

Patient Perspectives on Colorectal Cancer

Findings from a comprehensive survey of
150 patients with colorectal cancer

EDITOR

Neil Love, MD

FACULTY

John L Marshall, MD

TOPICS

- The initial diagnosis, consultation with a medical oncologist
- Risks and benefits of adjuvant chemotherapy
- Clinical trial participation
- Recovery from chemotherapy, prevention of a second colorectal cancer
- Patient grading of physicians, patient education needs

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Colorectal Cancer™
UPDATE



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Patient Perspectives on Colorectal Cancer

A CME Audio Series and Activity

STATEMENT OF NEED/TARGET AUDIENCE

Counseling patients on the natural history, treatment options and personal implications of the diagnosis of colorectal cancer is complex and time consuming. The many available treatment options for this disease make it a challenge for medical oncologists to explain important information to patients in an understandable manner.

This CME activity focuses on the perspectives of colorectal cancer clinical investigators and patients. The goal of this activity is to help physicians better understand how to optimally discuss colorectal cancer with patients in their practices.

GLOBAL LEARNING OBJECTIVES

- Inform patients with colorectal cancer about the specific risks and benefits of various adjuvant systemic therapies.
- Counsel patients with colorectal cancer about treatment options and ongoing clinical trials.
- Develop an increased understanding of the patient perspective on cancer information and treatment decisions in colorectal cancer.

PURPOSE OF THIS ISSUE OF *PATIENT PERSPECTIVES ON COLORECTAL CANCER*

The purpose of this issue of *Patient Perspectives on Colorectal Cancer* is to support these global objectives by offering the perspectives of Dr Marshall and patients with colorectal cancer on the translation and dissemination of complex information on colorectal cancer and its treatment in a format that would be helpful to patients diagnosed with the disease.

ACCREDITATION STATEMENT

Research To Practice is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

CREDIT DESIGNATION STATEMENT

Research To Practice designates this educational activity for a maximum of 1.75 category 1 credits toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

HOW TO USE THIS CME ACTIVITY

This CME activity contains both audio and print components, as well as corresponding PowerPoint slides on the CD. To receive credit, the participant should listen to the CD, review the monograph and complete the post-test and evaluation form located in the back of this monograph or on our website. This monograph contains edited comments, graphics and references. www.ColorectalCancerUpdate.com/Patients includes an easy-to-use, interactive version of this monograph with links to relevant full-text articles, abstracts, trial information and other web resources indicated here in [blue underlined text](#).



EDITOR'S NOTE

Neil Love, MD

Another perspective

Recent trends in the most common lethal cancers (breast, lung, colon-rectum and prostate) reveal that the clinical research advances with the greatest potential human impact have taken place in the treatment of tumors of the lower gastrointestinal tract.

Yes, breast cancer now has adjuvant trastuzumab (Herceptin®), which will significantly improve the long-term outcome for the approximately 25 percent of patients with HER2-positive disease, and lung cancer, thankfully, now has adjuvant chemotherapy, albeit with a research database that is pitifully underpowered. Prostate cancer continues to reside in the stone age of clinical research, but now for the first time, there appears to be an effective nonhormonal therapy for metastatic disease (docetaxel).

However, things look much brighter in colon cancer than they did just five years ago, and we now have three very important advances, which, taken together, have outpaced the recent progress in these other research fields:

1. The emergence of oxaliplatin as effective adjuvant therapy combined with a fluoropyrimidine

The relative reduction in recurrence rate (about 20 percent) with the FOLFOX and FLOX regimens compared to 5-FU alone is similar to the advantage seen with aromatase inhibitors compared to tamoxifen in ER-positive breast cancer.

While the “oxali” regimens are generally well tolerated, the challenges of administration are substantial, particularly related to the mostly short-term neuropathy that often limits the duration of treatment with this agent.

Nonetheless, for the first time in a decade, we have witnessed a significant therapeutic step forward, which should result in lower rates of colon cancer recurrence. This, of course, is good news for patients. Of great interest is that parallel studies of adjuvant irinotecan-containing regimens have basically been a bust.

This not only reinforces the power and value of well-conducted, large, multi-institutional randomized trials but also provides us with a definitive standard of care in this important clinical situation.

2. Demonstration that an oral agent can replace a parenteral therapy

Capecitabine (Xeloda[®]) is one of the most commonly utilized therapies for metastatic breast cancer (1), and its role in colon cancer is evolving. Many clinical trials are evaluating the substitution of this agent for infusional 5-FU combined with oxaliplatin.

While there is debate about this treatment strategy in clinical situations, the X-ACT trial, presented at the 2004 ASCO meeting, demonstrated that the use of capecitabine monotherapy can generally replace 5-FU monotherapy as adjuvant treatment. This, again, is an important step forward, as most patients consider oral therapy preferable to intravenous treatment.

3. The emergence of targeted biologic agents with efficacy in the metastatic setting and promise as adjuvant therapy

Bevacizumab (Avastin[®]) and cetuximab (Erbix[®]) have clear cut activity in patients in the advanced, noncurative setting, and an exciting new generation of large randomized trials will evaluate these agents combined with chemotherapy in the adjuvant setting. We should begin to see initial results from these studies in three to five years, and it will not be surprising if we witness another important step forward in the management of this ubiquitous disease.

The unprecedented explosion of new research findings and the launch of a number of new clinical trials in colon cancer mean that many more options are available to patients, and sorting through these alternatives is far more complicated than it was even three years ago.

Our oncology CME group has encountered many similar situations with other tumors over the last 18 years, and we believe that a critical need is to integrate the perspective of patients into the discussion. In both breast and prostate cancer, we conducted a number of projects in the past that attempted to gather information from patients that was then delivered to our healthcare-professional audiences (2-8).

We have now launched a similar initiative in colorectal cancer. The following report describes the first phase of this project,* which began in Houston on November 20, 2004, when we spent a day with approximately one hundred colorectal cancer patients and their guests at a “town meeting” featuring a panel of clinical investigators with whom we had previously worked on our physician education programs.† Our goal for this event was to learn from these attendees about their experiences not only with the disease and its treatment but also with their physicians. We also wanted to obtain input on how they saw treatment trade-offs in a variety of challenging clinical situations.

* *The Research To Practice Colorectal Cancer Patient Education Initiative is supported by an education grant from Sanofi-Aventis.*

† *Axel Grothey, MD, Leonard B Saltz, MD, Lee M Ellis, MD, Steven A Curley, MD and Heinz-Joseph Lenz, MD*

These patients and guests were provided electronic keypads — a familiar tool at physician education meetings — and during the day we polled the audience on their perspectives. We also made available print response cards and a couple of dozen networked computers, which served as vehicles for us to obtain additional qualitative information. In past years, we have hosted similar town meetings for both breast and prostate cancer patients, and our first impression from this event was that all cancer patients have similar needs and interests.

Based on the positive feedback and the interesting preliminary data we generated in Houston, we launched the second phase of this compelling project: a comprehensive telephone survey of 150 people with colorectal cancer from 35 states. The patients were recruited through a variety of mechanisms, including advocacy and support groups and oncology offices staffed by oncologists and oncology nurses who listen to our audio continuing education program. The protocol for this project was IRB-approved (Western #1064605), and patients were paid a modest honorarium (\$125).

Overview of the survey

We understand that people who participate in these types of projects are not necessarily representative of all patients, and the demographics of the participants (pages 12-15) reinforce this assertion. However, our goal was not to execute a scientific study but rather to develop an awareness-raising education initiative that would arm oncology healthcare professionals with valuable patient input. For this phase of the project, each participating patient was sent a 50-minute audio CD featuring an interview I conducted with John Marshall, a GI oncology investigator from Georgetown University. In the program, John expertly reviews the information he provides to his patients about the risks and benefits of adjuvant chemotherapy and the advice he delivers on how they can manipulate their lifestyles to avoid another colorectal cancer.

We instructed the patients in the study to stop the CD every eight to ten minutes and fill out an accompanying questionnaire, documenting their reactions to the information. This was followed by an in-depth telephone interview with a member of our CME group. We are presenting some of the findings from this study as a poster at the 2006 ASCO, ASTRO, SSO and American Gastroenterological Association Gastrointestinal Cancers Symposium in San Francisco. This report reviews and expands on those data and a number of other interesting areas of input from the participating patients. The CD accompanying this program and our website (www.ColoRectalCancerUpdate.com/Patients) provide PowerPoint slides with graphics from this report, along with the interview with Dr Marshall.

One of the key objectives of this project was to gain insight into how patients with colorectal cancer perceive the trade-offs of adjuvant systemic therapy and to determine whether the patient mindsets that we have observed in breast and prostate cancer also apply to colorectal cancer. Specifically, we were interested to see whether patients with colorectal cancer are equally focused on doing

everything reasonably possible to decrease the likelihood of cancer relapse, even if it means undergoing therapies that introduce considerable toxicity.

In a nutshell, we learned that many patients with colorectal cancer have very proactive attitudes toward therapy. The CME implication of this finding is that information on treatments with borderline benefits should be discussed with patients, even if the physician plans on recommending against these types of interventions. Another interesting overriding theme emerging from this study is that although most patients are extremely satisfied with their overall oncologic care, they are somewhat less pleased with the supportive information they receive from their doctors.

Patients' grading of physicians

Figure 29 on page 35 demonstrates that although most patients give their treating physicians "A" grades overall, substantially fewer rate their doc an "A" as a teacher. Moreover, when patients were asked about their interest in obtaining information on a variety of topics, we again observed a gap in terms of what they actually received (Figure 30 on page 35) and what they would like to have at their disposal. It should be noted that we observed essentially the same findings in our study last year of patients with breast cancer (5, 6). It isn't very difficult to make an educated guess about the dynamics that have led to this gap. Physician reimbursement is being constrained at the same time that increasing administrative demands are sopping up precious time and resources that could be used for patient care.

Additionally, and in parallel with this discouraging trend in daily practice, a magical new tool (the web) has made unprecedented volumes of information instantly available to patients. With their appetites whetted by this tsunami of compelling content, patients have many more questions for their physicians, who unfortunately have less time for answers. To this end, we are pleased to announce that an earnest attempt to help is on the way. As we enter the next phase of this patient education project, our goal is to use the experiences and resources we have developed over the last 18 years in physician education to assist patients.

2006 plan: Evaluation of an audio/text patient education program

Over the next few months, with the support and assistance of a band of clinical investigators, community-based clinicians, oncology nurses, patients and their loved ones, we will attempt to produce Version 1.0 of an audio/text patient education program designed to provide information and perspectives on three critical aspects of adjuvant systemic therapy for colorectal cancer:

1. The risks and benefits of a variety of adjuvant interventions, including clinical trial participation
2. Information on how to effectively traverse the challenging path of adjuvant systemic therapy
3. Recovery from adjuvant therapy

If this initial focus on one of the most common and compelling clinical dilemmas in colorectal cancer medicine proves successful, many other clinical topics will be considered for future colorectal cancer patient education programs, including neoadjuvant chemoradiation therapy for rectal cancer, the choice of surgery in colon and rectal cancer and local management of hepatic-only metastases.

For our initial patient education foray, we expect to produce more than seven edited hours of audio programming with accompanying text transcripts, all of which will be provided without charge to patients, via the web or through a special boxed set of six audio CDs, for evaluation and feedback. Although it's unlikely that most users of this program will listen to or read every comment, we want to provide a spectrum of perspectives and opinions on these critical issues, and as with the initial phase of this project, we will carefully evaluate how this approach is received. One important objective is to allow patients the opportunity to compare notes as they listen to a number of nationally recognized clinical research leaders from our most prestigious cancer research and treatment facilities describe what they tell their patients about decisions regarding adjuvant chemotherapy and recovery from treatment. We will also interview oncology nurses, community-based medical oncologists and patients who have been through the experience.

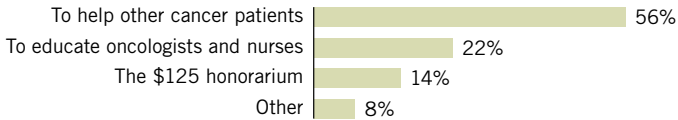
The use of audio as a primary medium for this purpose will be particularly interesting, and we will determine whether patients — who often are as busy as their physicians — also like the idea of obtaining information while driving their cars or exercising and then supplementing that with a perusal of the text transcript. No education vehicle can ever replace one-on-one interaction with a physician, but our hypothesis is that the colorectal cancer patient education program we are about to create will be a helpful adjunct that will allow patients to pick up additional valuable nuggets from interviewees featured in this program.

Finally, we send a huge and humble “thank you” to the patients who participated in this project: the attendees at our Houston meeting and the patients who listened to the audio CD, completed the survey and then chatted with our staff on the phone. It should be noted that we asked these patients why they participated in the study, and the most common motivation was a desire to help future patients (Figure 1). We are pleased that so many of the participants found this experience to be positive (Figures 2, 3), and we hope they will feel additional gratification that their viewpoints have been incorporated into continuing education for oncology healthcare professionals. In 2006, we will determine whether some of the existing needs for patient education that are evident in these findings can be addressed through an audio/text approach that provides important perspectives on these complex but eminently understandable clinical situations. ■

— Neil Love, MD
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January 5, 2006

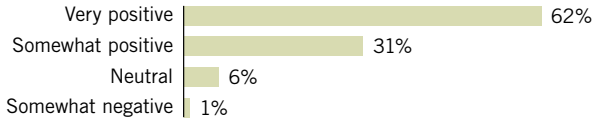
1

What was your primary reason for participating in this survey?



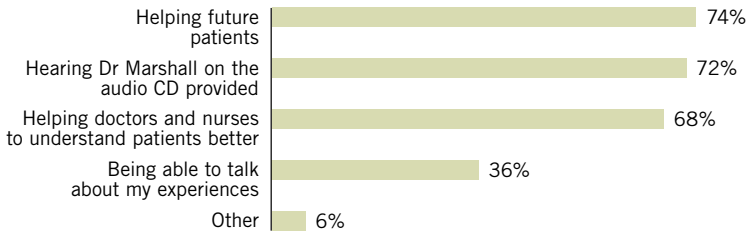
2

What was it like for you to participate in this education project?



3

What did you find to be positive about participating in this project?



About this monograph

The following report graphically presents the major findings of this study and is supplemented by selected anonymous computer-generated comments from patients during the Houston meeting and sound bites from Dr Marshall's interview. One important consideration is whether the relatively sophisticated data discussed by Dr Marshall are understandable, relevant and valuable to patients, and for each segment of his discussion, we provide patient self-ratings on these questions.

Note that the interview with Dr Marshall occurred prior to the 2005 ASCO presentation of the initial findings of NSABP-C-07, and therefore the FLOX regimen is not discussed. The data from this trial will be included in the next phase of this education project. Note also that Dr Marshall's comments reflect his own perspective and interpretation of available clinical research data. Clearly, others may have different perceptions and provide different information to patients on these same issues, which is why the next phase of this project will include the perspectives of a number of nationally recognized clinical investigators.

**Anonymous, computer-generated comments from attendees at
the Houston Colorectal Cancer Patient Meeting:
Reaction to the initial diagnosis, interactions with physicians**

- The best way for me to describe my feelings when I was first told my diagnosis of colorectal cancer is to equate it to being hit in the forehead with a two-by-four. I was numb, in shock, and it took quite a while for me to be able to process any information regarding my disease and treatment options.
- Because I have a very accepting and loving wife, who at the time was a 14-year breast cancer survivor, I remained very optimistic regarding the outcome of my surgery. It was probably a year and a half after the surgery before I experienced a brief period of anger and resentment regarding the changes brought about in my lifestyle by the colostomy. Since that time, I have learned to appreciate and be thankful for having been given a second chance to live a healthy life.
- I was shocked, angry, disappointed and felt powerless. All I could think was, "I am going to die."
- I was depressed for two or three days after I was diagnosed, and I expected to die. Then I got mad. I decided that I was in charge of my healthcare. I questioned the doctors, went to a medical library and refused to accept defeat. Cancer blinked first.
- I also have chronic lymphocytic leukemia — CLL — so some of the surprise was gone this time. Mostly, I got mad, sad, glad and any other feeling you can have in a very short time span. I guess, also, that I had learned what questions to ask, so that helped.
- Anger, denial and then the decision to fight it in a positive manner. I feel it's very important to have another person with you most times in the beginning when consulting doctors, to take a lot of notes. For me, even though I had some professional medical experience decades ago, I was overwhelmed with the information.
- When I was first told about my cancer, I was devastated even though I was somewhat prepared for the diagnosis. I think I was in shock and just did as I was told. It was like being in a fog for the first few months of treatment, and then slowly I came around and started asking questions.
- My first reaction was that I might not live much longer but that feeling did not affect my ability to understand what the doctors told me.
- I was shocked and a bit in disbelief. However, normally I am a positive person, and I adjusted to the diagnosis with my usual degree of humor. But because I am so active, I wanted every possible avenue investigated before undergoing surgery that would result in a permanent colostomy. At no time did I ever doubt the recommendations and decisions of the oncologist, radiologist and surgeon.

**Anonymous, computer-generated comments from attendees at
the Houston Colorectal Cancer Patient Meeting:
Reaction to the initial diagnosis, interactions with physicians (continued)**

- The doctor's tone, facial expressions and body language made a big difference in my understanding the facts. Most of us have read similar "facts" in the newspaper or on the internet, but the concepts took on a much more clear meaning when he presented them logically and calmly.
- After surgery, the GI doctor came to me and said that everything looked good and further treatment would not be necessary. Then, two days later, he came back and said that the lab results showed one lymph node was affected and I would have to have chemotherapy and radiation therapy. The oncologist and radiation oncologist painted the best-case scenario of chemotherapy and radiation therapy. They told me I would be able to live a fairly normal life, be able to work and just be fatigued. I experienced just the opposite, which ultimately led to the loss of employment, and was very frustrated with my physicians for not explaining to me all of the possibilities of treatment. However, my day-to-day treatment was compassionate and thorough.
- My interactions with physicians have been positive overall. It does take time to develop a rapport with them, which I think patients need in order to believe that someone else is on their side. The other great positive is my oncologist's willingness to email me answers to my questions. I have emailed questions periodically because it's hard to contact him by phone. All patients want to hear that they are doing well, but I think telling them this is a hard thing for doctors to do. I know you can't compare patients at all, but it would be nice to hear, "You are doing well with your treatment."
- For the most part, I am satisfied with my interactions with my physicians. I like the fact that they speak in terms I can understand and use analogies to help explain things better. I also like that I can look at my x-rays and CT scans and actually see what is going on inside my body and that my doctors are upbeat and aren't gloomy when sharing news with me. Sometimes I think they can be a little vague with the information, which frustrates me because I have to ask a lot of questions.
- I found my physicians to be very helpful. My treatment was explained, and I felt comfortable with the protocol chosen.
- I was not very satisfied, especially with the surgeon. He was arrogant and very matter of fact, and due to this, my husband suffered needlessly. Ultimately, we changed surgeons. We were not informed that the surgeon we had was just a general surgeon and not a colorectal surgeon. Our oncologist is not much better, and we will be changing after the first six months of chemotherapy are complete.
- Patients who don't have an assertive personality may actually feel guilty or disrespectful in seeking a second opinion. It may be helpful for the initial doctor to encourage patient education and the reasonableness of obtaining another professional viewpoint.

**Anonymous, computer-generated comments from attendees at
the Houston Colorectal Cancer Patient Meeting:
Reaction to the initial diagnosis, interactions with physicians (continued)**

- At first, when I was a less-informed patient, frustrations ran high because the doctors did not take the time to explain to my satisfaction what was happening to me or what some of the things were that I should expect. The more educated and informed I became, the more I found it easier to ensure I received the data from the doctor that I wanted. Learning to listen with a minimal personal agenda was key.
- Initially, my experiences with my gastroenterologist, oncologist and radiation oncologist were negative. Since then, my interaction with all the doctors has been positive, but additional training in supplying information to patients is needed. Some terms are on a high level, and because this is a change in a person's life, an explanation about what has happened, how it has happened and what will happen must be made in common terms. Also, once a form of treatment is recommended, details of what happens to the body, side effects and physical and mental changes should be explained. Of course, patient involvement in reading and talking to other patients and doctors is important, but most of this information should be provided by the doctors.
- I found my team of doctors to be very good listeners, and they answered most of my questions. I wanted to have a detailed understanding of my illness.
- My initial interaction with the physician who diagnosed my cancer was probably the worst experience in my life. My entire family and I were completely traumatized, including my children. The only good thing that came out of that experience is that I now realize that had that physician been kind, we might have followed his advice. Cancer is a very personal illness.
- I felt my physicians showed great customer service and bedside manners. They took their time and explained to me what was going on, and they drew diagrams to further assist me in understanding. They also provided me with names of survivors to contact for encouragement and a list of books to read. By touching my shoulder and legs when I laid in bed, they helped me to relate to them as human and not larger than life.
- I had a great surgeon who told it like it was. All my doctors were truthful and very straightforward. My oncologist and I had a very good relationship.
- In watching the panel today discuss disease-free survival, it occurred to me that my family member is fortunate to be free of colon cancer after her surgery, but even so, she is not "healed." After three years of good health, she is still fearful and depressed. She thinks of herself as a sick person who just happens to be well right now. It is almost as if she is waiting for a recurrence and hasn't gone back to a well-balanced, healthy outlook. This isn't an issue for the surgeon, but maybe it is something for other doctors to recognize and then refer the patient to a nurse educator, social worker, psychiatrist, et cetera. In short, the tumor is gone, and physical health is restored, yet the patient is not healed in the whole sense with regard to quality of life after cancer diagnosis.

Overview of patients participating in the survey

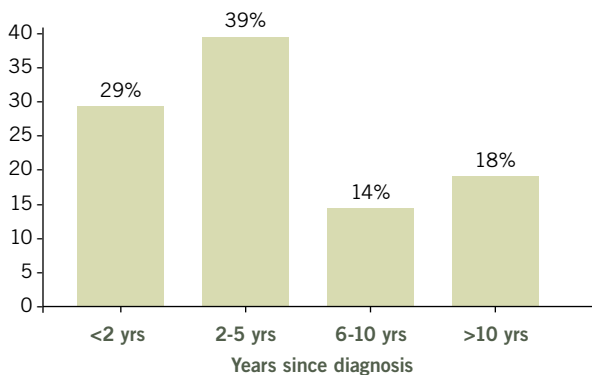
Comment: *The patients in this survey have received extensive anticancer therapy. Almost all have undergone surgery, and many have received radiation therapy and systemic treatment including chemotherapy and biologic agents. Demographically, there is considerable diversity in the age and life circumstances of the participants. Conversely, the survey population was 95 percent Caucasian. This initial effort clearly provides input from only part of the population of patients with colorectal cancer, and future phases of this initiative will attempt to gather perspectives from patients with a greater diversity of backgrounds.*

4

What was your original cancer diagnosis?



How long ago were you first diagnosed with colorectal cancer? (Mean = 6 years)



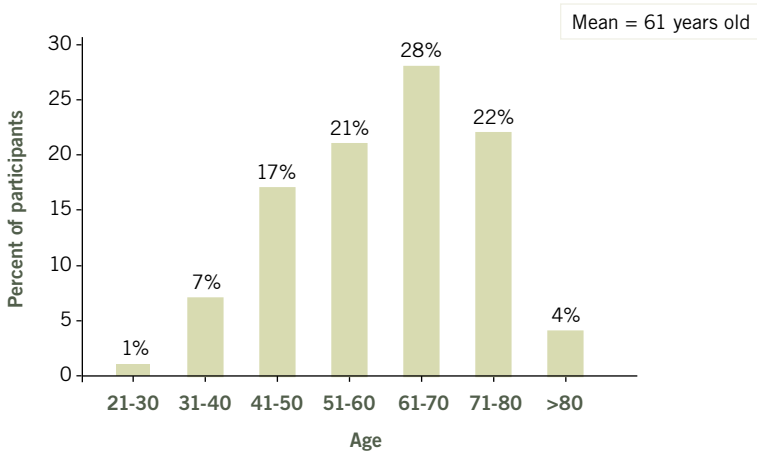
To the best of your knowledge, has the cancer spread outside the colon, rectum or lymph nodes to another part of the body?



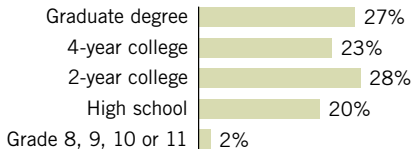
How long ago did you develop a spread of the cancer?

Mean | 2.4 years ago

Age and education level of patients in survey



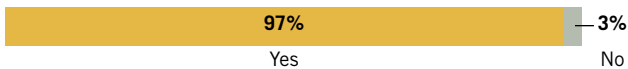
What is your highest level of education?



Are you currently being treated for any other serious medical conditions?



Have you undergone surgery for your colorectal cancer?



Have you received or are you receiving radiation therapy for your colorectal cancer?

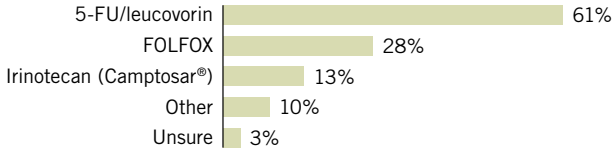


Have you received or are you currently receiving:

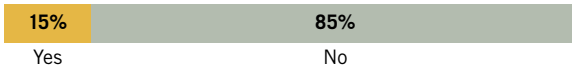
Intravenous chemotherapy



Type of chemotherapy



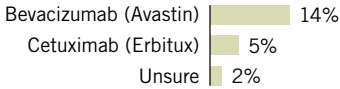
Oral chemotherapy



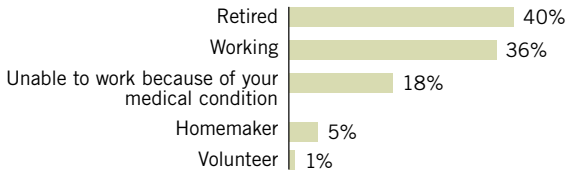
Antibody therapy



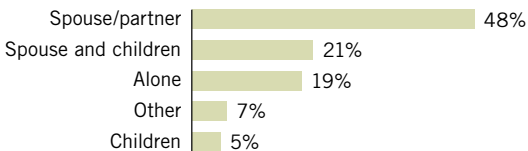
Type of antibody therapy



Are you:

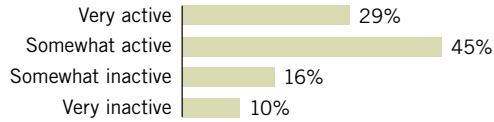


With whom do you live?



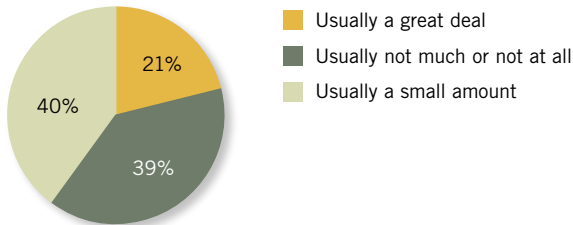
10

How active is your lifestyle?



11

Do you or did you speak with other patients in either the waiting room or treatment room during your doctor's visits, and to what extent?

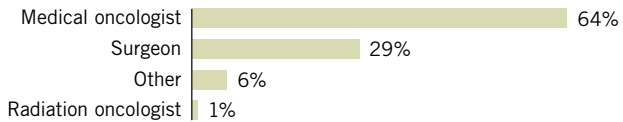


If you do speak with other patients, do you discuss your disease and treatments?



12

What is the specialty of your primary treating physician?

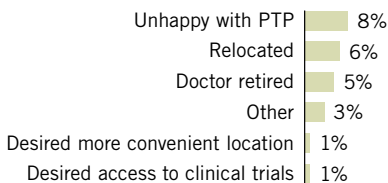


13

Have you ever switched your primary treating physician (PTP)?



If yes (24%), why?



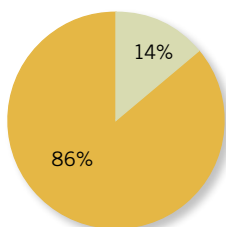
The initial diagnosis, consultation with a medical oncologist

Comment: *The diagnosis of colorectal cancer is a life-changing, stressful experience, yet the survey participants generally felt capable of understanding the risks and benefits of therapy and participating in treatment decision-making. The first section of the audio CD — like the entire interview with Dr Marshall — relates to sophisticated oncologic concepts such as prognostic factors for recurrence and micrometastases. However, the survey participants found the information generally understandable and relevant.*

14

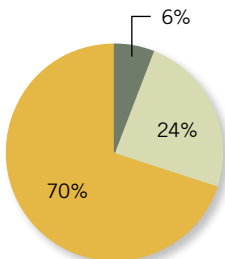
Audio CD Segment 1. Overview of adjuvant systemic therapy for colon cancer: Staging and prognosis

To what extent were you able to understand the discussion you just heard?



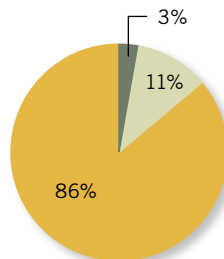
I understood it completely
I understood most of it

To what extent are you interested in the discussion you just heard?



Extremely interested
Very interested
Somewhat interested

How valuable is this information to a patient with colorectal cancer?



Extremely valuable
Very valuable
Somewhat valuable



Select excerpts from audio CD segment 1

► **DR LOVE:** Most patients treated with surgery for colon cancer visit a medical oncologist postoperatively to consider chemotherapy. What are some of the key factors in this consultation?

► **DR MARSHALL:** When the medical oncologist meets a patient for the first time, the most important thing we review is the pathology report. How much cancer was there? Has it spread anywhere? What were the characteristics of the tumor under the microscope? Then, secondly, we want to determine how well

the patient tolerated surgery. Did the patient go through it with flying colors and recover in a week or so, or did the patient have a harder time of it?

Another important factor in making a decision about chemotherapy is the patient's general health status. Many patients have no other significant medical problems, but if a patient has perhaps several other medical problems, that's another story. And so one takes all of those factors — the surgery, what was found at the surgery, the characteristics of the tumor and, if you will, the characteristics of the patient — and puts them together to make the decision about treating the patient after surgery.

► **DR LOVE:** Typically, these patients have had the tumor removed surgically. If that's the case, why would you use chemotherapy?

► **DR MARSHALL:** These patients have had all the *visible* tumor removed, but, depending on the situation, a risk exists that some *seeds* have been sown that have made it past the removed lymph nodes and aren't visible to the surgeon's naked eye, on CAT scans, or in blood tests. In fact, it's unsettling, but if you put a million cells down on a table, you can't actually see them, because our ability to detect such things is pretty limited.

We can define the risk for each patient, depending on the stage and the characteristics of the tumor, assessing the chances that the patient is cured or that the patient has these seeds. And the point of giving the chemotherapy to these patients is to get rid of those seeds and prevent those seeds from ever taking root and ultimately showing themselves as metastatic, or Stage IV, disease.

► **DR LOVE:** For patients who have surgery for localized cancer of the colon, what are the different stages of the disease, with the different risks of developing a future cancer relapse?

► **DR MARSHALL:** Colon cancer has four stages. Stage I is when the tumor is very small. It really hasn't penetrated very deeply into the colon. And the majority of those patients — in fact, 90 to 95 percent of them — are cured by the surgery alone, are very unlikely to have any seeds and, therefore, don't receive chemotherapy.

Patients with Stage II and Stage III colon cancer have a different story. In Stage II disease, the tumor has invaded all the way through the bowel but has not spread to any of the lymph nodes. Treatment for this group of patients is quite controversial. Some doctors will treat these patients with chemotherapy and some will not. As a group, about 75 percent of Stage II patients do not have any seeds and will not have their cancer come back and therefore are essentially cured of their cancer after surgery. That leaves 25 percent or so that will experience recurrence.

Patients with Stage III disease represent about a quarter to maybe a third of all the colon cancer patients who are diagnosed in the United States. In this group of patients, the cancer has spread to the lymph nodes, and even just one lymph node with tumor in it qualifies the disease as Stage III. We know that

the more lymph nodes that have tumor in them, the more worrying it is for patients that they might have seeds somewhere else, such as in the liver or the lungs. In this group, the odds are about 50-50 of having seeds or not having seeds.

► **DR LOVE:** For the patients who do have seeds of the tumor elsewhere, why not just wait until they grow and cause a problem, and treat at that point?

► **DR MARSHALL:** That’s a great question and a very common question. The real reason is that once these seeds have taken root and have become visible metastases or spread of the tumor, our chemotherapy drugs cannot eliminate the last cell. Usually, our only chance at curing the cancer, at least today, is to treat before it sets up shop, before it grows roots and is visible.

So we treat patients before we see any spread. That’s our window of opportunity to add to the number of patients that are cured. Said another way, we, as medical oncologists, try to kill the last cancer cells, the ones that we can’t see, by giving chemotherapy.

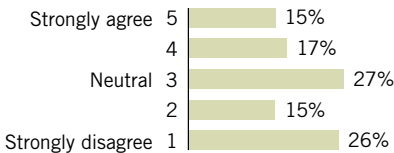
► **DR LOVE:** What about Stage IV?

► **DR MARSHALL:** In patients with Stage IV colon cancer, the disease has already made it past the lymph nodes and has spread to the liver or the lungs. And traditionally, this group is not curable. Usually surgery cannot remove this disease, which has spread. And those patients, unfortunately, do not have treatment options that will cure them. But we do have very good treatments that can extend their survival and help them live longer lives. ■

15

Agree, disagree or in between?

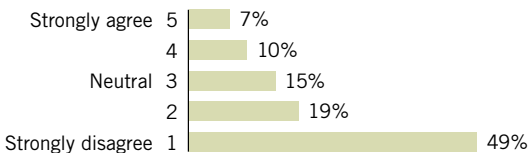
“When I was first diagnosed, I was so upset that I had a very difficult time understanding what the doctor was explaining to me...”



16

Agree, disagree or in between?

“When I was first diagnosed, I had a very difficult time understanding what the doctor was explaining to me because it was too complex...”



Survey of 150 people with colorectal cancer

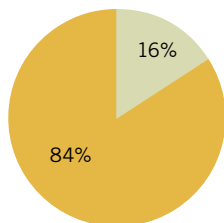
Risks and benefits of adjuvant chemotherapy

Comment: *The risk-benefit discussion for adjuvant chemotherapy of colon cancer forms the core of the interview with Dr Marshall. Although somewhat complex statistics and concepts are presented, patients said the information made sense. Based primarily on the information presented by Dr Marshall, patients speculated on what they might recommend to a 60-year-old loved one with Stage II or Stage III disease. The most common choice was FOLFOX, followed by capecitabine. Of great interest is that even for Stage II disease, 99 percent of participants would recommend some form of adjuvant chemotherapy. When asked specifically how much of an improvement in the five-year recurrence rate would justify receiving adjuvant FOLFOX, almost two thirds of patients would recommend treatment for an improvement of five percent or less.*

17

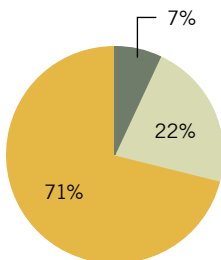
Audio CD Segment 2. Potential benefits of adjuvant chemotherapy for Stage III tumors

To what extent were you able to understand the discussion you just heard?



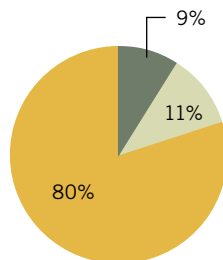
■ I understood it completely
■ I understood most of it

To what extent are you interested in the discussion you just heard?



■ Extremely interested
■ Very interested
■ Somewhat interested

How valuable is this information to a patient with colorectal cancer?



■ Extremely valuable
■ Very valuable
■ Somewhat valuable



Select excerpts from audio CD segment 2

▶ **DR LOVE:** How do you explain to patients how adjuvant therapy affects the risk of relapse? For example, you mentioned that without treatment, patients with Stage III tumors have about a 50-50 chance of the tumor coming back. How does chemotherapy affect those odds?

► **DR MARSHALL:** Let's begin by focusing on the traditional chemotherapy, 5-FU. The best way to think of this is that you're in a group of 100 patients that have the same cancer as you do. Now, 50 of those 100 patients could not benefit from chemotherapy because they don't have residual cancer. The surgeon did get it all, and no seeds are taking root. That leaves 50 patients of the 100 that we started with who have seeds. Now, frankly, in all of those 50 patients, if left alone, eventually those seeds would grow and eventually the cancer would kill them.

We've known for about 20 years that if you give chemotherapy to this group — and here, we're really talking about the 50 patients that have seeds — 20 of those patients will now not grow seeds. We'll cure those 20 with chemotherapy. So, the odds go from 50-50 to more like 70-30. Our real shortfall is that we can't figure out who's in the good 50 and who's in the bad 50. They look alike to us. We can't tell. We don't have tests yet that distinguish the group that should be getting chemotherapy from those who don't need it because they're already cured.

The other point I want to make is that even with the chemotherapy, in a fair number of patients — in this example, as many as 30 of the 100, altogether — the cancer will come back anyway. And it's that group of patients with which our new medicines have begun to whittle away the numbers, and that 30 is getting smaller as we cure more of those patients with the newer medicines.

► **DR LOVE:** So to follow that out in terms of the Stage III patients, essentially, you would say to a patient, "If there were 100 patients like you, about a fifth of the total, or about 20 people, by receiving the treatment, will go from eventually developing an incurable situation to being cured."

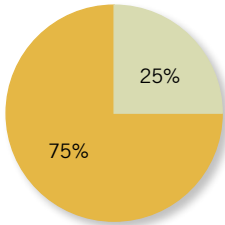
► **DR MARSHALL:** That's right. And I also tell patients that they themselves may never know if they benefited from the chemotherapy. If their cancer never comes back, they won't know whether they were in the good 50 or they were in the group that actually got the last few seeds knocked off by the chemotherapy. By the same token, if their cancer does come back, they won't know whether the chemotherapy may have delayed the time for it to come back or whether it may have killed some but not all of the cancer cells. So it's very hard for patients themselves to understand if they're benefiting from the treatment.

► **DR LOVE:** Now, again focusing on patients with Stage III disease, how is the risk of relapse affected when you utilize the newer approach that has come into practice the last few years, the regimen of FOLFOX, with 5-FU and oxaliplatin, or Eloxatin[®], compared to 5-FU?

► **DR MARSHALL:** The numbers get better. We probably pick up about an additional five percent chance of remaining relapse free, maybe a little bit higher. To put some hard numbers to it, in the actual major study that has been reported — the MOSAIC trial — of the patients who only received 5-FU, about 65 percent remained free of relapse. But when the oxaliplatin was added, the number went to 72 percent.

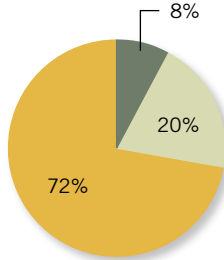
Audio CD Segment 3. Potential benefits of adjuvant chemotherapy for Stage II tumors

To what extent were you able to understand the discussion you just heard?



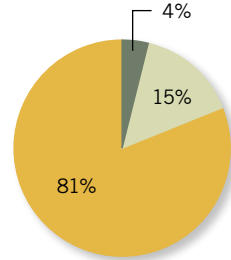
■ I understood it completely
■ I understood most of it

To what extent are you interested in the discussion you just heard?



■ Extremely interested
■ Very interested
■ Somewhat interested

How valuable is this information to a patient with colorectal cancer?



■ Extremely valuable
■ Very valuable
■ Somewhat valuable



Select excerpts from audio CD segment 3

▶ **DR LOVE:** How do you discuss the numbers with the patients who have lower-risk tumors or Stage II colon cancer?

▶ **DR MARSHALL:** With Stage II disease, of course, you start off with slightly better odds. There, your numbers are roughly 75-25, so the potential benefit isn't as much. And in fact, when one looks at the data that we have for this group of patients, the best guess we have is that overall, with the older 5-FU regimens, about three out of 100 will be cured as a result of treatment, which means that we have to treat 100 patients to cure three who would otherwise have a recurrence.

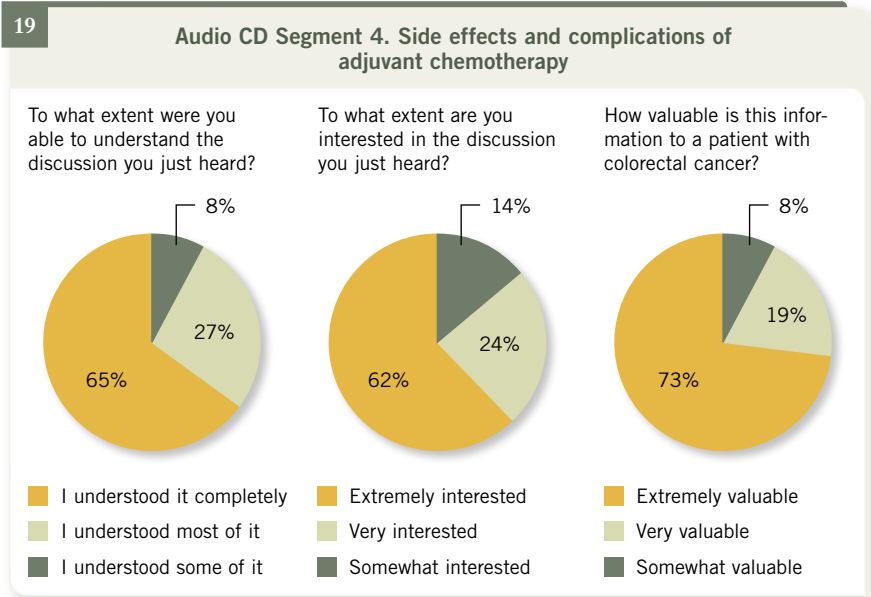
▶ **DR LOVE:** What are the numbers with FOLFOX?

▶ **DR MARSHALL:** Of patients in the MOSAIC trial with Stage II disease who received FOLFOX, a surprising 87 percent were without relapse, which was about three percent higher than in the 5-FU group.

▶ **DR LOVE:** How do you see patients reacting to those numbers?

▶ **DR MARSHALL:** It's very interesting to see that different patients will make different decisions based on that information. Some will say, "Shoot. If it's one percent, I'll do it." Others will say, "Three percent is not enough for me to risk it." And when it comes down to the final decision, the key is the side effects of therapy.

If treatment were completely without side effects, I think we'd all do it. What the heck? This is a life-and-death thing, and if you were going to improve your chances of being alive past the next five years by a small percentage, you probably would do it (although most of us who smoke keep smoking, so you wonder).



🎧 Select excerpts from audio CD segment 4

▶ **DR LOVE:** What do you say to patients about the risks of adjuvant chemotherapy?

▶ **DR MARSHALL:** The older therapy of giving intravenous (IV) 5-FU is relatively easy. A patient comes to the clinic, usually one day a week, and receives a quick injection of the 5-FU, almost always administered with another medicine called leucovorin, which enhances the effects of 5-FU against the cancer.

But now a bunch of different recipes exist for administering 5-FU. Some doctors administer it one day a week for several weeks in a row and then give the patient a break. Others like to administer it five days in a row and then give the patient several weeks off. Recently, what I think is an even better way to administer the medicine has emerged, in which it is infused over a longer period of time, which seems to produce fewer side effects for patients as well as working better against the cancer.

▶ **DR LOVE:** How long does the patient receive the treatment?

▶ **DR MARSHALL:** The total package is about six months of treatment.

► **DR LOVE:** Other than the inconvenience of having the infusion done, what kinds of side effects do patients experience?

► **DR MARSHALL:** About 15 percent of patients will lose enough hair to notice. But the bigger side effect with this medicine is mouth sores — tenderness and peeling in the mouth. Some diarrhea is also seen with 5-FU. The blood counts can go down a bit, and fatigue is commonly seen. But all in all, it's pretty well tolerated. As I tell patients, it's not usually "crawl-under-a-rock-and-die" chemotherapy. It's compatible with normal daily living. Patients usually drive themselves in their cars to receive this chemotherapy. And there's not a great deal of nausea and vomiting associated with it. So it's relatively easy chemotherapy.

► **DR LOVE:** What about capecitabine?

► **DR MARSHALL:** Capecitabine, or Xeloda, is a wonderful invention. For 40 years we've been playing with 5-FU as an intravenous therapy, and finally, about a decade ago, an oral version of this medicine was developed. And as we've said, the best way to administer 5-FU does appear to be a prolonged exposure, spreading it out instead of administering it all at once. An oral medicine allows us to do that without having to use a port for the IV and a pump.

A recent study now allows us to bring the oral 5-FU or capecitabine into use for patients with Stage II and Stage III disease. In this study, half the patients received the old IV 5-FU, five days in a row and then a month off to recover, and the other half received capecitabine two weeks in a row, having one week off. And we're very pleased to report that the group who received the oral medicine did better. They had slightly fewer cancer relapses and, most significantly, a better side-effect profile. So the oral medication won in the two most important areas, how well it works and how safe it is.

And so capecitabine has become a very popular option for patients with Stage II and Stage III disease after surgery. It prevents the need for coming in regularly for IV infusions. The medicine has side effects but is relatively well tolerated. Patients don't lose their hair, and nausea is not a big issue.

► **DR LOVE:** Let's talk about some of the newer forms of adjuvant therapy that you are now offering to your patients in this situation.

► **DR MARSHALL:** The most exciting new research comes from a study that added the medicine oxaliplatin, or Eloxatin, to 5-FU. This recipe of giving oxaliplatin and 5-FU together is known as FOLFOX. It's a little trickier, a little bit more intensive, if you will, than the old 5-FU/leucovorin regimens that we just talked about or capecitabine. This recipe requires that patients receive an IV infusion for two days. So they come to the clinic and receive about two to three hours' worth of intravenous treatment in the clinic, but then they go home with a small battery-powered pump. It's about the size of a traditional Walkman, and they carry this pump for two days.

At the end of the two days, typically patients come back to the clinic and have the pump disconnected. As I describe it to patients, you're two days on, 12 days off. And that pattern repeats for 12 cycles, or, in essence, six months.

► **DR LOVE:** What do you tell patients to expect in terms of side effects or effects on their quality of life by adding oxaliplatin?

► **DR MARSHALL:** Oxaliplatin has, as its major side effect, a nerve toxicity, which comes in two flavors. One happens on the day you receive the treatment. On that night, when you go home and go into the refrigerator or go into the freezer and touch something cold or drink something cold, you possibly experience an unpleasant feeling in the fingertips and in the throat.

Also, if you're one who likes to walk around barefoot on a cold kitchen floor, you might notice it in your toes as well. It's really not that big of a deal, medically, but it's a nuisance for patients. It lasts about two to three, up to five to seven days with each cycle. You learn to tolerate it. You drink your beer warm, if you will.

But the other flavor of nerve toxicity, the cumulative nerve toxicity, is a pins-and-needles feeling in the fingertips and in the toes that almost everybody gets if they keep receiving oxaliplatin for 12 cycles, or six months. I also describe it to patients as feeling as if these parts of their body are asleep. And some patients will get this fairly badly, to the point where they have trouble buttoning buttons, tying shoes, writing checks, that sort of thing. So that's something that both the patient and an oncologist have to keep in mind and keep as a very open dialogue as this chemotherapy goes along.

Fortunately, that nerve toxicity, even though it's pretty common, reverses in essentially everybody by about a year to a year and a half after the end of the treatment. So it's not a permanent nerve toxicity, but it is something we want to watch out for and try and prevent, if we can.

► **DR LOVE:** Overall, in what fraction of patients is the nerve toxicity enough that it interferes with their quality of life?

► **DR MARSHALL:** It's rare for it to get that bad. In the MOSAIC study, only 12 percent of patients experienced that degree of nerve toxicity. And frankly, most of us have adapted our behavior recently, so that when patients come in with more severe complaints — which might be at cycle 10, 11, or 12, really the last month of the chemotherapy — we might back off on the oxaliplatin and not give as much, or even hold it altogether, to avoid that toxicity from getting any worse. So, as we've gotten smarter about the side effects, we're better able to keep patients out of that trouble.

► **DR LOVE:** What about the more global effects on people's quality of life: nausea, vomiting, hair loss, feeling tired? What's the difference between 5-FU or capecitabine and FOLFOX?

► **DR MARSHALL:** Some differences do exist. We talked about the nerve toxicity. Hair loss is not a big issue with oxaliplatin versus 5-FU. We do use

nausea medicines to prevent nausea, and because we're so good at that now, it is rare that patients experience nausea and vomiting with this treatment.

Oxaliplatin is a little bit harder on the bone marrow than 5-FU, so patients will more commonly have low platelet counts or low white blood cell counts. But again, we're pretty good at managing that and adjusting around it. Patients can also develop low red blood cell counts, and when patients are anemic, they of course get tired. And we do have new medicines that will help with the fatigue and keep it from getting too bad.

But notably, the phenomenon that I've noticed is that because we're so much better at chemotherapy treatments and because patients are tolerating chemotherapy better and living fairly normal lives, we are wearing them out. Probably the most common symptom that patients complain of with each cycle is a day or two of sit-around-the-couch fatigue — not hit-the-bed-and-can't-get-up fatigue but really just not feeling motivated to get up and do much. But then, after a couple of days, they pick up pretty quickly.

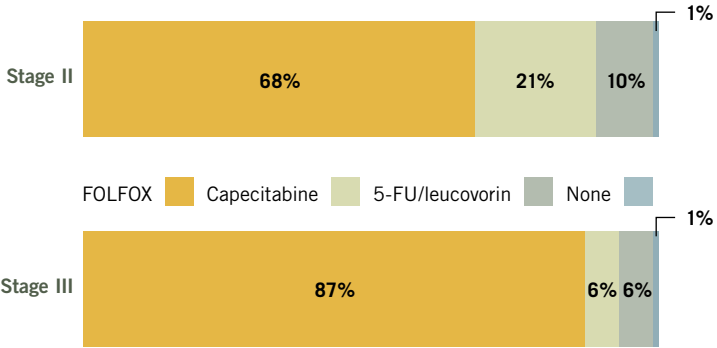
So fatigue is a big element of chemotherapy. It fortunately does not seem to be overly limiting in terms of patients going to work and driving and doing daily activities. But in an occasional patient the fatigue is more of a major issue, so we watch out for that as well.

► **DR LOVE:** Listening to you, trying to put myself in the place of a patient, what's coming across is that the traditional 5-FU or capecitabine has a relatively minor impact on the patient, particularly compared to some of the other chemotherapies out there. It sounds as if adding in the oxaliplatin with the FOLFOX regimen makes treatment a little bit more challenging, but it doesn't sound dramatically worse. Is that what you tell your patients?

► **DR MARSHALL:** That's right. And I don't want to underplay the side effects that happened with the old regimen. The old 5-FU regimens often landed people in the hospital with dehydration, either with diarrhea or with mouth sores. The newer regimen really does not have that effect. It's rare that we would admit a patient because of side effects from the newer chemotherapy regimens. So in terms of the safety of FOLFOX, we're trading for a little bit more hassle with the port and the pump and the nerve toxicity. ■

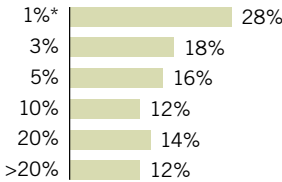
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After hearing this discussion and considering any other information or experiences you have had in the past, at this point, if you had a friend or loved one in their sixties, in relatively good health but with colon cancer, which chemotherapy would you recommend?



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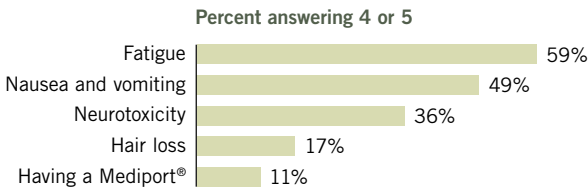
What would be the minimum reduction in the chance that your cancer would come back in five years you would require to undergo therapy with FOLFOX?



* 1 out of every 100 people would benefit.

22

Based on the discussions you just heard, in general, how problematic do you view the following side effects? (1 = not a problem; 5 = major problem)



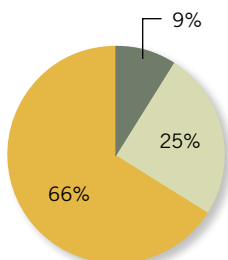
Clinical trial participation

Comment: *It is widely estimated that only about two to three percent of cancer patients participate in clinical trials. In this study, 12 percent participated, but more than 90 percent of those who did not take part in a trial had not been offered participation. After hearing Dr Marshall's description of ECOG trial 5202, randomly assigning patients with higher-risk Stage II tumors to FOLFOX alone or with bevacizumab, three quarters of the patients stated that they would participate if eligible.*

23

Audio CD Segment 5. Clinical trial participation: ECOG trial 5202 as an example

To what extent were you able to understand the discussion you just heard?

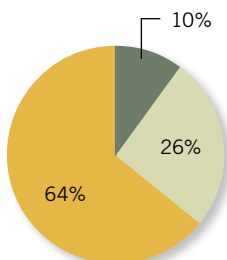


I understood it completely

I understood most of it

I understood some of it

To what extent are you interested in the discussion you just heard?

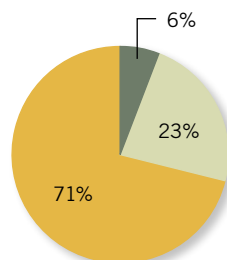


Extremely interested

Very interested

Somewhat interested

How valuable is this information to a patient with colorectal cancer?



Extremely valuable

Very valuable

Somewhat valuable



Select excerpts from audio CD segment 5

► **DR LOVE:** After listening to you discuss some of the statistics for adjuvant chemotherapy, it seems that decisions for patients with Stage II disease are particularly challenging. Can you talk about some of the research that's going on to try to improve therapy for these patients?

► **DR MARSHALL:** If you're faced with Stage II disease, you recognize that maybe 70 to 80 percent of the time, you're getting chemotherapy and going through all the hassle and the risk, and you don't need it. What we need is to be smarter about who should get the chemotherapy and who shouldn't. If we

could figure out which group of patients is at the higher risk, the bad quarter of the patients, if you will, and give only that group of patients chemotherapy, that would be a major advance.

This is done with some diseases. For example, with breast cancer, it's fairly routine to obtain a molecular profile of the tumor to understand more about an individual patient's cancer and make decisions based on that profile. We have now finally moved toward such a world in colon cancer in the form of a major new and very large study for patients with Stage II colon cancer.

The first step in this study, which is being run through the ECOG, or Eastern Cooperative Oncology Group, is that the individual patient's tumor is analyzed for genetic characteristics. If the results suggest a favorable prognosis, we believe we should leave that patient alone and not administer the chemotherapy, because our best guess is that the patient is in the good three quarters of the patients. And therefore, only those patients with the bad cancer genetics will receive chemotherapy.

► **DR LOVE:** Can any oncologist enter a patient on this study?

► **DR MARSHALL:** It's an Intergroup study, so it's being done all across the country at most major cancer centers and should be accessible through a variety of clinicians. So most patients should be able to get ahold of this study.

► **DR LOVE:** So part of entering this study is that the patient's tumor is studied with new specialized tests?

► **DR MARSHALL:** That's right. Before a decision is made about whether to treat an individual patient, the genetics of the patient's tumor are studied.

► **DR LOVE:** Is that an advantage of being in the study, that these tests are done on a patient's tumor?

► **DR MARSHALL:** It is one of the only ways you can get the test done. So it absolutely is an advantage, because if someone gives me a hint that my tumor is more favorable and I don't need chemotherapy, that's a nice thing to hear.

► **DR LOVE:** What happens if the test shows a less favorable prognosis?

► **DR MARSHALL:** That part of the study involves a randomization — and I'll tell you what that means — between the standard FOLFOX that we've discussed and FOLFOX with a new medicine, bevacizumab, or Avastin, added to it. In other words, this study is looking not only at finding the right patient to receive chemotherapy but also at whether adding bevacizumab to the FOLFOX will further improve a patient's outcome.

Now, randomization often spooks patients. But in this setting, for example, there is no placebo. Everyone's receiving the standard of care, FOLFOX. But half of the patients also receive the bevacizumab. Randomization is done by a computer, which assigns each patient to one of the two treatments.

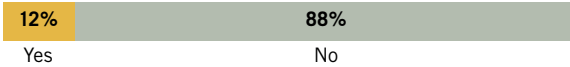
► **DR LOVE:** And, in fact, isn't it true that all of the treatments that we've been talking about today have been studied in these large randomized trials?

► **DR MARSHALL:** That's right. The only reason we have the new medicines that our patients today enjoy is because the generation or so of colon cancer patients who came before them put themselves into clinical trials to move the bar, to improve the outcome for everyone.

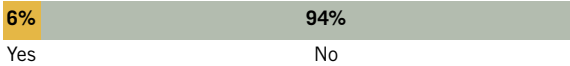
I really feel it's an obligation not only for us, as doctors, but for our patients as well to carry that torch of clinical research and get questions answered as quickly as we can so that our children can enjoy the benefits of the research that we do today. ■

24

Have you participated in a colorectal cancer treatment research trial?



If no, have you ever been offered?



25

Would an audio discussion similar to the one you just heard presented by Dr Marshall have made it more likely that you would participate in a clinical trial?



26

Based on this discussion, if you were eligible to participate in ECOG trial 5202, would you be willing to participate?



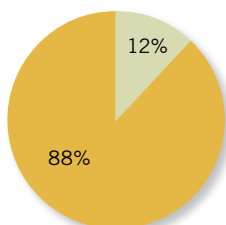
Recovery from chemotherapy, prevention of a second colorectal cancer

Comment: *The most highly rated segment of the discussion was Dr Marshall's advice on recovery from chemotherapy and his "five things" to reduce the risk of a second cancer. Only about one in five of the participants was altering his or her diet related to the cancer, but four of five participants engage in regular exercise, which may not only reduce the risk of a second colorectal cancer but, according to a CALGB report at the 2005 ASCO meeting, may also reduce the risk of tumor recurrence.⁹*

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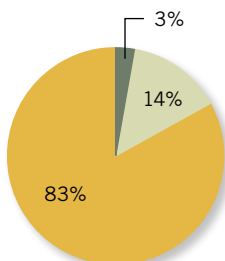
Audio CD Segment 6. Recovery from chemotherapy; prevention of second colorectal cancers

To what extent were you able to understand the discussion you just heard?



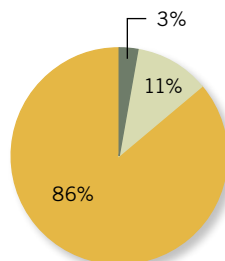
■ I understood it completely
■ I understood most of it

To what extent are you interested in the discussion you just heard?



■ Extremely interested
■ Very interested
■ Somewhat interested

How valuable is this information to a patient with colorectal cancer?



■ Extremely valuable
■ Very valuable
■ Somewhat valuable



Select excerpts from audio CD segment 6

► **DR LOVE:** What do you advise your patients to expect in the months following the completion of adjuvant chemotherapy?

► **DR MARSHALL:** The first thing I talk to them about is that recovery from any fatigue or side effects from chemotherapy takes upwards of three to six months

⁹ Meyerhardt JA et al. **The impact of physical activity on patients with stage III colon cancer: Findings from Intergroup trial CALGB 89803.** *Proc ASCO* 2005; [Abstract 3534](#).

before they shake it all off and feel back to 100 percent. So I suggest that they be patient about recovery.

Secondly, I talk about the anxiety that usually increases after they finish their chemotherapy. Since their diagnosis, they've been doing something about their cancer. They've been undergoing surgery, radiation, or chemotherapy. And now, all of a sudden, they're left alone and left exposed and they're not doing anything. They're just waiting, and it's very common for folks' anxiety at that point to increase. So I tell patients to expect that, but I also reassure them that if they have questions or issues, we're here to answer those questions.

Before your cancer diagnosis, if you had a pain in the belly or a pain in the leg, you didn't spare a second thought about it. But once you've had a cancer diagnosis, with every pain you have, the first thought that comes to your mind is, "Oh, my God! There's my cancer coming back." And the answer is, no it's not. That's not what it is. But you can't convince your brain. So we really try to reassure folks about that.

And then, finally, I present what I call "the five things." These are factors that have been pretty well linked to decreasing one's risk of having a second colon cancer. Not so much with keeping the original cancer from coming back, but from having another tumor appear.

► **DR LOVE:** And just to clarify, patients who've had one colon or rectal cancer are at higher risk than the average person to get a second one?

► **DR MARSHALL:** At least three times higher. And because of that, they must go through a different screening process. They need colonoscopies and the like more often than patients who've never had cancer. But these five prevention ideas are separate from the screening tests that we do routinely. These are behavioral changes.

The first, which is probably the hardest one, is a high-fiber, low-fat diet. A very good data set suggests a high-fiber, low-fat diet will prevent colorectal cancer in patients. Specifically, I tell patients it doesn't mean you can't go to Outback Steakhouse®, just don't go there every night. And try to reduce the amount of fat in your diet.

The second — perhaps equally hard — is exercise. The best guess is that we should be raising our heart rate for about 30 minutes every day. That's a challenge for any of us. But there's no one more motivated than a former cancer patient. So they usually make that change quite readily.

The third item is the vitamin folate, or folic acid. There is very good evidence to indicate that supplementing one's diet with folate is a good thing, particularly for colon cancer. If you are on a high-fiber, low-fat diet, you're getting plenty of folate — you may be killing two birds with one stone.

The fourth thing is calcium. Very good data suggest that the more calcium we can take in, over 1,300 milligrams a day, the more we decrease the likelihood of having colon cancer or dying from colon cancer.

And the last one, which is a little bit controversial but less so every year, is taking a baby aspirin a day, which is 81 milligrams.

If one looks at these five practices, interestingly, they are all linked to what we call heart-healthy behavior. It appears that what's good for your heart — and, therefore, also good for risk of stroke — also seems to be good in preventing colon cancer.

Many of these same things have also been linked to a decreased risk of breast cancer. These “five things” are just good things to do, good ways for patients to live. ■

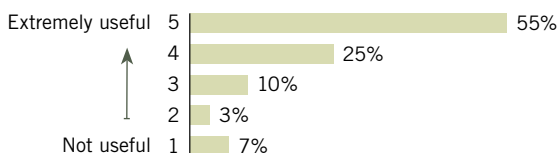
Patient grading of physicians, patient education needs

Comment: *Oncologic healthcare presents a unique challenge that requires an integrated biopsychosocial approach to clinical practice. As with our 2004 survey of 260 people with metastatic breast cancer,⁴ we found that patients with colorectal cancer in general hold their physicians in very high regard, particularly in terms of trust and empathy. Ratings for the provision of information were slightly less supportive. Patients discussed a variety of topics for which they wanted much more information. Our plan for this project in 2006 is to pilot the production of a comprehensive audio/text patient education program to supplement and complement what is provided in oncologists' offices.*

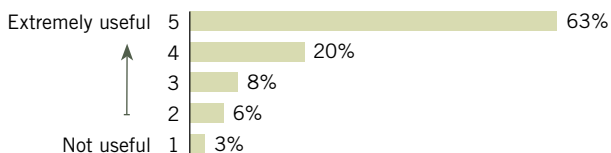
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Sources of information other than your doctor's office
(percent of patients citing utilization)

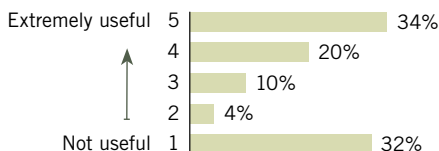
Internet (80% of patients)



Other patients and support groups (81% of patients)



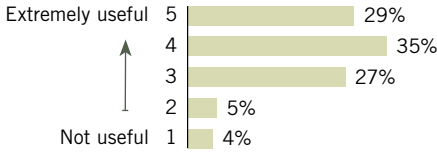
Online support groups (49% of patients)



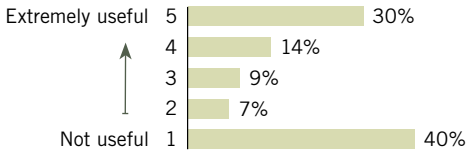
⁴ Love NH et al. A "report card" on medical oncologists and oncology nurses: Survey of patients with metastatic breast cancer and companion surveys of medical oncologists and oncology nurses. San Antonio Breast Cancer Symposium 2004; [Abstract 3069](#).

Sources of information other than your doctor's office (percent of patients citing utilization, continued)

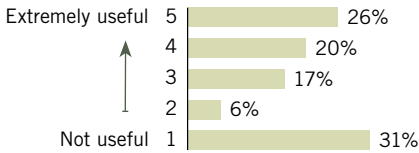
Booklets or brochures (93% of patients)



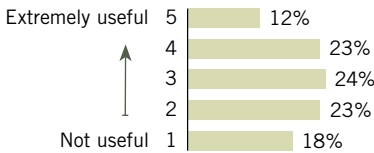
Audiotapes (37% of patients)



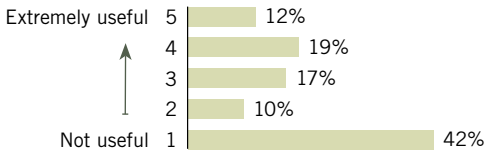
Videotapes (36% of patients)



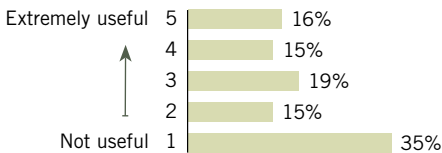
News media (70% of patients)



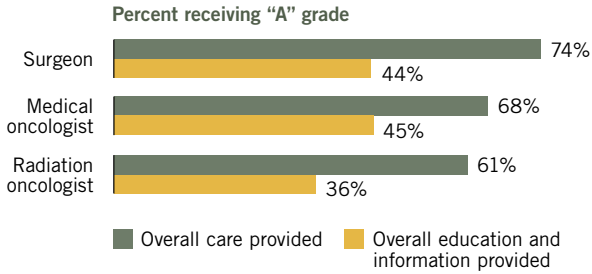
Pharmaceutical advertising (63% of patients)



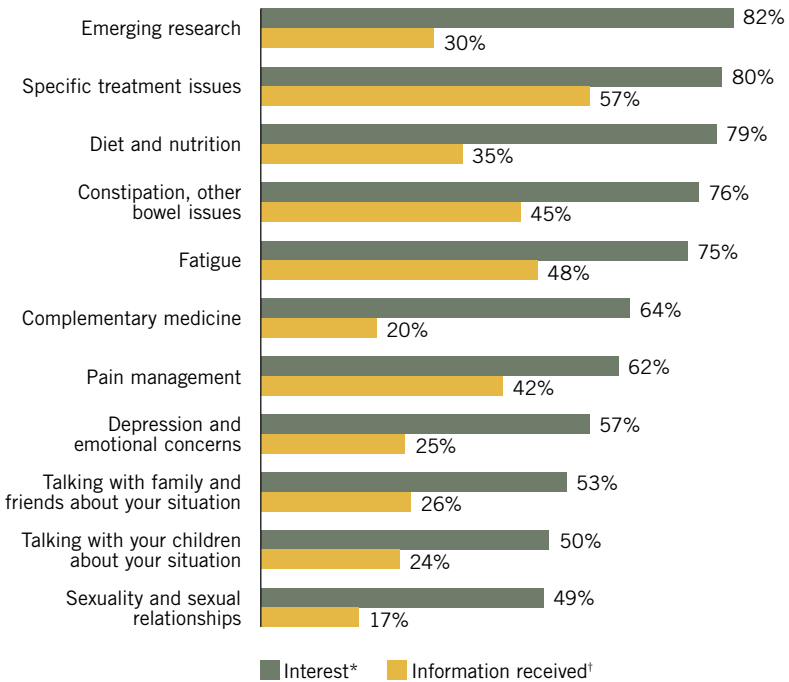
Telephone information and 800 hotlines (45% of patients)



Patient Grading of Oncologic Care



Patients' interest in specific education topics and the quality of information received



* Patients who rated this topic a 4 or 5 on a 1-5 scale of their interest in this issue (5 = greatest rating)

† Patients who rated the quality of information they received as a 4 or 5 on a scale of 1-5 in terms of the quality of information they received from their oncologist (5 = greatest rating)

Bibliography

SELECT PUBLICATIONS

1. *Breast Cancer Update* Patterns of Care in Medical Oncology 2005;2(3).
2. Love NH et al. **Heterogeneity in breast cancer survivors' perceptions of adjuvant systemic therapy options after verbal counseling from a physician panel in a "town meeting."** San Antonio Breast Cancer Symposium 2003;[Abstract 142](#).
3. Love NH et al. **How do prostate cancer survivors perceive treatment trade-offs for hypothetical clinical situations?** *Proc AUA* 2003;[Abstract 1707](#).
4. Love N et al. **Influence of prior therapy on breast cancer survivors' preferences for adjuvant systemic therapy in hypothetical scenarios.** *Proc ASCO* 2004;[Abstract 591](#).
5. Love NH et al. **A "report card" on medical oncologists and oncology nurses: Survey of patients with metastatic breast cancer and companion surveys of medical oncologists and oncology nurses.** San Antonio Breast Cancer Symposium 2004;[Abstract 3069](#).
6. Stanley KJ et al. **A report card on oncology nurses: Survey of patients with metastatic breast cancer.** Oncology Nursing Society Congress 2005;[Abstract 64](#).
7. Love NH et al. **Preferences for oral versus parenteral antitumor therapy: A survey of patients with metastatic breast cancer.** Oncology Nursing Society Congress 2005;656. No abstract available
8. Paley M et al. **Preferences for oral and parenteral antitumor therapy: A survey of 260 patients with metastatic breast cancer.** *Proc ASCO* 2005;[Abstract 619](#).
9. Love N et al. **Perspectives of patients with colorectal cancer (CRC): A pilot project to determine interests in and understanding of patient education on clinical research.** *Proc ASCO* 2005;[Abstract 3635](#).
10. Meyerhardt JA et al. **The impact of physical activity on patients with stage III colon cancer: Findings from Intergroup trial CALGB 89803.** *Proc ASCO* 2005;[Abstract 3534](#).
11. Blend MJ. **Can we learn from our patients?** *Perspect Biol Med* 2005;48(1):138-42. [Abstract](#)
12. Couture J et al. **Patient's preferences for adjuvant postoperative chemoradiation therapy in rectal cancer.** *Dis Colon Rectum* 2005;48(11):2055-60. [Abstract](#)
13. Solomon MJ et al. **What do patients want? Patient preferences and surrogate decision making in the treatment of colorectal cancer.** *Dis Colon Rectum* 2003;46(10):1351-7. [Abstract](#)
14. Jansen SJ et al. **Review of determinants of patients' preferences for adjuvant therapy in cancer.** *J Clin Oncol* 2004;(15):3181-90. [Abstract](#)
15. Beale P et al. **Adjuvant chemotherapy (ACT) for early colon cancer (ECC): What do investigators think makes it worthwhile?** *Proc ASCO* 2004;[Abstract 6112](#).
16. Baddi L, Benson A 3rd. **Adjuvant therapy in stage II colon cancer: Current approaches.** *Oncologist* 2005;10(5):325-31. [Abstract](#)
17. Benson AB 3rd et al. **American Society of Clinical Oncology recommendations on adjuvant chemotherapy for Stage II colon cancer.** *J Clin Oncol* 2004;22(16):3408-19. [Abstract](#)
18. Van Cutsem E, Costa F. **Progress in the adjuvant treatment of colon cancer: Has it influenced clinical practice?** *JAMA* 2005;294(21):2758-60. No abstract available
19. Diaz-Rubio Garcia E et al. **A panel discussion of controversies and challenges in the adjuvant treatment of colon cancer.** *Clin Transl Oncol* 2005;7(1):3-11. [Abstract](#)
20. Gill S, Goldberg R.M. **Duration of adjuvant therapy for colorectal cancer: Are we overtreating our patients?** *Nat Clin Pract Oncol* 2005;2(6):276-7. No abstract available

21. Goufopoulos V et al. **Treatment of colorectal cancer in the elderly: A review of the literature.** *Cancer Treata Rev* 2005;[Epub ahead of print]. [Abstract](#)
22. Hobday TJ. **An overview of approaches to adjuvant therapy for colorectal cancer in the United States.** *Clin Colorectal Cancer* 2005;5(Suppl 1):11-8. [Abstract](#)
23. Iacopetta B. **A biological perspective on the selection of stage II colorectal cancer patients for adjuvant chemotherapy.** *Ann Oncol* 2002;13(9):1510. No abstract available
24. Johnston PG. **Stage II colorectal cancer: To treat or not to treat.** *Oncologist* 2005;10(5):332-4. No abstract available
25. Lawes D, Taylor I. **Chemotherapy for colorectal cancer — An overview of current management for surgeons.** *Eur J Surg Oncol* 2005;31(9):932-41. [Abstract](#)
26. Midgley R, Kerr DJ. **Adjuvant chemotherapy for stage II colorectal cancer: The time is right!** *Nat Clin Pract Oncol* 2005;2(7):364-9. [Abstract](#)
27. Ong S et al. **Predictors of referral for adjuvant therapy for colorectal cancer.** *Can J Surg* 2005;48(3):225-9. [Abstract](#)
28. Sobrero A et al. **New directions in the treatment of colorectal cancer: A look to the future.** *Eur J Cancer* 2000;36(5):559-66. [Abstract](#)
29. Sonpavde G. **Communicating the value of adjuvant chemotherapy.** *J Clin Oncol* 2003;21(5):948-9. No abstract available
30. Sun W, Haller DG. **Adjuvant therapy for colon cancer.** *Curr Oncol Rep* 2005;7(3):181-5. [Abstract](#)
31. Andre T et al; Multicenter International Study of Oxaliplatin/5-Fluorouracil/Leucovorin in the Adjuvant Treatment of Colon Cancer (MOSAIC) Investigators. **Oxaliplatin, fluorouracil, and leucovorin as adjuvant treatment for colon cancer.** *N Engl J Med* 2004;350(23):2343-51. [Abstract](#)
32. De Gramont A et al. **Oxaliplatin/5-FU/LV in adjuvant colon cancer: Results of the international randomized MOSAIC trial.** *Proc ASCO* 2003;[Abstract 1015](#).
33. De Gramont A et al. **Oxaliplatin/5FU/LV in the adjuvant treatment of Stage II and Stage III colon cancer: Efficacy results with a median follow-up of 4 years.** *Proc ASCO* 2005;[Abstract 3501](#).
34. Grothey A, Sargent DJ. **FOLFOX for stage II colon cancer? A commentary on the recent FDA approval of oxaliplatin for adjuvant therapy of stage III colon cancer.** *J Clin Oncol* 2005;23(15):3311-3. No abstract available
35. Scheithauer W et al; X-ACT Study Group. **Oral capecitabine as an alternative to iv 5-fluorouracil-based adjuvant therapy for colon cancer: Safety results of a randomized, phase III trial.** *Ann Oncol* 2003;14(12):1735-43. [Abstract](#)
36. Twelves C et al. **Capecitabine as adjuvant treatment for stage III colon cancer.** *N Engl J Med* 2005;352(26):2696-704. [Abstract](#)
37. Twelves C et al. **Updated efficacy findings from the X-ACT phase III trial of capecitabine (X) vs bolus 5-FU/LV as adjuvant therapy for patients (pts) with Dukes' C colon cancer.** *Proc ASCO* 2005;[Abstract 3521](#).
38. Choi J et al. **Delayed oxaliplatin-associated neurotoxicity following adjuvant chemotherapy for stage III colon cancer.** *Anticancer Drugs* 2006;17(1):103-5. [Abstract](#)
39. Diaz-Rubio E, Schmoll HJ. **The future development of bevacizumab in colorectal cancer.** *Oncology* 2005;69(Suppl 3):34-45. [Abstract](#)
40. Ellis PM. **Attitudes towards and participation in randomised clinical trials in oncology: A review of the literature.** *Ann Oncol* 2000;11(8):939-45. [Abstract](#)
41. Sorensen JB et al. **Patient-physician communication concerning participation in cancer chemotherapy trials.** *Br J Cancer* 2004;90(2):328-32. [Abstract](#)
42. Porter GA et al. **Access to care and satisfaction in colorectal cancer patients.** *World J Surg* 2005;29(11):1444-51. [Abstract](#)

Patient Perspectives on Colorectal Cancer

QUESTIONS (PLEASE CIRCLE ANSWER):

- What percentage of participants considered their medical oncologist to be their primary physician?
 - 90
 - 6
 - 33
 - 65
- What chemotherapy side effect was found to be the most problematic by the participants?
 - Hair loss
 - Nausea and vomiting
 - Neurotoxicity
 - Fatigue
- Other than the doctor's office, which source of information did the largest percentage of participants use?
 - News media
 - Other patients and support groups
 - Booklets or brochures
 - The internet
- Which source of information, other than the doctor's office, did the most patients find to be extremely useful?
 - Other patients and support groups
 - The internet
 - Pharmaceutical advertising
 - Telephone information and 800 hotlines
- The most common reason for participating in the survey was to help other cancer patients.
 - True
 - False
- Of the participants who switched their primary treating physician (PTP), the largest percentage did so for what reason?
 - Relocation
 - Unhappy with PTP
 - Desired a more convenient location
 - Desired access to clinical trials
- The percentage of colorectal cancer patients who were willing to undergo therapy with FOLFOX for a one percent reduction of two-year recurrence rate was _____.
 - 50
 - 28
 - 12
 - 5
- After hearing the discussion with Dr Marshall, _____ percent of participants would recommend FOLFOX for friends in their sixties with Stage III colon cancer.
 - 87
 - 65
 - 20
 - 6
- After hearing the discussion with Dr Marshall, _____ percent would recommend capecitabine for friends in their sixties with Stage II colon cancer.
 - 68
 - 21
 - 10
 - 5
- Based on the discussion, _____ percent of participants would participate in a randomized trial in the adjuvant setting offering bevacizumab with FOLFOX or FOLFOX alone, if eligible.
 - 60
 - 72
 - 75
 - 80
- An audio discussion similar to the one by Dr Marshall would have made it more likely for 80 percent of the patients to participate in a clinical trial.
 - True
 - False
- Participants were most interested in which educational topic?
 - Pain management
 - Depression and emotional concerns
 - Emerging research
 - Sexuality and sexual relationships

EVALUATION FORM

Patient Perspectives on Colorectal Cancer

Research To Practice respects and appreciates your opinions. To assist us in evaluating the effectiveness of this activity and to make recommendations for future educational offerings, please complete this evaluation form. A certificate of completion is issued upon receipt of your completed evaluation form.

Please answer the following questions by circling the appropriate rating:

5 = Outstanding 4 = Good 3 = Satisfactory 2 = Fair 1 = Poor N/A = Not applicable

GLOBAL LEARNING OBJECTIVES

To what extent does *Patient Perspectives on Colorectal Cancer* address the following global learning objectives?

- Inform patients with colorectal cancer about the specific risks and benefits of various adjuvant systemic therapies. 5 4 3 2 1 N/A
- Counsel patients with colorectal cancer about treatment options and ongoing clinical trials. 5 4 3 2 1 N/A
- Develop an increased understanding of the patient perspective on cancer information and treatment decisions in colorectal cancer. 5 4 3 2 1 N/A

EFFECTIVENESS OF THE INDIVIDUAL FACULTY MEMBERS

Faculty	Knowledge of subject matter	Effectiveness as an educator
John L Marshall, MD	5 4 3 2 1	5 4 3 2 1

OVERALL EFFECTIVENESS OF THE ACTIVITY

Objectives were related to overall purpose/goal(s) of activity.	5	4	3	2	1	N/A
Related to my practice needs.	5	4	3	2	1	N/A
Will influence how I practice.	5	4	3	2	1	N/A
Will help me improve patient care.	5	4	3	2	1	N/A
Stimulated my intellectual curiosity.	5	4	3	2	1	N/A
Overall quality of material.	5	4	3	2	1	N/A
Overall, the activity met my expectations.	5	4	3	2	1	N/A
Avoided commercial bias or influence.	5	4	3	2	1	N/A

EVALUATION FORM

Patient Perspectives on Colorectal Cancer

REQUEST FOR CREDIT — please print clearly

Name: Specialty:

Degree:

MD PharmD NP BS DO RN PA Other.....

Medical License/ME Number: Last 4 Digits of SSN (required):

Street Address: Box/Suite:

City, State, Zip:

Telephone: Fax:

Email:

Research To Practice designates this educational activity for a maximum of 1.75 category 1 credits toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

I certify my actual time spent to complete this educational activity to be _____ hour(s).

Signature: Date:

Will the information presented cause you to make any changes in your practice?

Yes No

If yes, please describe any change(s) you plan to make in your practice as a result of this activity:

.....

What other topics would you like to see addressed in future educational programs?

.....

What other faculty would you like to hear interviewed in future educational programs?

.....

Additional comments about this activity:

.....

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As part of our ongoing, continuous quality-improvement effort, we conduct postactivity follow-up surveys to assess the impact of our educational interventions on professional practice. Please indicate your willingness to participate in such a survey:

Yes, I am willing to participate in a follow-up survey. No, I am not willing to participate in a follow-up survey.

To obtain a certificate of completion and receive credit for this activity, please complete the Post-test, fill out the Evaluation Form and mail or fax both to: Research To Practice, One Biscayne Tower, 2 South Biscayne Boulevard, Suite 3600, Miami, FL 33131, FAX 305-377-9998. You may also complete the Post-test and Evaluation online at www.ColorectalCancerUpdate.com/CME.

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