A Clinician and Patient Education Program



Patient Perspectives on Adjuvant Systemic Therapy of Early Colorectal Cancer

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FACULTY INTERVIEW

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AUDIO PROGRAM GUIDE

Track 7 Discrepancies in the approach to adjuvant therapy for breast

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CANCER Q AND A: COLORECTAL CANCER EDITION — CME/CNE INFORMATION

STATEMENT OF NEED/TARGET AUDIENCE

Counseling patients on the adjuvant treatment options and personal implications of the diagnosis of early colorectal cancer is complex and time consuming. The many variants of this disease make it a challenge to explain important information to patients in an understandable manner.

This audio activity focuses on interviews with clinical and research specialists in colorectal cancer and specifically reviews how these clinicians educate and counsel their patients. In addition, this program provides interviews with patients and their spouses to illustrate the patient's experience. The goal of this series is to help physicians and nurses better understand how to optimally discuss adjuvant therapy of colorectal cancer with patients in their care.

PURPOSE STATEMENT

To present the most current research developments and systemic adjuvant therapy options in early colorectal cancer, the perspectives of clinicians on how to present this information to patients and the experience of patients diagnosed with early colorectal cancer.

GLOBAL LEARNING OBJECTIVES

- Discuss the diagnosis and staging of early colorectal cancer, the risk of recurrence and the rationale for adjuvant therapy.
- Describe treatment options and clinical trials in the adjuvant setting for patients with colorectal cancer.
- Discuss side effects and benefits of various systemic adjuvant therapies for colorectal cancer.
- Describe potential benefits and risks to patients associated with clinical trial participation.
- Identify behavioral changes patients can employ to reduce their risk of recurrence.
- Describe the psychosocial and emotional impact associated with the diagnosis and treatment of early colorectal cancer on patients and their loved ones.
- Discuss the Patient Perspectives on Adjuvant Systemic Therapy of Early Colorectal Cancer survey and the implications for clinicians.

ACCREDITATION/CREDIT DESIGNATION STATEMENT

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HOW TO USE THIS CME/CNE ACTIVITY

This activity contains both audio and print components, as well as corresponding PowerPoint slides on the enclosed CD. To receive credit, the clinician should listen to the six audio CDs, review the monograph and complete the Post-test and Evaluation Form on our website, www.CancerQandA.com. In addition, appropriately selected patients can use part or all of the materials contained on the five patient CDs. The participant can distribute copies of the audio discs or direct patients to download the MP3 files or read the transcripts at www.CancerQandA.com. The transcripts of these programs are included on the audio CDs. Kindly let us know whether this experiment in patient education works and how we can make it better. We welcome any feedback or questions to Info@ResearchToPractice.com.

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EDITOR'S NOTE



Neil Love, MD

What it's like

A few years ago, our ever-exploring CME group in Miami conducted a highly interesting education experiment. We gathered a dozen urologists, radiation oncologists and medical oncologists for a daylong roundtable audio recording on the management of prostate cancer. What made this event particularly interesting was that all 12 of these men had been previously diagnosed with the disease.

In their practices over the years, these physicians had treated many patients with prostate cancer, and the first message that came out of this discussion was that living through the diagnosis and therapy turned out to be far more challenging than they expected.

My most vivid memory of this amazing day was the story of a urologist from Nebraska. In practice for more than 30 years, this experienced clinician, who was quite familiar with the current prostate cancer database, became so convinced of his imminent death following the news that he had Gleason 5 disease in one core (95 percent cure rate) that he refused to purchase new clothes for more than six months.

What these physicians also learned is that for most of us, an internal courage switch comes on in these crises, and often the drive to get through the maelstrom revolves around concerns for others who depend on us, particularly our families.

Although the clinician "patients" with prostate cancer described here are unique in understanding their disease, they are in no way alone with regard to feelings, emotions and fears. As we have come to learn, cancer patients, regardless of their tumor type, are far more alike than we might expect.

The enclosed report describes the third phase of a fascinating project that our group began in 2004 to further build on our understanding of the cancer experience. For this unique endeavor, we focused on colorectal cancer and more specifically the important topic of adjuvant chemotherapy for this disease.

Adjuvant chemotherapy is a critical issue throughout cancer medicine because cases involving this treatment approach in breast, colorectal and lung cancer alone account for approximately one third of all medical oncology office visits.

For the first phase of this colorectal cancer project, we hosted approximately 100 survivors of the disease and their loved ones at a town meeting on adjuvant

therapy in Houston. During the event, participants listened to presentations by clinical investigators and used interactive keypads and networked laptop computers to provide perspectives on the information they heard (Love 2005).

Based on the preliminary findings from the town meeting, we then produced a pilot audio education program and surveyed 150 more survivors for their thoughts on a number of key issues related to adjuvant therapy and their perceptions about the value and benefit of the audio program (Love 2006a).

Last year, the project shifted into high gear with the production of a five-hour audio patient education program on adjuvant treatment of colorectal cancer (delivered as a companion to this report) and a survey of 150 people who recently received adjuvant therapy for this disease.

The major survey findings are described in the report, and it would be fair to say that this work has received considerable attention. The results were first presented during a plenary session at the Gastrointestinal Cancers Symposium in Orlando in January 2007 (Love 2007c) and then again as a poster discussion at the June 2007 ASCO annual meeting in Chicago (Love 2007b). This work has also generated significant enthusiasm and interest among the lay and medical press and was featured in a prominent article in *USA Today* (Szabo 2007) and in a number of other publications.

The real value in completing this project was not just in the specific findings but that we were able to contribute to and continue what needs to be a major ongoing effort to ask patients about their experiences and perspectives. Oncology healthcare professionals must be constantly made aware of this valuable information so that they can properly address the needs and desires of their patients. The enclosed audio CD further describes this project and includes the related comments of NSABP Chair Dr Norman Wolmark, who was interviewed in Orlando after our initial presentation of the data.

For our next step in this compelling voyage, we hope to prospectively survey people about to undergo or in the midst of receiving adjuvant chemotherapy and those in the recovery process. We want not only to learn more about how to assist and support these patients in whatever way possible but also to better understand how we can more effectively incorporate these individuals into clinical trials. It is unfortunately clear that our current treatment tools for this disease are suboptimal, and we must find better answers quickly through research.

To this point, hundreds of patients and family members willingly contributed their time and effort to this compelling "research" project. We salute these participants and deeply appreciate their commitment to moving the field forward. They understood what many of us have come to realize — namely, that their stories, just like that of the urologist paralyzed by the fear of prostate cancer, need to be listened to and understood.

— Neil Love, MD NLove@ResearchToPractice.com June 10, 2007

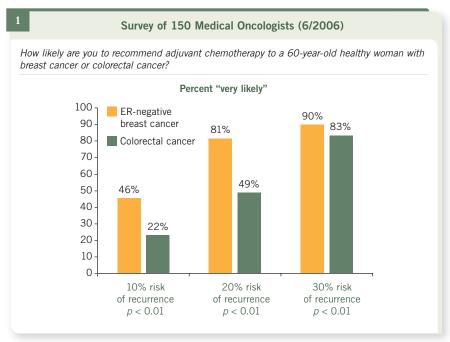
How well do we communicate with patients concerning adjuvant systemic therapy? Project results and discussion

BACKGROUND

Clinical decision-making regarding adjuvant systemic therapy for solid tumors presents a substantial patient education challenge to medical oncologists. The treatment strategy is subtle and challenging to explain to patients; the potential benefits involve complex numeracy; and the potential risks of therapy may be substantial.

Despite these potential obstacles, clinicians are regularly called upon to counsel patients about this treatment option, and approximately one third of office visits for US-based medical oncologists relate to adjuvant systemic therapy of breast, colorectal and lung cancer (Love 2007).

Patterns of Care surveys conducted by our CME group (Love 2006) and other similar surveys (Ravdin 1998; Bremnes 1995; Jansen 2001) indicate a discrepancy in the way oncologists approach this treatment strategy across tumor types. For example, oncologists are more likely to recommend chemotherapy to a woman with triple-negative breast cancer than to a patient at similar risk with colorectal cancer (Figure 1).



Many factors contribute to this dichotomy, including a less well-established research database supporting adjuvant therapy in colorectal cancer. However, in breast cancer, a series of patient surveys over the last 20 years has also had an important impact on the clinical practice of adjuvant therapy.

For example, a sentinel 1986 Australian study by Coates and Simes (Coates 1992; Simes 2001) of 104 women treated for breast cancer with adjuvant CMF for six months demonstrated that approximately half would receive the same therapy again for a one percent improvement in five-year overall survival.

Because no similar study had been conducted for patients with colorectal cancer, our CME group launched several preliminary needs assessment activities to better understand the perspectives of people in this clinical situation. These included a 2004 interactive town meeting with approximately 100 colorectal cancer survivors and guests and a 2005 national survey of 150 people with colorectal cancer who reviewed an audio interview with clinical investigator John L Marshall, MD.

We then initiated the current study to validate and expand on previous findings by exploring the experiences of people with colorectal cancer who had recently received adjuvant chemotherapy. The project had several major objectives (Figure 2).

2

Patient Perspectives Project Objectives

- Evaluate patient attitudes and physician beliefs regarding treatment tradeoffs in adjuvant therapy of colorectal cancer.
- Document patient expectations of chemotherapy and how these compared to actual
 experiences.
- Ascertain the level of patient interest in and understanding of an audio/web education program featuring clinical investigators and patients discussing the potential risks and benefits of adjuvant chemotherapy.

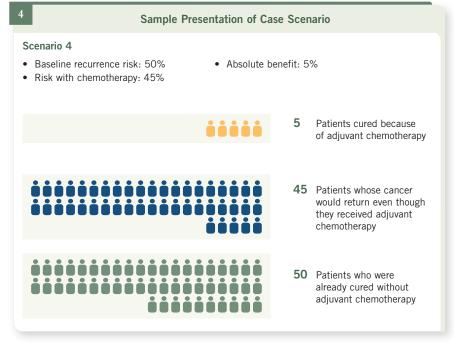
METHODS

People with colorectal cancer (N = 150) who had received adjuvant chemotherapy in the past five years were recruited through advocacy groups and medical oncology practices to listen to an audio education program and complete a survey relating to the information provided in that program.

The educational program, which provided a standardized information platform, featured interviews with clinical investigators (Leonard Saltz, John Marshall, Neal Meropol, George Fisher, Robert Wolff and Axel Grothey) and seven patients (and two spouses) previously treated with adjuvant chemotherapy for colorectal cancer.

Participants were then provided with six theoretical case scenarios (Figure 3) and corresponding graphics illustrating the changes in risk of relapse associated with adjuvant chemotherapy (Figure 4).

Tradeoff Situations Presented					
	Recurrence risk				
Scenario	Baseline	With chemotherapy	Absolute benefit		
1	50%	49%	1%		
2	20%	19%	1%		
3	20%	17%	3%		
4	50%	45%	5%		
5	20%	15%	5%		
6	50%	40%	10%		



Participants were queried about their willingness to undergo the same chemotherapy regimen they had previously received for each of the described scenarios.

The survey included a number of additional questions relating to the participants' expectations of and experiences with adjuvant therapy, the quality of the care delivered and information provided by their oncologists and the options presented for clinical trial participation. Patients were also asked to evaluate the understandability, value and relevance of an audio/web education supplement.

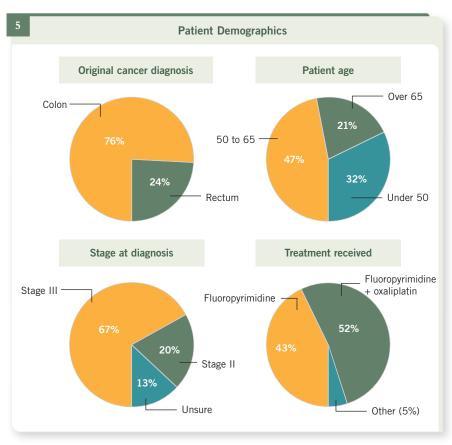
A companion survey of 150 medical oncologists and 24 gastrointestinal (GI) cancer specialists was conducted, and participants were asked to consider the

same six scenarios evaluated by the patients and then estimate the percent of patients in their practice they thought would be willing to undergo chemotherapy again for the benefits described.

PATIENT DEMOGRAPHICS

Most participants had been diagnosed with colon cancer and had Stage III disease (Figure 5). The median age was 55, 67 percent of participants were female, 86 percent were Caucasian and 79 percent had some college education. Approximately half had received adjuvant therapy with oxaliplatin and a fluoropyrimidine (mainly variations of FOLFOX), and the other half had mostly received a fluoropyrimidine alone. At the time of the survey, 87 percent of the patients were free of cancer recurrence.

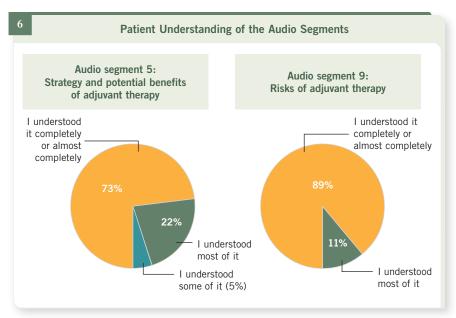
The educational content presented on the audio program was evaluated for understandability and relevance. Despite the relatively sophisticated concepts presented, most patients stated that they understood the information completely or almost completely (Figure 6) and believed that it would be relevant and of interest to other patients diagnosed with colorectal cancer.

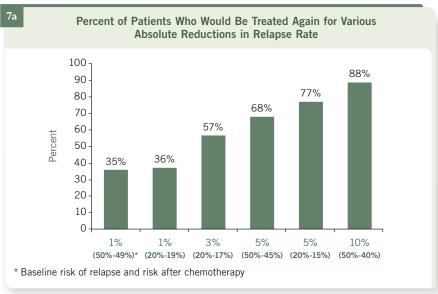


RESULTS

More than one third of the patients would be treated again with the chemotherapy regimen they previously received for a one percent reduction in the risk of relapse, although more than 10 percent would not receive treatment again even for a 10 percent reduction in the risk of relapse (Figure 7a).

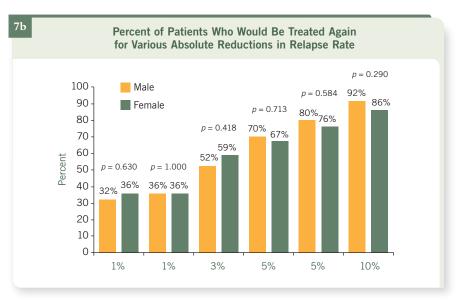
The responses of men and women were not statistically different, and no

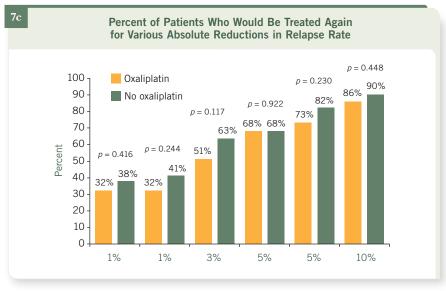


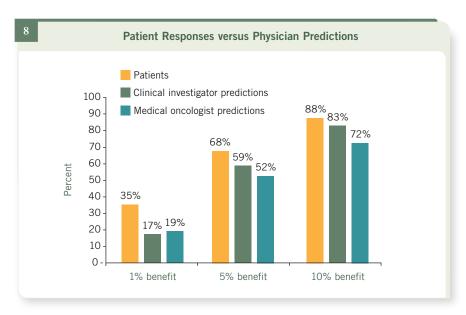


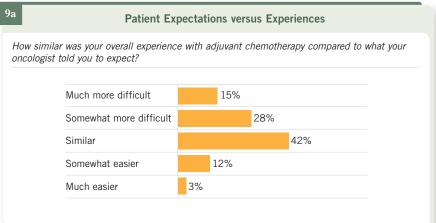
gender-related trends were found in treatment tradeoff perspectives (Figure 7b). Nor were significant differences apparent in the responses of patients receiving oxaliplatin-containing regimens compared to other regimens, mainly fluoropyrimidine monotherapy, despite the potential increase in side effects and toxicity associated with the addition of oxaliplatin (Figure 7c).

When these findings were compared to the related Patterns of Care survey, data demonstrated that the predictions of practicing oncologists were lower than the responses of the patients surveyed. A parallel survey of GI oncology investigators showed similar predictions (Figure 8).





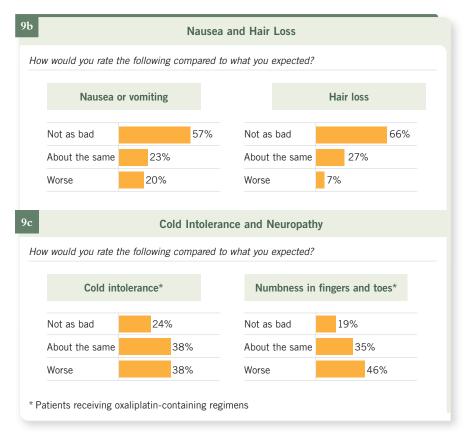


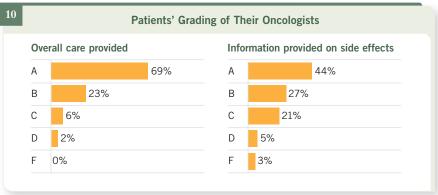


The patient participants were also queried about their experiences with the side effects and toxicities of treatment, and their experiences with adjuvant chemotherapy were somewhat different than anticipated (Figure 9a). Specifically, more than half of the patients expected more GI toxicity and alopecia than they experienced (Figure 9b).

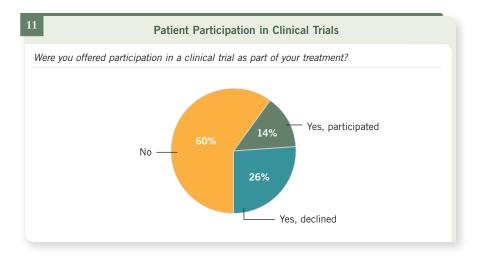
In contrast, more than one third of the of patients receiving oxaliplatin-containing regimens experienced more troubling cold intolerance and peripheral neuropathy than they expected (Figure 9c).

Most patients were satisfied with the overall quality of care received from their medical oncologists, but fewer were satisfied with the amount of information provided on side effects and treatment benefits (Figure 10).





Most patients were not offered participation in a clinical research study, and of those patients who were not, more than 80 percent would have liked to learn about research-based opportunities. However, of the patients who were offered clinical trial participation, approximately two thirds declined entry (Figure 11).



CONCLUSIONS

- The perspectives of people with colorectal cancer can be challenging to understand for those not facing the experience firsthand, even oncology professionals. Physicians should consider that potential heterogeneity exists in patient attitudes with regard to the risk-benefit tradeoffs of adjuvant chemotherapy, and individualized treatment decisions should consider the perspectives of that person.
- Patients' experiences with the side effects of adjuvant chemotherapy may be
 quite different from what they expect, and it is important to consider that
 external sources such as other patients or friends and relatives may be contributing to gaps in physician-patient communication about treatment-related
 toxicities.
- These findings are limited by the potential bias introduced because participants had previously decided to receive adjuvant chemotherapy and were generally free of recurrence. However, the survey suggests an opportunity to supplement the information patients receive from their medical oncologists. To confirm the findings and explore how improvements may be implemented, the next step will be to conduct a prospective, real-time evaluation of patients undergoing this decision-making process and to evaluate the impact of an audio/web program to enhance physician-patient communication. ■

SELECT PUBLICATIONS

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Abstract



INTERVIEW

Norman Wolmark, MD

Dr Wolmark is Professor and Chairman in the Department of Human Oncology at Allegheny General Hospital. Professor at the Drexel University College of Medicine and Chairman of the National Surgical Adjuvant Breast and Bowel Project in Pittsburgh, Pennsylvania.

Select Excerpts from the Interview with Dr Wolmark



Track 7 (See Figure 1)

- DR LOVE: This survey demonstrates that in lower-risk settings, oncologists are more likely to use adjuvant chemotherapy in breast cancer than they are in colon cancer. Any thoughts?
- DR WOLMARK: I believe it underscores a disconnect. It underscores a heterogeneity and an inconsistency among oncologists, primarily. It's not an inconsistency in the benefit for and responsiveness of the tumor in breast cancer as opposed to colon cancer. The philosophy of a medical oncologist specializing in breast cancer is somewhat different from the philosophy of an individual treating colon cancer.
- DR LOVE: One of the issues regarding breast versus colon cancer in the lowerrisk, node-negative situation is that there is not as much data in colon cancer as there is in breast cancer.
- **DR WOLMARK:** We may not have as much support in the number of patients treated. However, I believe it's consistent to state that we have no reason. biologically, to assume that low-risk colon cancer will respond or benefit in a different manner than Stage III colon cancer.

You can make the same statement for Stage I and II breast cancer. And yet we haven't been inhibited by the threshold to be reached before administering chemotherapy in breast cancer, whereas we have been inhibited by that threshold in colon cancer.

I do want to clarify something: I'm not suggesting that every patient who has Stage II colon cancer should receive chemotherapy — it may be that the majority should not. But I do believe that the patient has to be an integral part of the decision-making process. The patient should be provided with an opportunity to participate in determining whether he or she will receive chemotherapy.



- DR LOVE: It's challenging to understand the mindset of someone who's just been diagnosed with breast cancer or colon cancer. For people without the disease, it's difficult to comprehend why someone might want to receive chemotherapy for a one percent reduction in relapse rate.
- DR WOLMARK: I'm not sure we have to analyze what's going through their minds, but we do need to assure ourselves that they understand the information we're presenting.

The stick figure diagrams you used in the survey make it unequivocally clear what the benefit is, and despite that fact, we still see that a significant proportion of patients, even for a one percent absolute benefit in terms of recurrence, would still have elected to proceed with adjuvant chemotherapy.

- **DR LOVE:** It's also interesting that at the other end of the spectrum, where we presented a scenario with a 10 percent reduction in the absolute chance of experiencing recurrence, 12 percent of people still wouldn't want chemotherapy in that situation.
- DR WOLMARK: Absolutely, and one has to respect that. I believe this information is quite useful.



Track 9 (See Figures 7b and 7c)

DR LOVE: Another goal of this survey was to evaluate what the difference in opinion was between men and women. Some people interpreted the proactivity expressed in the surveys of patients with breast cancer as gender related.

Interestingly, in this survey of people with colorectal cancer, we really didn't see a difference in the responses between men and women.

- DR WOLMARK: I was struck by that result, but I wasn't surprised by it. Certainly, these are data rather than speculation, and there does not appear to be a large difference between the responses or preferences of men versus women. You didn't find any disparate preference relative to age. That's all comforting, supportive and meaningful information.
- DR LOVE: Another interesting observation is that these were patients who had received adjuvant chemotherapy, and there wasn't a large difference between patients who did and did not receive oxaliplatin, which potentially brings additional side effects and toxicity.
- DR WOLMARK: I would have expected a difference, yet there was none. So again, I think we have to listen.



DR LOVE: We also surveyed 150 randomly selected medical oncologists and 24 researchers in gastrointestinal cancer. We presented exactly the same scenarios that we presented to the patients and said, "What fraction of patients do you think would want to be treated in this situation?" Now, they're considering every patient they might see in their practice.

The kinds of people who might have come into this type of survey might have been atypical in some respect. Yet, in any event, the clinicians' predictions anticipated a much lower willingness to undergo therapy than what the patients expressed. What were your thoughts on that?

DR WOLMARK: I wasn't surprised, but a consistent trend is evident — that regardless of whether they are medical oncologists or clinical investigators, they underestimate the desire of their patients to proceed with chemotherapy. You showed this in your previous study, and I believe you've shown it again here.



Track 10 (See Figures 9a, 9b and 9c)

DR LOVE: The other interesting and unexpected finding from this survey relates to the patients' experiences compared to what they expected. We interviewed seven patients and a few spouses for our audio program, and I started to hear a consistent story in the interviews that was reflected in the survey.

This was expressed in statements like, "They told me I wasn't going to experience nausea, vomiting and hair loss, but then I talked to my aunt, who underwent chemotherapy, and she was really sick and lost all of her hair," or, "My friend had chemotherapy..."

In fact, more than half of the patients went into this expecting to experience nausea, vomiting and hair loss and then were surprised that the symptoms didn't appear.

DR WOLMARK: I believe that's useful information that we can share with patients for whom we're contemplating chemotherapy, as a tool to put these percentages into proportion and tell them, "This is what other patients who have received chemotherapy thought of the toxicity."

We overestimated the impact of nausea, vomiting and hair loss, just as you point out here, and we underestimated the neurotoxicity in that patients thought the neurotoxicity was worse than what they had expected. That's useful information for patients who are faced with making the decision of whether to go forward with it.

DR LOVE: My hypothesis, too, is that "Aunt Nellie" might have received AC for breast cancer, which doesn't cause neurotoxicity but does cause alopecia and potential GI toxicity.

The patients might be receiving a lot of information, perhaps in the oncologists' waiting rooms, that's being transferred around.

DR WOLMARK: Our trial data can talk about "an eight percent incidence of Grade III neurotoxicity," but what does that actually mean? Obtaining feedback from patients who've received the same regimen, I believe, could be helpful to other patients.



Track 11 (See Figure 10)

DR LOVE: We also asked the patients to grade the care they received from their oncologists using an A through F system. Again, the types of people who participated in this survey may not be representative of people in practice, but ninety percent or more of the oncologists received As or Bs for overall care.

However, when we asked specifically about providing information, approximately one quarter of these patients weren't happy with the information they were receiving. They graded the doctors with a C or worse.

DR WOLMARK: The fact that patients were happy and awarded high marks to the medical oncologists is gratifying. When we hear some of the reports as to how well we're doing, particularly from entities outside of the medical profession, it is reassuring to have that objective information.

I believe the fact that the vast majority gave high marks overall is important. The next issue becomes a matter of how we fine tune our methods so that we can relay the additional information to patients in a meaningful manner.

- DR LOVE: I wonder whether oncologists underestimate how much competing information is reaching patients, particularly through the Internet and talking to people, including other patients, and that people receiving huge volumes of information want more out of their oncologists.
- **DR WOLMARK:** Perhaps it's a matter of wanting information specifically tailored to their personal situations, because the survey indicates that patients respect their physicians as capable individuals.

I believe the medical oncologists want this as much as the patients do. Oncologists want their patients to be informed. This discloses areas in which we can do better.

- **DR LOVE:** The patients obviously are tremendously interested in treatment side effects. And one of the things that an oncologist can't tell them is what it's like to go through this.
- DR WOLMARK: Precisely.

Track 12 (See Figure 11)

- **DR LOVE:** The last thing I want to talk to you about is what the patients said to us about participation in clinical trials. First, most of these patients did not receive information about participating in clinical trials, but they listened to our audio program in which we discussed clinical trials, and of the people who didn't receive information, 80 percent would have liked to have received this information.
- DR WOLMARK: That underscores the fact that the vast majority of patients are not apprised of clinical trials as an option. In response to the question, "Were you offered participation in a clinical trial as part of your treatment?" most said no.

We have to acknowledge that our great hope that resources would be available to increase participation in clinical trials as a result of the initiatives from the NCI has taken an unfortunate turn. Clinical trials are time consuming. Medical oncologists who participate in clinical trials have to do so with an altruistic intent, believing that the state of the art will benefit by their participation. We're not providing the resources and the support to make that something the medical oncologists can do in a practical fashion.

The amount of effort, time and paperwork and the logistic labyrinth required to participate in clinical trials, and a shrinking budget, make this a daunting task.

What we can say candidly to patients is that if they participate in a clinical trial, they will be receiving the highest standard of care, which is mandated prospectively by the protocol document. I sincerely believe that the level of care within a clinical trial is better than the average level of care delivered outside of a clinical trial.

The fact that participating in a clinical trial will further the state of the art, even when an intervention is considerably less of a hurrah than trastuzumab in breast cancer, as undoubtedly most of them will be, is also a great assurance.

If the patient says, "No, I don't think this clinical trial is for me. I'm not comfortable with the fact that my therapy is going to be decided at random," you can try to inform that patient that therapy selected at random isn't necessarily therapy that's going to put him or her at a disadvantage — quite the contrary.

In the end, you have to respect the wishes of the individual. However, I would like to see them arrive at their conclusion after being informed of the opportunity rather than not being offered the opportunity to participate.

I will always remember one anecdote. We had a panel of patients who participated in NSABP trials, and we asked them, "Why did you participate?"

One individual, a nurse, made quite a poignant remark: "I've heard over and over the concern about therapy being selected at random. Well, before I heard

about the NSABP protocol, I went to six medical oncologists and heard six different recommendations for treatment. Here, I see with this study that it's limited to two or three options." She continued, "You want random, you go out there and poll eight or nine medical oncologists, and you'll see what random is."

All the recommended therapies are based on research, and they're all therapies that I believe are effective — yet they differ from one oncologist to the next.

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