

Decision Making and Communication Regarding Cancer Treatment and Prevention

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Neal J. Meropol, M.D., Senior Member, Director, Gastrointestinal Cancer Program, Gastrointestinal Tumor Risk Assessment Program

Joanne Buzaglo, Ph.D., Senior Scientific Associate

Melissa Klein Cabral, M.A., Project Manager

Jennifer Millard, B.S., Health Educator

Hetal Sheth, M.S., M.G.C., Genetic Counselor

Susan Antaramian,* B.S., Research Study Assistant

Caroline Ridgway,* B.A., Research Study Assistant

Nicholas Solarino, M.S., Research Study Assistant

Jonathan Trinastic, B.A., Research Study Assistant

Ann Pellegrino, C.R.N.P., Nurse Practitioner

Diane Baier, Administrative Assistant

Pam Meister, Administrative Assistant



Decisions regarding cancer therapy involve a complex interplay between patients and providers. Often, several treatment options exist for patients, including standard therapies, investigational therapies, and a supportive care approach. Medical decision making for cancer patients is unique in that these individuals are frequently facing mortality, and choosing among therapies with potential for severe side effects. In arriving at a treatment choice, patients must weigh the benefits and risks associated with each therapeutic option. This process involves evaluation of information obtained from the health care team and other sources, in the context of one's medical condition, individual values, background, and personality characteristics. The overall objective of our research is to understand and support the process by which cancer patients select treatment (and those at risk for cancer chose health behaviors), in an effort to optimize decisions consonant with individual patient values.

Patient decision making: Phase I clinical trials.

Meropol, in collaboration with Balshem,[§] Manne,[§] Ross,[§] Castel,^a DePuy,^a Schulman,^a Sulmasy,^b Weinfurt^a

A focus of our program has been to characterize the decision-making calculus of patients considering clinical trial participation. We previously conducted a survey of 328 patients who were considering phase I trials, 80% of whom chose to participate. In this study, patients expressed high expectations of benefit, and these expectations were predictive of phase I study participation (Meropol et al., *J. Clin. Oncol.* 21:2589, 2003; Gaskin et al., *Med. Decis. Making* 24:614, 2004). On average, patients choosing to participate in a phase I trial thought that they had a 65% chance of benefiting. We subsequently sought to describe the influences on patient expectations. Specifically, we were

interested in assessing whether patients truly understand all of the information presented to them during the informed consent process. We hypothesized that a patient's ability to understand the type of statistical information commonly communicated during medical encounters would impact treatment outcome expectations. We developed a measure of 'numeracy,' and found that 28% of patients were not able to understand a simple frequency statement. Poorer numeracy was associated with higher expectations of benefit (1). In subsequent analyses, we identified several demographic factors associated with poor numeracy. These include non-White race, older age, and lower income and education levels. Previous cancer treatment and previous participation in clinical trials was associated with better numeracy (1). These data suggest that patient

demographics may assist in tailoring information such that the informed consent process for clinical trials can be optimized.

Communication aid for cancer patients and physicians. Meropol, Buzaglo, Millard, in collaboration with Balslem,[§] Benson,[©] Burnett,^d Collins,[§] Diefenbach,^e Fleisher,[§] Miller,[§] Schulman,^a Sulmasy,^b Weinfurt,^a Wolff^f

Patients with advanced cancer exist in a unique medical context in which they are facing mortality and may be considering treatment options that have significant potential for toxicity. In addition, therapeutic choices may be varied and complex, including supportive care alone, standard treatments (e.g. chemotherapy, radiation, biologic), and investigational approaches. We previously reported (Meropol et al., *J. Clin. Oncol.* 21:2589, 2003; Cheng et al., *J. Clin. Oncol.* 18:421, 2000) that advanced cancer patients have discordant expectations from their physicians with regard to potential benefits and toxicities of therapeutic options. Although high expectations of benefit among patients may not always be a source of bioethical concern (Weinfurt et al., *Cancer* 98:166, 2003), we also found that patients and their doctors differ markedly in their assessments of topics discussed during their consultations, thus raising concern regarding the adequacy of communication. Whereas 73% of doctors reported that they discussed the impact of treatment on quality of life, only 28% of patients reported that this topic was discussed (Meropol et al., *J. Clin. Oncol.* 21:2589, 2003). This observation is of particular interest given that 95% of these patients reported that quality of life was at least as important as length of life for them. Based upon these findings, we have developed a Web-based intervention for patients with advanced cancer and their physicians with a goal of improving doctor-patient communication. This communication aid has two components: 1) communication skills training for patients; and 2) assessment of preferences and values with summary report to physician. A randomized clinical trial is underway to determine whether this communication aid, with or without a summary report of patient survey responses provided to the physician before the consultation, will impact patient satisfaction, decisional conflict, patient treatment outcome expectations, and consultation content.

Barriers to clinical trial participation across Pennsylvania. Meropol, Buzaglo, Millard, in collaboration with Balslem,[§] Miller,[§] Ross,[§] Watts[§]

Although clinical trial research is required for the development of improved treatment strategies, very few individuals participate in such studies. To a great extent, the focus of research into barriers to clinical trials has been on practical issues for both physicians and patients (e.g., costs, administrative and staffing insufficiencies, limited access to clinical trials, restrictive inclusion criteria, and logistical issues such as distance to the treatment site, time away from home and work, and lack of awareness of clinical trial options). To date, there has been little research regarding the psychosocial or cognitive-affective barriers to clinical trial participation. To fill this empirical gap, the primary objective of this study, funded by the Pennsylvania Department of Health, is to characterize cognitive, affective, and practical barriers to participation in clinical treatment trials among oncologists, their cancer patients, and first-degree relatives (surrogates for an "at-risk" population who might consider prevention studies) across Pennsylvania. We distributed a survey to all medical oncologists in Pennsylvania and a subset of their patients and patient first-degree relatives. Relevant background information and assessment of practical and psychosocial barriers to clinical trial participation were assessed.

One hundred thirty-seven oncologists, 170 patients, and 82 first-degree relatives completed surveys. Eighty-four percent of patients were aware of clinical trials. Ninety-eight percent of oncologists and 85% of patients agreed that clinical trials are important to improving cancer treatment. Patient race and education, and physician practice setting were associated with knowledge and attitudes towards cancer treatment clinical trials. Both oncologists and patients were more likely to consider clinical trials in the case of advanced or refractory disease. When considering seven potential barriers to clinical trials, random assignment and fear of receiving a placebo were ranked highly by both patients and oncologists. While patients identified fear of side effects as the greatest barrier to clinical trial participation, oncologists ranked this psychosocial barrier as least important ($P < 0.0001$). In general, oncologists and patients are aware of clinical trials and

have favorable attitudes toward them. Although there is some concordance between oncologists and patients in their perceptions of the psychosocial barriers to participation, we also identified significant discrepancies. Our ongoing research will attempt to improve communication and decision making about treatment clinical trials by assessing and addressing barriers for individual patients. Analysis of first-degree relative survey data is underway.

Understanding patient expectations of treatment outcomes. *Meropol, Millard, in collaboration with R. Cohen,[§] Weinfurt,^a Schulman^a*

In clinical research, the crux of the informed consent process is patient understanding of pertinent information about their treatment options. Our previous work and that of others has raised concerns about the adequacy of this process. In an earlier study, we found that patients who were offered participation in early phase oncology trials frequently reported high expectations about the benefit of an experimental therapy, and these expectations were significantly higher than those of their oncologists. If these high expectations reflect false beliefs about the nature of treatment, then they raise concern about adequacy of the informed consent process. It is unclear from the available evidence, however, whether patients are demonstrating faulty knowledge about a treatment every time they express high expectations of benefit. Without knowing the meaning of patient's expectations of benefit, one cannot conclude that the informed consent process has failed to ensure the patient's understanding.

The overall objective of this ongoing study, which is led by a collaborator at Duke University, is to better understand the meaning of patients' reported expectations regarding treatment outcomes in the informed consent process. We plan to ascertain how patients understand questions about their treatment expectations and identify some of the factors that influence patients' responses to these questions. There are three research aims: 1) to determine how cancer patients who are offered participation in phase I and II studies understand questions regarding their expectations of treatment outcomes; 2) to determine how patients' estimates of treatment outcomes depend upon how the patients are asked to provide the estimates; and

3) to describe patient characteristics that are associated with higher expectations regarding treatment outcomes.

Understanding patients enrolling in phase I trials. *Meropol, Pellegrino, in collaboration with Agrawal,^g Emanuel^h*

Ethical issues surrounding phase I oncology trials include concerns that patients lack information necessary to make informed decisions. For example, incomplete understanding of the goals of the study, and low awareness of other options (e.g., hospice care) are potential issues. This multicenter study, led by E. Emanuel and M. Agrawal at NIH, seeks to inform deliberation of these issues through empirical data obtained from patients participating in phase I cancer studies. One hundred forty-two patients who enrolled in phase I trials took part in an in-person survey interview. Preliminary analyses suggest that among these patients, awareness of options other than a phase I trial was high. Eighty-four percent of patients were aware of treatment for symptoms only, 81% were aware of hospice care, and 69% were aware of other clinical trials. However, only 10% and 6% seriously considered treatment of symptoms only and hospice care, respectively, as an alternative for them. Only 7% seriously considered no cancer treatment as an alternative, and 35% considered other clinical trials. (Agrawal et al., *J. Clin. Oncol.* 16S:6014, 2005 (Abstract)). These data suggest that patients who enroll in phase I trials are generally informed regarding other options, but tend to discount those approaches restricted to palliative/supportive care. Ongoing analyses will further define the psychological characteristics of these patients.

Gastrointestinal Tumor Risk Assessment Program. *Meropol, Klein Cabral, Sheth, in collaboration with Balshem,[§] Bellacosa,[§] Cooper,[§] Daly,[§] Engstrom,[§] Godwin,[§] Manne,[§] Ross,[§] Weinberg[§]*

Identification of risk factors for colorectal cancer (CRC) and other GI cancers permits screening strategies based upon individual patient characteristics. Influences on CRC risk include diet, family history, personal history of CRC or polyps, and inflammatory bowel disease. In addition, germline mutations in genes such as

APC, MLH1, MSH2, PMS2, MSH6, and MYH which are responsible for familial adenomatous polyposis (FAP) and hereditary non-polyposis CRC (HNPCC), have been identified, and clinical testing is available for suspected affected individuals. The availability of genetic testing for cancer predisposition raises a variety of ethical, legal, and social issues for individual patients, their families and society at large. The GI Tumor Risk Assessment Program was designed with two major objectives: 1) to provide a service to patients wishing to undergo risk assessment, counseling and screening; and 2) to conduct laboratory, epidemiologic, and psychosocial studies of hereditary and familial GI cancers. The members of this program comprise a multidisciplinary team including gastroenterologists, genetic counselors, medical oncologists, pathologists, laboratory and clinical scientists, and health educators. Services offered include education, individual risk assessment, counseling, and recommendations regarding screening, including the appropriateness, risks, and benefits of genetic testing. An Institutional Review Board (IRB)-approved registry and tissue bank for collection of family health history information and psychosocial data, as well as germline and tumor DNA from affected and non-affected members of 'high risk' cancer families, serves as a resource for multidisciplinary research of cancer risk.

Development & evaluation of a Web-based tool for genetic risk counseling and education: Internet Risk Assessment Program (IRAP).
Meropol, Klein Cabral, Sheth, in collaboration with Daly,[§] Manne,[§] Zubarev,[§] Manion[§]

The identification of hereditary cancer syndromes and the availability of clinical genetic testing heighten the importance of risk assessment and counseling. In particular, the decision of whether to pursue genetic testing requires a careful risk assessment, which ideally involves not only individuals but also their family members. Unfortunately, families are frequently geographically dispersed, with many individuals not

having access to appropriate professional expertise in cancer genetics. The purpose of this project is to develop and evaluate an internet-based method for provision of live, on-line cancer risk assessment and education for families at increased risk for colorectal, breast, or ovarian cancers. Recruitment to this study has begun. Participants at remote locations are provided a webcam and software to permit their connection via the Internet to a risk assessment session at Fox Chase Cancer Center. All subjects view an on-line prerecorded educational presentation, followed by a live counseling session with a genetic counselor. Outcomes include feasibility, acceptability, and impact on risk perception, anxiety, and genetic knowledge.

Informed decision making regarding microsatellite instability testing. *Meropol, Sheth, Klein Cabral, in collaboration with Manne,[§] Driesbaugh,[§] Cooper,[§] Godwin,[§] Catts,^h Chung,ⁱ Manning,^j Petrelli,^h Shannonⁱ (See [Manne report](#))*

Germline defects in several DNA mismatch repair genes, including MSH2 and MLH1, predispose people to a hereditary form of colorectal cancer (CRC) called hereditary nonpolyposis colorectal cancer (HNPCC). HNPCC accounts for approximately 5% of all colorectal cancers. Microsatellite Instability (MSI) testing and immunohistochemistry (IHC) for DNA mismatch repair proteins are commonly used as screening tests for hereditary nonpolyposis colon cancer (HNPCC) before proceeding to germline mutation analysis. Before undergoing MSI/IHC testing at Fox Chase and other centers, patients routinely provide written informed consent. The purpose of this study is to improve knowledge and understanding of the MSI and IHC tests, and overall patient satisfaction with the process of informed consent for this testing. In collaboration with investigators from Massachusetts General Hospital and Triad Interactive, Inc., we are conducting a randomized clinical trial to evaluate the impact of standard consent versus a CD-ROM education intervention.

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§ Fox Chase researcher

* Personnel left Fox Chase

^a L. Castel, V. DePuy, K. Schulman, K. Weinfurt: Duke University, Durham, NC 27710

^b D. Sulmasy: St. Vincent's Medical Center, New York, NY 10011

^c A. Benson: Northwestern University, Evanston, IL 60201

^d C. Burnett: University of New Mexico, Albuquerque, NM 87131

^e M. Diefenbach: Mount Sinai School of Medicine, New York, NY 10029

^f S. Wolff: Meharry at Nashville General Hospital, Nashville, TN 37208

^g M. Agrawal, E. Emanuel: National Institutes of Health, Bethesda, MD 20892

^h Z. Catts, N. Petrelli: Helen F. Graham Cancer Center, Christiana Care Health Services, Newark, DE 19713

ⁱ D. Chung, K. Shannon: Massachusetts General Hospital, Boston, MA 02114

^j C. Manning: Tria Interactive, Inc., Washington, DC 20005