressional Review Board
    d. Both a and b

Appendix J

Sociodemographic Questionnaire

Please answer the following questions.

Date of Birth_____

Gender: (circle) Male Female

Ethnicity: (circle) Caucasian/White
African American/Black
Hispanic/Latino
Other_____

Education: (circle one) 12th grade or below
High School Graduate
Some college
College Graduate
Graduate School

Have you ever known anyone with cancer? (circle one) yes no

Have you helped someone make a decision about treatment for cancer? (circle one) yes no

Have you ever known anyone with lymphoma? (circle one) yes no

Appendix K

Opinion of the Decision Aid

Please answer the following questions.

What aspects of the Decision Aid were the most helpful in making your decision about treatment?

What aspects of the Decision Aid were the least helpful in making your decision about treatment?

Appendix L

Patient Responses to Semi-Structured Interview Questions

What information about the disease is important in evaluating treatment options?

- Patient 1: broad information in an understandable format
- Patient 2: early symptoms, can have for a long time before you know it
- Patient 3: difference between Hodgkin's and non-Hodgkin's, symptoms and signs
- Patient 4: explain the disease and that the disease is long-term
- Patient 5: chance of being in remission
- Patient 6: how fast the disease needs to be treated
- Patient 7: what type it is, how fast does it grow
- Patient 8: what causes lymph nodes to become aggressive, list symptoms
- Patient 9: likelihood of spreading to other organs, causes

What information about treatment is important in evaluating treatment options?

- Patient 1: side effects
- Patient 2: side effects, instructions for treatments
- Patient 3: how long the procedures take
- Patient 4: explain all treatments, side effects
- Patient 5: that it's not as bad as everyone thinks
- Patient 6: talk about good stuff as well as bad
- Patient 7: length of treatment, that you won't always be sick, what the drug does in lay terms
- Patient 8: explain them in lay language, emphasize that not everyone gets sick
- Patient 9: explain options available

What questions should patient ask a physician about treatment options?

- Patient 1: What treatments can I have?, Are there options besides standard treatments?
- Patient 2: Will I have pain?, Which treatment would you choose, doctor?
- Patient 3: How far along is my cancer?, Will I get side effects from treatments?, What is my chance of it coming back?, How long will I have to have treatment?
- Patient 4: What are the side effects? What side effects are likely to affect me?
- Patient 5: How long will the treatment last?
- Patient 6: What are the side effects? Will this hurt? What will this do to my body?
- Patient 7: Am I going to live? When can we start? Where can I get emotional support? What should I expect?
- Patient 8: How much risk to other vital organs?, What is normal time span for being in remission?
- Patient 9: What causes lymphoma?, What is the chance of it spreading?

What format would you prefer in the decision aid (e.g., picture illustrations, amount of information per page, overall length of aid, bullet points vs. paragraphs).

Patient 1: would like pictures and examples, 5-10 pages, bullets and paragraphs combined
Patient 2: pictures would be nice, 4-5 pages, paragraphs preferable, would like patient examples
Patient 3: not sure about pictures, 15-20 pages, both paragraphs and lists, patient examples good
Patient 4: no pictures, no more than 10 pages, not too detailed, prefer listed information, examples could be helpful
Patient 5: lists of information, pictures are useful, examples could be useful
Patient 6: would like pictures, 15-18 pages, examples would be useful but make sure they know the decision is their own, would like paragraphs
Patient 7: visuals like a smiley face and tearful face, both paragraphs and lists, more than 4 pages, examples would be a good idea
Patient 8: picture of lymph system, at least 20 pages, lists and paragraphs, examples would be helpful
Patient 9: pictures would be good, 4 to 5 pages, would prefer lists of information, lay language, patient example would be good

What information do you think would be important to include in a treatment decision scenario for a patient who is attempting to choose among treatment options for recurrent follicular lymphoma?

Patient 1: family information
Patient 2: which treatment does the doctor recommend
Patient 3: which treatment options, if they have medical leave of absence, do they have family support
Patient 4: which treatments considering, distance from hospital
Patient 5: describe the patient's disease
Patient 6: don't know
Patient 7: family information, history with cancer, options available to them
Patient 8: how early the disease was detected
Patient 9: when it was diagnosed

Appendix M

Patient Responses to Patient Scenario Evaluation

What information do you think should be added to the information presented in Max's situation that might influence his decision about treatment?

Patient 1: more detail about each treatment option and side effects
Patient 2: what information is available about each treatment option
Patient 3: no comment
Patient 4: what symptoms, side effects of each treatment
Patient 5: treatments should start ASAP

What information do you think should be deleted from the information presented in Max's situation that would be irrelevant or unimportant in his decision about treatment?

Patient 1: boss giving him time off unpaid
Patient 2: delete the treatment options that are not as effective
Patient 3: no comment
Patient 4: all fine
Patient 5: remove option of watch and wait

What other modifications do you think should be made to Max's situation that might influence his decision about treatment?

Patient 1: more information about each treatment option
Patient 2: more information regarding available clinical trials
Patient 3: no comment
Patient 4: all treatment options explained, make sure insurance will cover
Patient 5: explain the cycle of growth of the cancer

Appendix N

Patient Written Responses to Decision Aid Evaluation Questionnaire

Lymphatic System
Patient 1: no response
Patient 2: no response
Patient 3: no response
Patient 4: would like lymphoma drawing in more detail and larger
Patient 5: say you need to follow instructions in order to recover, make sure aware of side effects
Patient 6: diagram is small, can you enlarge it?

The Lymphomas and Follicular Lymphoma
Patient 1: no response
Patient 2: no response
Patient 3: no response
Patient 4: no response
Patient 5: I understand the information, no other suggestions
Patient 6: consider "treatable but not curable" rather than "incurable"

Chemotherapy
Patient 1: no response
Patient 2: no response
Patient 3: no response
Patient 4: no response
Patient 5: this was all I learned when I had chemo
Patient 6: wide variety available and tested

Radiation
Patient 1: no response
Patient 2: no response
Patient 3: no response
Patient 4: no response
Patient 5: make sure patient understands what needs to be done before starting treatment
Patient 6: no response

Biologic Therapy
Patient 1: no response
Patient 2: no response
Patient 3: no response
Patient 4: no response
Patient 5: Would the meds for nausea help with this treatment?, no other suggestions
Patient 6: no response

Stem Cell Tranplantation
Patient 1: no response
Patient 2 :no response
Patient 3: no response
Patient 4: no response
Patient 5: the time it takes to bring platelets back up to normal is a slow process
Patient 6: SCT now done with or without complete ablation of bone marrow

Watch and Wait
Patient 1: no response
Patient 2: no response
Patient 3: no response
Patient 4: no response
Patient 5: make sure patients know what to look for as far as symptoms
Patient 6: under risks-patient can become reluctant to begin treatment when necessary

Clinical Trials
Patient 1: no response
Patient 2: no response
Patient 3: no response
Patient 4: no response
Patient 5: no response
Patient 6: trials in various stages or phases of testing

Appendix O

Table 17

Pearson Correlation Coefficients for Change in Satisfaction with Decision, Change in Decisional Conflict, and Predictor Variables

	Satisfaction	Res. Satis.	Dec. Conf.	Res. Conf.	Age	Need for Cog.	M/B	STAI	CES-D	Gender	Educ.
Satisfaction	1.00	.481**	-.569**	-.256	-.473**	.017	.127	.094	-.181	-.089	-.031
Satis. Residualized	.481**	1,00	-.143	-.494**	-.103	.339*	.074	.082	.153	.126	.133
Decisional Conflict	-.569**	-.143	1.00	.582**	.672**	-.058	-.412*	-.278	.017	.091	-.005
Conflict Residualized	-.256	-.494**	.582**	1.00	.502**	-.189	-.290	-.115	-.127	-.105	-.151
Age	-.473**	-.103	.672**	.502**	1.00	.053	-.415*	-.217	.016	.137	.029
Need for Cognition	.017	.339*	-.058	-.189	.053	1.00	-.045	-.067	.255	.488**	.046
Mon/Blunt	.127	.074	-.412*	-.290	-.415*	-.045	1.00	.161	.136	-.074	.002
STAI	.094	.082	-.278	-.115	-.217	-.067	.161	1.00	.437**	-.249	-.207
CES-D	-.181	.153	.017	-.127	.016	.255	.136	.437**	1.00	.160	.090
Gender	-.089	.126	.091	-.105	.137	.488**	-.074	-.249	.160	1.00	.209
Education	-.031	.133	-.005	-.151	.029	.046	.002	-.207	.090	.209	1.00

* $p < .05$, ** $p < .01$

Appendix P

Table 18

Mean values of continuous predictor variables for decision aid group

Variable	*M (SD)*
Age	59.03 (9.14)
Need for Cognition	58.33 (13.00)
Monitoring/Blunting	4.00 (1.83)
STAI	35.33 (8.16)
CES-D	9.33 (7.61)

Appendix Q

Table 19

Pearson Correlation Coefficients for Change in Knowledge, Reading Time, and Time until Decision

	Change in Knowledge	Reading Time	Time until Decision
Change in Knowledge	1.00	.386**	.033
Reading Time	.386**	1.00	.345*
Time until Decision	.033	.345*	1.00

* p < .05, ** p < .01

Table 20

Mean values of reading time and time until decision for decision aid group

Variable	*M (SD)*
Reading Time	16.43 (4.89)
Time until Decision	14.00 (6.63)

Appendix R

Participant responses to Opinion of the Decision Aid Questionnaire

What aspects of the Decision Aid were the most helpful in making your decision about treatment?

Male

1. benefits vs. risks
2. description of each type of treatment and how they work and effects of each
3. pros and cons, fact that final decision is mine, excellent explanations
4. info and explanations
5. Catherine's situation
6. no response
7. comparison of pros and cons
8. pros and cons with each treatment
9. no response
10. pros and cons
11. benefits and risks
12. frankness, side effects, each treatment discussed in same format
13. benefits and risks of each treatment
14. lists of treatments, pros and cons
15. all the different situations

Female

16. pros and cons, made personal and realistic, think I'd still ask doctor
17. was helpful and informative, thought it was great
18. lists of pros and cons
19. explained what lymphoma is, what treatment options are available, and pros and cons
20. risks and benefits
21. none
22. benefits/risks
23. actual information about choices
24. pros and personal importance to me
25. what each treatment involved and side effects
26. oncologists option
27. describing approaches of treatments, what uses would be, side effects, outcomes
28. pros and cons
29. benefits and risks
30. description of treatments, benefits and risks

What aspects of the Decision Aid were the least helpful in making your decision about treatment?

Male

1. examples of therapy
2. lists of authors and footnotes

3. found all helpful due to how uneducated I am on this subject
4. research listings
5. no comment
6. possible consequences of choosing a treatment
7. N/A
8. felt I needed more information about the decision
9. the "clinical trial" was left rather open-ended
10. no response
11. my inability to remember what each one was
12. can't think of any
13. not knowing what might be best for me
14. list of materials used to gather info
15. not knowing what's right

Female

16. each person's case is different so hard to say which treatment is best right now
17. it's still a tough decision
18. would like to know more about exact treatment time, hospital stay time, possible "remission" time
19. well-written, explained disease and treatments in layman terms, there was nothing that was not helpful
20. background info
21. none
22. would have liked more information about survival time
23. not knowing information about the choices
24. all helpful so I can't really answer this question
25. I think it was all helpful
26. treatment already given
27. no in-depth stud of the personal health and other factors that could contribute to the decision-making process
28. no clue ahead of time what this was about
29. probably discussion on lymphatic system
30. anatomy and function of the lymphatic system