Short Communication

Perceptions of Informed Consent by Participants in a Prostate Cancer Prevention Study

Carolyn Cook Gotay
University of Hawai’i, Cancer Research Center of Hawai’i, Honolulu, Hawaii 96813

Abstract
This study examined perceptions of the informed consent process in healthy men participating in a cancer prevention clinical trial. Specifically, we examined influence of the consent form on participation and understanding, adequacy of the consent process in preparing participants for trial experiences, and perceived needs for additional follow-up strategies. Participants (n = 69) enrolled in the Prostate Cancer Prevention Trial at our institution completed mailed questionnaires 2 years after joining the study. Results indicated that many participants had no remembrance of the consent process, and only a minority reported that the consent process had helped in decision-making about study participation. Eleven men (16%) reported experiencing unexpected study side effects, most related to sexual functioning. Most men (78%) did not feel that they currently needed more information about the study, although virtually all of the respondents wanted to learn the study results. Almost one-third wished to interact with other Prostate Cancer Prevention Trial participants. Results indicate that a signed consent form and initial counseling for a prevention study does not ensure that participants feel they are adequately informed about the study or the side effects. Providing and reinforcing information on a regular and continuous basis is especially important in studies where compliance is required over a period of years.

Introduction
Obtaining informed consent from patients and potential research participants is a basic requirement in clinical care and research. Previous studies demonstrate that consent forms used in cancer treatment research are overly complex (1–3). Even Institutional Review Board review does not necessarily improve consent form readability (4, 5). Cancer patients frequently remain confused about the nature and consequences of their participation, even after reading and signing consent forms (6, 7). Patients undergoing cancer therapy failed to recall major portions of the information provided in the consent process within 1 day of signing a consent form (8), and nearly one in four patients who provided informed consent for radiation therapy could not recall having been told of a single side effect of the therapy (9).

Research to date has focused on cancer patient perspectives, whereas little attention was paid to the views of healthy volunteers in cancer prevention studies. The anxiety associated with cancer diagnosis may cloud patient ability to process information such as that found in consent forms. In healthy populations, consent forms may be more successful in achieving understanding of the study initially and over the course of long-term trials.

This study focused on healthy male participants who were 2 years into a 7-year cancer chemoprevention clinical trial. We examined their perspectives about the adequacy of the consent process at time of study enrollment and currently.

Materials and Methods
Participants were enrolled in the PCPT conducted by the University of Hawai’i Community Clinical Oncology Program. The PCPT is a randomized, double-blind, placebo-controlled study testing the efficacy of finasteride in preventing prostate cancer (10, 11) in healthy men ≥55 years of age. The trial includes 18,882 participants nationwide who take a daily pill (either finasteride or placebo) for 7 years with four contacts with PCPT staff each year. At the end of year 7, participants are scheduled for prostate biopsy. At our institution, all of the potential participants received extended counseling about the study from a physician or clinical research associate before signing a detailed consent form, of which they are provided a copy.

At the time of this study, the respondents were in their second year of PCPT participation. After approval by their referring physicians, individuals were mailed explanatory covering letters and self-administered questionnaires including closed-ended and free-response questions about their PCPT experience, both initial informed consent and current information needs. Items included some adapted from Cox and Avis (12). This study was submitted to and approved by the University of Hawai’i Committee on Human Studies.

Results
Participation Rates. Eighty-five men were sent questionnaires and 69 (82%) participated. The Hawai’i Community Clinical Oncology Program registered 109 men on the PCPT. Referring physicians refused permission to contact 24 patients for reasons including low English language ability or participants lost to follow-up, ill, or dead.

Average respondent age was 67.6 years (range 50–83).
Most were highly educated (74% had at least some college education), married (80%), and Caucasian (n = 27; 39%) or Japanese (n = 23; 33%). Participants in other ethnic groups were African American (n = 1), Chinese (n = 5), Filipino (n = 2), Hawaiian (n = 2), Hispanic (n = 2), Korean (n = 2), Pacific Islander (n = 1), and multiethnic/other (n = 5). No statistical differences (using χ² analysis) were found between respondents and nonrespondents for education, ethnicity, or marital status; participants were 9 years older than nonrespondents (t(83) = 4.2; P < 0.001). Most respondents rated themselves as healthy, with 29% saying “excellent” and 62% “good,” and most viewed their quality of life favorably (a mean of 6.1 on a 1–7 scale of quality of life, where 7 is the highest rating).

**How Did the Participants Learn about the Study?** Forty of the 69 respondents cited newspaper advertisements as the source of information about the PCPT. Other sources included the Cancer Information Service (n = 11), friends (n = 7), physicians (n = 3), and family members (n = 3), as well as seven other sources cited once.

**Did Respondents Report That the Consent Form Influenced Their Participation in the Study?** Table 1 indicates that many participants had no remembrance of the consent process. Nearly 25% could not recall reading a consent form, 25% could not remember someone explaining the form, and 7% said that no one had explained the form. Of participants, 42% said, “I don’t remember” whether the consent process helped in their decision to participate in the study. Twenty-seven of the remaining 40 participants reported that the consent process did not help them in deciding to participate.

**Did Respondents Report That the Consent Form Was Understandable?** Table 1 indicates that nearly one-half of respondents (46%) did not remember whether the consent form was understandable. Of the 37 remaining men, 29 (78%) rated the consent form as “easy” or “very easy” to understand. Information on education was available for 31 of these men, 24 of whom had at least some college and 7 of whom had a high school education or less. One-third (n = 8) of individuals with college experience felt the form was “very easy” to understand compared with none of the men with less education. Forty-six (70%) reported that “it didn’t affect how I felt about the medication.” More than half (52%) said “I don’t remember” about the amount of information in the consent form, whereas 94% of those who could remember (30 of 32) reported that the amount of information was “just right.” Almost all of the men (91%) said that they had not needed more information before deciding to take part in the PCPT.

**Did Respondents Believe That the Consent Process Had Been Adequate in Preparing Them for Their Trial Experiences?** Table 1 shows ~25% did not remember enough about the consent process to answer this question. Of the remaining men, 39 of 52 (75%) reported that the consent process had been adequate. Eleven men (16%) reported experiencing unexpected trial side effects, most often related to sexual functioning. One man identified: “(a) fewer erections; (b) a definite change in the shape of my penis; (c) a very definite diminishing of sensation at orgasm plus little to no ejaculate,” and he remarked, “You tell me.” Almost all of the respondents (93%) were aware that they could quit the trial at any time.

**Did the Participants Want Additional Follow-up Information?** Most men (78%) did not feel they needed more information now. Of the participants, 31% responded affirmatively when asked if they would like to talk to another person on the study. Desired discussion topics included “to compare notes,” “to see if this person has noticed any positive or negative effects from being in the program,” “have others had the same experience as me, what have they done about it, and are they continuing on the pill,” and to compare clinical experiences, such as “thinning hair line and sexual problems,” “does he have to go to the bathroom once or twice during the night?” and “what is his PSA (prostate-specific antigen) reading?” Large percentages wanted to learn the results of the PCPT trial (96%) and of this survey (80%).

**Discussion**

This study is among the first to examine the informed consent process among participants in a cancer prevention trial. Our data reflect perceptions of participants in a long-term clinical trial well after study enrollment, which are likely to differ from perceptions at the time of enrollment. The study is limited by its small sample from a single community and by the fact that responses over-represent perspectives of older participants. We encourage other research in larger and varied populations, especially groups that may have distinct cultural values and attitudes regarding informed consent (13, 14).

The findings strongly suggest that many participants did not recall either the informed consent process or the consent form that they had signed 2 years earlier despite their high educational and health status. These findings mirror what has been found in cancer patient populations. It is heartening that almost every participant knew he could stop study participation at any time; although men did not remember the consent process, something was effectively communicated. On the other hand, some sexual side effects that some men found surprising are discussed in the consent form.

Whereas most men recalled little about the consent process, they were nearly uniform in affirming that they had not needed more information before deciding to take part. Factors outside the consent process per se are significant influences on the interest of potential trial participants in studies. In this community, 58% of the men cited brief notices about the study that had been featured prominently in daily newspapers as their source of information about the study. In actuality, the news ads contained very little information. However, they may have provided the men with enough particulars (in their minds) so that the informed consent process was merely a formality or an opportunity to reaffirm their initial decision to participate.

Our results suggest that signing a consent form and discussing the study with members of the research team does not imply that subjects are adequately informed about the study or that they can remember treatment side effects. Although we did
not explicitly ask the men if they retained a copy of the consent form, it is possible and even likely that individuals may mislay their copy over a period of years. The PCPT design includes periodic contact with participants; it may be useful to ask if another copy of the consent form is needed at these contacts. Meetings of trial participants (in person, by telephone, or on the internet) might be considered, because almost one-third of the men in this study indicated interest in this area.

With the implementation of additional, large-scale, long-term prevention studies like the PCPT, where compliance with study procedures is required over a period of years, participants need to be informed about the study, reminded about potential side effects, and given an opportunity to ask questions on an ongoing basis. Even the best consent form and intensive patient counseling at the beginning of the study are inadequate to accomplish this goal, although novel attempts to make the informed consent process more interactive (e.g., use of new technologies such as videodisks; Ref. 15) may result in important information being retained longer. Continued communication also can enhance commitment to the study and ensure that the participants are full partners in the research process.

Acknowledgments
We thank Sarah Bruner, Christopher Chan, Brian Issell, Gilbert Madrid, and James Tom for their assistance.

References