ATTITUDES OF PRIMARY CARE PHYSICIANS TOWARD CANCER-PREVENTION TRIALS: A FOCUS GROUP ANALYSIS

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Purpose: Recruitment of low-income and minority women to cancer-prevention trials requires a joint effort from specialists and primary care providers. We sought to assess primary care providers' attitudes toward participating in cancer-prevention trial recruitment.

Procedures: We conducted a focus group with seven Boston-based primary care providers serving low-income and minority women. Providers discussed knowledge, attitudes, and beliefs regarding their role in recruitment to prevention trials.

Findings: A qualitative analysis of the focus group transcript revealed nine categories. Three categories related specifically to the primary care physician: 1) the dual role physicians play as advocates for both patient and research; 2) threats to maintaining the primary care relationship; and 3) general philosophy toward prevention. An additional six categories could be subdivided as they apply to the primary care physician, the patient, and the community: 4) trust/commitment; 5) benefits of the research; 6) access to the research; 7) knowledge and recall of the research; 8) influences of media coverage about the research; and 9) cultural sensitivity.

Conclusions: Investigators conducting cancer-prevention trials must address the concerns of primary care physicians to optimize recruitment of subjects—especially low-income and minority women—into trials. (*J Natl Med Assoc.* 2001;93:450–457.)

Key words: clinical trials ♦ research design ♦ selection bias ♦ patient selection ♦ minority groups ♦ African Americans ♦ female ♦ human ♦ primary health care

Cancer-prevention trials pose subject-recruitment challenges not faced in cancer-treatment trials. Oncologists conducting cancer-treatment trials are often involved in subjects' care regardless of trial enrollment. This expedites subject recruitment. Cancer-prevention trials, in contrast, seek to

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Table 1. Questions Presented in the Focus Group (Condensed)

1.	What exposure to or experiences with the BCPT have you had?
2.	What issues have you faced in interfacing with clinical trials (e.g., in suggesting that a patient enroll, in counseling a patient seeking advice about whether to enroll, in caring for a patient who has already enrolled)? What barriers do you face? What solutions have you identified?
3.	Do you have experiences with or thoughts about special issues relevant to subject recruitment in the particular case of prevention trials?
4.	Based on things like adverse media coverage, has mistrust of researchers been a consideration for you or your patients?
5.	Do you have insights about why recruitment of older women and minority women into prevention trials has been particularly difficult?
6.	Do you think that efforts to prevent breast cancer are even worth attempting? Are they worth the effort?

enroll high-risk subjects without disease who are not being treated by an oncologist. Such trials require the joint efforts of oncology researchers and primary care providers in the recruitment and retention of subjects.[1] As the number of cancer-prevention trials has risen, there has been little attention to the ways in which investigators and primary care providers can coordinate their efforts to recruit and retain subjects.[2]

We sought to characterize primary care physicians' perceptions of patient-level and physician-level barriers to subject recruitment for cancer-prevention trials. We were particularly interested in recruitment of low-income and minority women, as these groups are frequently under-represented in trials.[3–11] We examined primary care physicians' perspectives in general and then used a specific trial [the Breast Cancer Prevention Trial (BCPT)][12] as a case study to stimulate more specific comments.

METHODS

The goal of this focus group was to characterize perceived barriers to recruiting patients into cancer-prevention trials among a sample of primary care providers serving low-income and minority women.

Recruitment

A convenience sample of primary care physicians practicing in the Boston area was selected to represent diverse physician gender and practice setting (private group practice, academic practice, and urban neighborhood health centers). All subjects cared for primarily low-income and minority patients, many of whom were women. Ten physicians were approached by telephone for possible inclusion; seven physicians participated in the focus group. The study was approved by the Internal Review Board at Boston University Medical Center and informed consent was obtained from all participants.

Data Collection

The focus group was conducted at Boston Medical Center in December 1996, during the accrual period for the BCPT trial. Our conceptual model was that enrollment into a prevention trial requires several preceding steps where the primary care provider serves as intermediary: primary care provider becomes aware of the trial, primary care provider decides to alert the patient about the trial, discussion between provider and patient about the merits of the trial, and decision by the patient to enroll. Drawing upon this conceptual model and upon the literature documenting patient-level[2,13–21] and provider-level[2,17,18,22] barriers to enrollment in trials, the four investigators used a consensus approach to develop six open-ended, predetermined questions (see Table 1) to present in the focus group. These questions addressed: barriers to and facilitators of recruitment to clinical trials; experiences with and attitudes toward the particular case of prevention trials (using BCPT as an example); attitudes of their patients (especially women and minority patients) toward prevention trials; and physicians' attitudes toward prevention in their clinical practice. A physician with training and experience in qualitative research (SMF) facilitated the 1-hr focus group, and two coinvestigators observed in person. The focus group session was audiotaped and a verbatim transcript was produced.

Qualitative Analysis

Four reviewers (the authors), each with a background in women's health research and familiar with the BCPT, independently reviewed the transcript of the focus group for content and identified

Table 2. Examples of Quotations For Categories Relating to the Physician Only

1. Dual role that the primary care physician plays as both advocate for the patient and for research
   - "We have a role advocating for studies that we think are good studies."
   - "We are undermining our own credibility as a primary care providers. We are advocates. Sometimes you feel like you are pushing too hard and starting to transition across the other side."
   - "I think that I start to lose a little relationship, if I start to be perceived as a part of this establishment. . .. They say, 'Wait a minute. Who are you working for? Where is your allegiance? To me? Or is it that you just want to sign me up for a research study?'"
   - "It is an ethical dilemma and I am crossing the line. But I know that it is different for some patients when I say,'No, no, no! Trust me, I know these folks. They. . .are well meaning and this is how this is really going to help you.'"
   - "You are willing to spend some of your capital that you have worked hard to collect with your patient to say 'Trust me' and overcome these barriers and go for it."
2. Threats to maintaining the primary care relationship
   - "We need to find that the study is minimally undercutting the primary care relationship, meaning that as much as can be done right there in the community, in the health centers, is better."
   - ". . .whenever you start sending people to other places things happen. The trouble is that ties break down."
   - "She's missed her last two appointments with me, but she's getting 500 bucks from you [the investigator] and she is making all your appointments and missing mine."
3. General philosophy towards prevention and chemoprevention strategies
   - ". . .the downside is that negative side effect that can present. . .5 years down the road. I think we are totally against being involved with that, unless it is a drug we have a lot of experience with."
   - "I think that's almost a completely different world in terms of drug studies. Because of the involvement of breast cancer and because the agent that is being used is an agent that is currently used as therapy for cancer patients."
   - "[There is] something very unique and very specific about a trial [for prevention of] cancer with drugs. In essence [this is] a trial of a chemotherapeutic agent in a healthy population."
   - "A primary prevention trial which is geared towards reinforcing a positive lifestyle is one thing, but [it is different] when you are using an active agent, such as a medication, that has a potential downside."

a list of key words and phrases. After this independent analysis, the reviewers met and jointly discussed the combined list of key phrases. From this list the reviewers used a consensus approach to develop a set of common categories into which these key words and phrases fell. Each reviewer then independently re-analyzed the transcripts and matched each key phrase to a category. The reviewers met again and jointly reviewed the lists. Interreviewer discrepancies were discussed. If consensus was not reached regarding the category to which a key phrase was mapped, that key phrase was dropped. From a total of 155 key phrases, 15 were dropped. A final list of categories linked to a set of key phrases and corresponding quotations from the transcript was developed.[23,24]

RESULTS

Four women and three men, six of whom were white and one African American, all trained in internal medicine or family practice, participated in the focus group. Participants practiced in a range of settings: private group practice, academic practice, and urban neighborhood health centers.

The qualitative analyses identified three categories relating specifically to physician-level concerns: 1) the dual role that physicians play as both advocates for patient and for research; 2) threats to maintaining the primary care relationship; and 3) general philosophy toward prevention. Table 2 lists these categories, and operationalizes them by citing examples of quotations from the transcript. Where the transcript included quotations illustrating both affirming and dissenting perspectives within the category, examples of both are provided.[23] Six additional categories emerging from the qualitative analysis had physician-level, patient-level, and community-level elements (see Table 3): 4) trust and commitment; 5) benefits of the research; 6) access to the research; 7) knowledge and recall of the research; 8) influences of media coverage about the research, and 9) cultural sensitivity. Categories 1 to 4 were emphasized by participants, and are discussed further here.

Dual Role

Physicians expressed considerable concern about role conflict. They found it difficult to encourage

Table 3. Examples of Quotations for Categories Relating to the Physician, Patient, and Community

4) Trust and commitment

Physician:

- ". . . maybe this study isn't all it's cracked up to be or maybe there are certain technical problems or even possible ethical problems involved."
- "What am I going to do? They made a choice that she fit that trial—they don't need our permission."
- "She's missed her last two appointments with me, but she's getting 500 bucks from you [the investigator] and she is making all your appointments and missing mine."
- "But I know that it is different for some patients when I say, 'No, no, no! Trust me, I know these folks. They. . .are well meaning and this is how this is really going to help you.'"
- "You are willing to spend some of your capital that you have worked hard to collect with your patient to say 'Trust me' and overcome these barriers and go for it."

Patient:

- "Or is it the idea of negative connotations caused from [being a] sequential guinea pig? That's at least 50% of the population, you know, 'I don't want to be a guinea pig.' Research supposedly. . . is a negative trust point with most patients."
- "African-Americans may feel very distrustful with the research process in many ways. . ."

Community

- ". . .I volunteered. . .for a year and it gave me the capital in the community so that I got some in's with people. . ." [Note: Speaker is a practicing physician who has also conducted research.]
- ". . .it's where the guys come in from the research institutes and it's like a safari. They are in the. . .outback for 2 weeks and they are going to take a lot of pictures and then go back and show their slides. And they are not committed at all. They come and they take."
- ". . .You have that same clout as well because it is not like you are coming in today and gone tomorrow, you have been there for years, you're going to be there for years, people know that, and that really does become worth something."
- "The HIV population is a good example. Where research. . .has been positive. . ."

5) Benefits of the research

Physician:

- ". . .[by participating in the study,] you [the patient] get a nurse, who is a superb nurse, who is ready to look over every detail and get to know you personally and is going to advocate for you and this is a higher standard of care than I can give by myself."

Patient:

- "There is not a lot of risk involved, but there is a lot of good. I feel like [the patients] feel good about themselves. I mean people really enjoy contributing"

Community:

- ". . .even in terms of defining benefit medically we may talk about life survival. But then if you talk to someone in the community that don't think that they'll live past 25 anyway, then you have no grounds to really discuss things; there is no common ground."

6) Access to the research

Physician:

- "If we can do that at the health centers, that's a plus. We can work out things where the patient is as much as possible kept involved in the study; we're helping collect the data. There is a very clear way that we can be involved in it."

Patient

- ". . .going through that tunnel [to get from a minority community to the medical center] is like for some of these people referring to another country."
- ". . .most of whom can't read and write. . .. It is very difficult for them. So there are a lot of barriers to enroll."

Community:

- "The issue is how much the institution is really buying into being a part of that community."
- "One is just logistical issues, in terms of the transportation, sort of taking away from people. . .in the community."

7) Knowledge and recall of the research

Physician:

- ". . .for me it's a matter of having information on the trial. . .something that is relatively easy to hand out to patients. . ."
- ". . .if I have the [trial] information I will go through it in time, but if I don't have the information, I won't."

Table 3. (Continued)

- "The data. . .suggest that after 5 years it is clear that people that have node-positive local disease would have an increased risk of contralateral breast cancer taking tamoxifen for that long." [Note: This is not true.]

Patient:

- "I have routinely spent time with patients trying to educate them on how research is done. . ."

Community:

- ". . .certain cultural groups will not be impressed by the known educational training of the PI's and that type of thing. They are much more impressed if you send [an] agent who will go find out who the key person is in their hierarchy that is formally invited to come to hear about it, to be given information about it."

8) Influences of media coverage about the research

Physician:

- "All I have is some sort of image that something came up [in the media] with this [researcher] doctor. I don't recall what it was."
- "And then something sort of vaguely, I don't know, something negative appeared in the news or media about this."
- ". . .the connection. . .may have sort of made this study, not quite as, something you don't want to get started with."

Patient:

- "[Patients are] bombarded weekly by 'new' information and I try to get across to them that people who do research for a living are invested in advertising the work they do because to them future funding is predicated on not only having good data, but also having people interested in what they are doing."

Community:

- ". . .there is a general distrust in the community, because there is a [belief] that African-Americans are represented inappropriately in the media and thus it taints anything that comes from the media."

9) Cultural sensitivity

Physician:

- " . . .cultural issues, particularly, I am a white male, wearing a white coat. . ."

Patient:

- "one [set of barriers] is just logistical issues, [but there are also the] cultural issues. . ."

Community:

- ". . .that [recruitment] issue came for the community where people said, come to the laundromat on Saturday mornings, and they actually moved their study [there] and it's working."

trial enrollment, while simultaneously acting as the patient's advocate within the health care system. They were concerned that embracing this dual role could erode their relationship with the patient. This was described in terms of "crossing the line," and of "spending trust" earned with the patient. For example:

"Sometimes you feel like you are pushing too hard and are starting to transition across the other side."

"I think that I start to lose a little relationship, if I start to be perceived as a part of this establishment. . . They say, 'Wait a minute. Who are you working for? Where is your allegiance? To me? Or is it that you just want to sign me up for a research study?'"

Despite these concerns, participants who trusted a particular investigator were willing to "spend" some of their trust capital with the patient.

"It is an ethical dilemma and I am crossing the line. But I know that it is different for some patients when I say 'No, no, no! Trust me, I know these folks. They. . . are well meaning and this is how this is really going to help you.'"

"You are willing to spend some of your capital that you have worked hard to collect with your patient to say 'Trust me' and overcome these barriers and go for it."

Threats to the Primary Care Relationship

Physicians reported considerable difficulties in the coordination of primary care with clinical research, especially when caring for poor and underserved populations. Several physicians described this issue as a loss of control over clinical management: "Whenever you start sending people to other places, things happen. The trouble is that ties break down." The threat to a continuous primary care relationship contributed to the mistrust by primary care providers described below.

Philosophy of Prevention

Primary care physicians articulated a strong philosophy of prevention involving lifestyle modification. However, their enthusiasm for prevention did not extend to pharmacologic agents used for preventive purposes. Their reservations were expressed most strongly for cancer medications less familiar to primary care physicians (e.g., tamoxifen taken for prevention rather than for treatment), but also extended to areas such as cardiovascular prevention.

For example:

"[There is] something very unique and very specific about a trial [for prevention of] cancer with drugs. In essence [this is] a trial of a chemotherapeutic agent in a healthy population."

"A primary prevention trial which is geared toward reinforcing a positive lifestyle is one thing, but [it is different] when you are using an active agent, such as a medication, that has a potential downside."

Trust and Commitment

Trust and commitment were prominent themes throughout the focus group discussion. At the individual and community levels, trust issues were expressed in both a positive and negative sense. While "the HIV population is a good example. . . where research. . . has been positive. . . ," patients may alternatively feel like "guinea pig[s]," especially when "the guys come in from the research institutes and it's like a safari. . . . They are in the. . . outback for 2 weeks and they are going to take a lot of pictures and then go back and show their slides. And they are not committed at all. They come and they take."

In addition to perceived distrust of individuals and communities we found that the primary care physicians themselves also expressed personal distrust of the research process. They had concerns that overall research goals may take precedence over the optimal care for the patient. "What am I going to do? They made a choice that she fit the trial, they don't need our permission." "She's missed her last two appointments with me, but she's getting 500 bucks from you [the investigator] and she is making all your appointments and missing mine."

DISCUSSION

We found that trust and commitment were central concerns for primary care doctors considering referral of their patients—especially patients from minority communities—to cancer-prevention trials. It was not surprising that focus group participants felt that their minority patients often mistrusted research. Such distrust has been described previously in minority populations,[2,13–16] and may stem from prior exploitation of minority populations.[13,25] However, the degree to which primary care physicians themselves distrust researchers deserves attention. It appears to be more important than previously recognized for researchers conducting cancer-prevention trials with minority and female subjects to demonstrate their commitment to the community and to win the trust of primary care physicians. Our subjects described incidents where they questioned whether the scientists conducting research had their patients' best interests in mind. Primary care providers in our study considered most trustworthy those researchers who demonstrated an ongoing commitment to the community.

Primary care physicians in our study were also concerned that they might become the targets of their patients' displaced distrust of investigators. Their "dual role"—as patient advocate at an individual level and as champion of research at a population level—was a source of conflict for our physician subjects. Physicians felt that to recruit patients into trials they had to "spend" some of the "trust capital" they had carefully built with their patients and with the minority communities they served. Trust capital spent on a prevention trial cannot then be spent to meet other worthy clinical goals. Primary care providers appeared to be willing to jeopardize the doctor-patient relationship in this way if they themselves trusted the researchers. Again, this points to how important it is for primary care providers to be able to perceive investigators as trustworthy. Role conflict between physician and scientist roles has been described previously,[2] although our subjects articulated the issue particularly well. Commitment and continuity are central to the primary care relationship,[26] and the professional culture of primary care providers values an advocacy role.

Providers had additional concerns about threats to the relationship with their patients. They worried that introducing additional providers (i.e., the physician-researcher) into the equation could lead to problems with coordination of care. In the extreme they felt this might lead patients to abandon continuous care entirely, lured by financial incentives or distracted and over-committed to frequent re-

search appointments. This concern is consistent with the findings of other authors that fear of losing the patient can preclude referral to trials,[2,18] and is likewise consistent with the primary care emphasis on coordination of care.[26]

Primary care providers' philosophy included a strong orientation toward prevention. This is consistent with the fact that preventive care is a major component of primary care.[26] It would be expected that this sentiment would fuel primary care providers' enthusiasm for cancer-prevention trials. However, an important caveat was evident from the focus group comments. Primary care providers were leery of pharmacologic preventive interventions. They saw the risk to benefit ratio as potentially unfavorable when a medication with potential adverse effects was used to prevent a condition that the patient might never acquire. They saw pharmacologic preventive interventions (e.g., tamoxifen to prevent breast cancer) more negatively than nonpharmacologic preventive interventions (e.g., smoking cessation to prevent lung cancer) or pharmacologic therapeutic interventions (e.g., tamoxifen to treat known breast cancer).

Other barriers to physician referral of patients to clinical trials have been described previously. Some physicians have limited access to clinical trials,[18] or experience participation as being too complex.[2,18] Physicians who are potential referral sources may be dissatisfied with the compensation they receive for making the referral,[18] and may experience the time commitment of helping with enrollment and retention as a burden.[17,22] These issues were not raised by our subjects.

Patient-level and community-level barriers to participation identified by our subjects were: trust/commitment, benefits of the research, access to the research, knowledge and recall of the research, influences of media coverage about the research, and cultural sensitivity. These topics have received attention in prior literature.[2,13–21] There are several limitations to this study. First, the study represented a small group of primary care providers from one geographical area. Our findings may not necessarily be generalizable to other communities. However, participating providers care for one of the most racially and ethnically diverse, low-income patient populations in the U.S., the very types of patients who tend to be under-represented in cancer-prevention trials. Thus, their views may be particularly relevant to researchers planning to conduct trials in such communities. The decision to adopt a qualitative research strategy precluded soliciting input from a large number of primary care providers from around the country. However, this qualitative approach was appropriate for our study goal, which was to identify barriers to prevention-trial recruitment; an in-depth, inductive approach like ours is ideal when perspectives not currently recognized in the literature are sought.[27] Second, the perspectives represented in the results are those of the primary care providers, and may not necessarily match those of members of the communities under discussion. However, the existing literature contains more information about the views of minority populations toward research; our study fills an important gap by soliciting the views of their health care providers, who often are a primary source of referral to prevention trials. Third, because this study was also specifically grounded in cancer-prevention trials, our findings cannot necessarily be generalized to other prevention trials. However, the decision to ground the study in a particular type of prevention trial (i.e., cancer-prevention trials) and the decision to include questions focusing on a particular ongoing cancer-prevention trial (i.e., the BCPT[12]), promoted more concrete, less theoretical responses.

In conclusion, cancer-prevention trials pose unique recruitment challenges. Unlike cancer-treatment trials, where eligible subjects are more easily identified (because they attend oncology clinics), cancer-prevention trials must identify healthy but at-risk populations. Such healthy populations may have low motivation to participate in a trial, seeing no major personal benefit to participation. Investigators seeking to recruit cancer-free patients to such trials typically turn to their primary care colleagues as a referral source. Primary care providers are in a position to identify prospective subjects, to supply prospective subjects with information about the trial and, most importantly, to draw upon a longstanding professional relationship with the patient to encourage or discourage the patient's participation. The views of these primary care providers are thus very important to researchers seeking to enroll minority and low-income women, who have been under-represented in such trials to date.[3–11]

Our preliminary findings from this small, hypothesis-generating study suggest that investigators seeking primary care physicians' support must be sensitive to their concerns. In particular, researchers need to exhibit genuine commitment to win the

trust of primary care providers and the patient communities they care for. Researchers also need to be sensitive to the fact that primary care providers who are expected to recruit their patients to trials while at the same time advocating for their patients may experience role conflict. These providers may fear that they will lose their patients' trust so carefully built over the years. Researchers must also take steps to assure that the patient's participation in a trial does not disrupt the continuity relationship with his/her primary care provider. Finally, researchers proposing to dispense pharmacologic preventive agents need to provide ample side-effects data to primary care providers in order to address potential skepticism about the risks of administering such investigational agents.

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