

SPECIAL ARTICLE

Patients' Views on Financial Conflicts of Interest in Research Trials

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ABSTRACT

BACKGROUND

Financial ties between researchers or medical centers and companies whose drugs are being tested have come under increasing scrutiny.

METHODS

We conducted in-person interviews with 253 patients in cancer-research trials (a 93% response rate) at five U.S. medical centers to determine their attitudes regarding potential financial conflicts of interest among researchers and medical centers.

RESULTS

More than 90% of patients expressed little or no worry about financial ties that researchers or institutions might have with drug companies. Most patients said they would have enrolled in the trial even if the drug company had paid the researcher for speaking (82% of those interviewed) or consulting (75%) or if the researcher had received royalty payments (70%) or owned stock in the company (76%). Similarly, most patients would have enrolled in the trial if their cancer center had owned stock in the drug company (77%) or received royalty payments from the company (79%). Most patients believed it was ethical for researchers to receive speaking fees (81%) or consulting fees (82%) from the company. However, a substantial minority of patients wanted disclosure of the oversight system for researchers (40%) and of researchers' financial interests (31%); 17% thought no disclosure to patients was necessary.

CONCLUSIONS

Most patients in cancer-research trials were not worried about financial ties between researchers or medical centers and drug companies and would still have enrolled in the trial if they had known about such financial ties. A substantial minority wanted to be informed about the oversight system to protect against financial conflicts of interest and about researchers' financial interests.

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N Engl J Med 2006;355:xxxx-xxxx.
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FINANCIAL CONFLICTS OF INTEREST IN clinical research are worrisome for at least two important reasons: such conflicts may increase the risk to patients, and they may undermine the scientific integrity of the research. To address this problem, the World Medical Association (in the Declaration of Helsinki), the American Medical Association, the Association of American Medical Colleges, and many commentators have called for full disclosure of financial interests to patients who may enroll in research trials.¹⁻⁶ Advocates argue that disclosure allows patients to assess whether the financial interests might influence their willingness to enroll. Disclosure to patients might also serve to maintain public trust in research and discourage the development of financial ties between researchers or their institutions and drug companies.²⁻⁷

Conversely, critics argue that such disclosure to patients who are being invited to participate in research trials passes the onus of accountability to those who have the least power and the fewest options.⁸⁻¹⁵ In addition, patients are frequently overwhelmed by information in consent documents and may not be well positioned to assess the effect of the disclosed information on their own interests.¹²⁻¹⁷ Finally, disclosure to patients cannot ensure scientific integrity.

Little is known about the views of patients in research trials regarding potential conflicts of interest, the disclosure of such conflicts, and other safeguards. In two previous surveys, both of which had low rates of response, investigators neither interviewed patients nor asked about institutional conflicts of interest.^{18,19} A recent study involving focus groups showed that an interest in and understanding of conflicts of interest were variable; some respondents suggested that if they were "sicker," they might be less concerned about financial conflicts of interest.²⁰ The respondents in these studies were not patients enrolled in research trials; hence, they may not have appreciated the burdens of understanding such information and applying it to actual enrollment decisions.

We interviewed patients in cancer trials on the hypothesis that most patients would be concerned about financial ties between researchers or institutions and drug companies, that they would favor the prohibition of such ties, and that they would want disclosure of any financial interests. We recognized that the views of patients enrolled in cancer trials might differ from those of pa-

tients participating in other types of research studies or those who have declined to participate in research. Nevertheless, cancer trials represent a substantial fraction of all clinical research and have extensive industry involvement. More important, patients with cancer face a serious, life-threatening disease, making them among the most vulnerable to any adverse effects of financial conflicts of interest.

METHODS

STUDY PATIENTS

Between November 2004 and November 2005, interviewers surveyed patients with cancer who were enrolled in clinical trials at the National Cancer Institute in Bethesda, Maryland; the Dana-Farber Cancer Institute in Boston; the Fred Hutchinson Cancer Research Center in Seattle; the University of Colorado Cancer Center in Denver; and the Yale Cancer Center in New Haven, Connecticut. English-speaking patients who were at least 18 years of age were eligible to participate in the study if they were involved in any cycle of a cancer trial; no patient was paid to participate. Of 272 patients who were approached, 253 agreed to be interviewed (a 93% response rate).

SURVEY DESIGN

Researchers from the National Institutes of Health (NIH) and the Research Triangle Institute designed the survey with the use of a five-step process. First, a literature search identified concerns about conflicts of interest, proposals about disclosure policies, and other safeguards. Second, questions from a previous survey were examined.¹⁸ Third, questions were developed about researchers' stock ownership and receipt of speaking fees, consulting fees, and patent royalty payments, as well as institutional stock ownership, per capita payments for patients in research trials, and patent royalty payments. Fourth, questions on proposed safeguards were developed. As a final step, questions were adapted from trust scales developed at Wake Forest University School of Medicine,²¹⁻²⁴ the Wisconsin Brief Pain Questionnaire,²⁵ and the mental health component of the Medical Outcomes Study 36-item Short-Form Health Survey (SF-36).²⁶ Performance status was also assessed according to guidelines of the Eastern Cooperative Oncology Group (ECOG) (with a score of 0 indicating normal performance status, 1 mildly

symptomatic, 2 symptomatic but in bed less than half the day, 3 symptomatic and in bed more than half the day, and 4 in bed the whole day.²⁷ A draft survey instrument was subjected to two rounds of cognitive interviews and, after revisions, behavioral testing to ensure comprehensibility and clarity.

The final instrument contained 45 questions in six domains: awareness of and concern about conflicts of interest, the effect of financial conflicts of interest on study participation, attitudes about policies and practices regarding research conflicts of interest, attitudes about disclosure of conflicts of interest, trust, and sociodemographic and medical characteristics. To determine whether asking about financial ties in the survey increased the concern of patients, the identical questions about concern were repeated at the end of the survey. (The complete survey appears in the Supplementary Appendix, available with the full text of this article at www.nejm.org.)

Because the phrase “conflict of interest” has a negative connotation, interviewers used the descriptive and less judgmental term “financial ties” (e.g., “Do you think the oversight system for regulating the financial ties of [the cancer center] and its researchers . . .”). Similarly, interviewers used descriptive phrases to convey types of financial ties. Patients were told to identify their doctor as “the doctor you see most often when you come to [the cancer center].”

SURVEY ADMINISTRATION

Interviewers, who included nurses and other health care professionals, administered the survey in person. The interviewers had been trained in nondirective interviewing techniques by personnel at the Research Triangle Institute and were not affiliated with the research trials in which the patients were enrolled. Patients were already attending the medical center for another appointment. The mean duration of the interview was 30 minutes (median, 29 minutes). The institutional review board at each participating cancer center approved the protocol, consent document, and survey instrument. All patients gave written informed consent.

STATISTICAL ANALYSIS

The survey results are summarized and presented according to the proportion of patients who had a response to each question. Differences between responses for subgroups, as defined by the characteristics of patients, were calculated by either

Fisher’s exact test or the Kruskal–Wallis test. Odds ratios were estimated, and their 95% confidence intervals calculated.

RESULTS

CHARACTERISTICS OF THE PATIENTS

Of the 253 patients, 56% were men and 92% were white (Table 1). Approximately 25% of the patients were under 50 years of age, 59% were between 50 and 69 years of age, and 16% were 70 years of age or older. The majority of patients had health insurance, had attended college, and had an annual income of \$50,000 or more.

Patients had a variety of cancers; no single diagnosis accounted for more than 12% of patients, and 21% of patients had various types of hematologic cancers. The mean duration of disease was 4 years (median, 2 years). Before enrolling in their cancer study, 35% of patients had not received any chemotherapy, biotherapy, or radiotherapy. Overall, 16% were just starting the trial, 23% had received one cycle of the experimental intervention, 20% had received two or three cycles, and the remaining 41% had received four or more cycles. Most of the patients (57%) had a normal level of physical activity, 30% had minor limitations in activity (an ECOG score of 1 for performance status), and 13% were in bed less than half of the day (an ECOG score of 2). About 25% of the patients had moderate pain or a great deal of pain, but only 5% had depression. About half of the patients had considered treatment options other than the experimental intervention in the current trial, 10% had “slightly considered” other options, and 35% had not considered any other option. More than 96% agreed or strongly agreed that they had complete trust in their doctor and in the cancer center.

CONCERN ABOUT FINANCIAL INTEREST

Only 7% of the patients had heard or read “a lot about financial ties related to clinical studies,” 16% had heard a moderate amount, and 77% had heard little or nothing. Only two patients (<1%) were very worried that the doctor running their study might have “financial ties with the company that makes the drug used in the study,” 17% were somewhat or “a little” worried, and 80% were not worried at all (Table 2). Of the patients who were not worried, 48% had not previously thought about such financial ties, 36% were confident that their

Table 1. Demographic and Clinical Characteristics of Study Patients.*

Characteristic	Patients (N = 253) no. (%)	Characteristic	Patients (N = 253) no. (%)
Sex		Religion	
Male	141 (56)	Protestant	79 (31)
Female	112 (44)	Catholic	80 (32)
Age		Jewish	17 (7)
<50 yr	61 (24)	Other	77 (30)
50–59 yr	82 (32)	Type of cancer	
60–69 yr	66 (26)	Hematologic‡	53 (21)
≥70 yr	41 (16)	Prostate	31 (12)
Race		Breast	30 (12)
White	233 (92)	Lung	21 (8)
Nonwhite	20 (8)	Renal	21 (8)
Education		Other§	96 (38)
High school graduate or less	53 (21)	Number of previous cancer treatments	
Some college	67 (26)	0	89 (35)
College degree	68 (27)	1 or 2	76 (30)
Graduate training	65 (26)	≥3	88 (35)
Annual income†		Phase of current research study	
<\$50,000	75 (30)	1	81 (32)
\$50,000–74,999	42 (17)	2	106 (42)
\$75,000–99,999	45 (18)	3	66 (26)
≥\$100,000	65 (26)		

* Percentages may not total 100 because of rounding.

† A total of 26 patients declined to state their annual income.

‡ Hematologic cancers included both acute and chronic leukemias, non-Hodgkin's lymphoma, multiple myeloma, Hodgkin's disease, and myelodysplastic syndromes.

§ Other cancers included those of the pancreas, ovary, colon, rectum, and brain, as well as melanoma and sarcoma.

doctor or their medical care would not be influenced by such financial ties, and 16% had a variety of other responses. Similarly, only two patients (<1%) were very worried about financial ties between their cancer center and the drug company, 28% were somewhat or “a little” worried, 70% were not at all worried, and 9% had a variety of other responses (Table 2). Of those who were not worried, 49% had not previously thought about such financial ties, 23% thought such ties would not affect their medical care, and 19% reported having trust in the oversight system in place.

FINANCIAL INTERESTS AND RESEARCH PARTICIPATION

Overall, 82% of patients would still have participated in the trial if the researcher had received

speaking fees from the company that made the drug in the trial, and a large majority would still have participated if the researcher had received consulting fees (75%), owned stock (76%), or received royalty payments (70%) (Table 3). Similarly, 77% would have enrolled in the trial if their cancer center had held stock in the company whose drug was being evaluated in their study, 79% would have participated if the institution received patent royalty payments, and 83% would have participated if the institution had received per capita payments for enrolling patients. Less than 15% of patients reported that knowledge of a financial tie would have kept them from participating in the cancer trial. More than a third of the patients (39%) would have participated in the trial despite financial ties because they believed either that

Table 2. Concern about Financial Ties between Researchers or Cancer Centers and Drug Companies.*

Response	Financial Ties of Researcher (N = 253)		Financial Ties of Cancer Center (N = 253)	
	Start of Interview	End of Interview	Start of Interview	End of Interview
	<i>percent of patients</i>			
Very worried	<1	<1	<1	0
Somewhat worried	6	5	7	6
A little worried	11	17	21	21
Not worried at all	80	77	70	72

* To assess whether asking about a range of financial ties might have made the patients more or less worried, interviewers asked patients at the start of the survey and as the last question of the survey before demographic questions: "Sometimes doctors running clinical research studies have financial ties with the company that makes the drug used in the study. How worried, if at all, are you about your doctor at [the cancer center] having these financial ties?" Percentages may not total 100 because of rounding.

they had no alternative or that such participation was the way to be treated by the best oncologist. Another 20% thought the cancer center was overseeing the financial ties, and 13% believed the financial interest would not influence their care (data not shown).

Overall, 64% of patients thought it was acceptable for researchers to own stock in the company whose drug was being evaluated in the trial; a larger majority of the patients thought it was acceptable for researchers to receive consulting fees (82%), speaking fees (81%), and patent royalty payments (70%) (Table 4). Similarly, a majority thought it was acceptable for the cancer center to "own stock in the drug company whose drug is being used" (57%), to accept patent royalty payments (72%), and to receive per capita payments for enrollment in such trials (78%).

SAFEGUARDS AGAINST CONFLICTS OF INTEREST

Of the patients surveyed, 62% believed there was an oversight system in place to monitor financial ties. However, when asked, most could not specify a system but suggested that there "must be a process during study implementation," such as an "independent oversight committee to screen M.D.'s credentials and relationship with drug companies." One third of the patients did not know whether there was such an oversight system.

When asked about the disclosure of financial ties, 31% of the patients thought researchers should be required to tell their patients about

such ties regardless of the monetary value (Table 5). Conversely, 40% thought researchers should tell patients only about the oversight system, and 26% thought disclosure to patients either should not be required or should be required only if the financial ties exceeded a certain amount. Similar results were reported for institutions' financial ties (Table 5).

At the end of the survey, only one patient (<1%) was very worried about financial ties between doctors or cancer centers and drug companies, 5% were somewhat worried, and 93% were a little worried or not worried at all (Table 2).

PREDICTORS OF ATTITUDES AND PREFERENCES

There was no consistent association among such factors as age, sex, race, religion, income, type of cancer, phase of study, or cancer center and a concern about financial interests, a willingness to enroll in research studies with conflicts of interest, or views of what were appropriate financial ties. Only educational level was consistently associated with patients' attitudes. Patients with a higher level of education were significantly more likely to be worried about the cancer center's financial interests in companies whose drugs were under evaluation (12% of those with a high school education, 27% of those who had either attended or graduated from college, and 47% of those who had graduate training; $P < 0.001$). A similar trend was found for researchers' financial ties with drug companies (8% of patients with a high school education were concerned, 17% of those who had either attended or graduated from college, and 31% of those with graduate training; $P = 0.001$). Finally, patients with more education were significantly less likely to find it acceptable that cancer centers would own stock in companies whose drugs were being researched at the institution (67% of those with a high school education, 65% of those who had either attended or graduated from college, and 44% of those with graduate training; $P = 0.008$). There was no significant association between having a higher level of education and having heard or read about financial conflicts of interest (data not shown).

DISCUSSION

In this study, most patients who were enrolled in trials at five cancer centers had few concerns about financial ties between their physicians or their

Table 3. Patients' Views about Effects of Financial Ties between Researchers or Cancer Centers and Drug Companies on Participation in the Current Clinical Trial.

Response	Financial Ties of Researcher (N=253)				Financial Ties of Cancer Center (N=253)		
	Stock	Consulting	Speaking	Patent Royalty	Stock	Per Capita Payments	Patent Royalty
	<i>percent of patients</i>						
Would have no effect on participation	76	75	82	70	77	83	79
Would stop participation	11	12	9	14	12	9	10
Would encourage participation	1	6	4	7	2	3	3
Other*	11	7	6	9	9	5	8

* Other responses included "It depends," "Don't know," and refusals to answer. Percentages may not total 100 because of rounding.

Table 4. Patients' Views on the Types of Financial Ties between Researchers or Cancer Centers and Drug Companies That Should Be Permitted.*

Response	Financial Ties of Researcher (N=253)				Financial Ties of Cancer Center (N=253)		
	Stock	Consulting	Speaking	Patent Royalty	Stock	Per Capita Payments	Patent Royalty
	<i>percent of patients</i>						
Should be permitted	64	82	81	70	57	78	72
Should be permitted within limits	8	5	5	8	9	5	7
Should be absolutely prohibited	27	13	13	23	34	17	21

* Percentages may not total 100 because of rounding.

cancer centers and the companies whose drugs were being tested. A large majority of patients did not view such financial ties as inappropriate, would not have changed their decision to participate in the study even if they had known about the financial ties, and were confident about the existence of an oversight system.

Despite substantial media coverage of financial conflicts of interest during the survey period, more than 75% of patients had not heard or read about such financial ties. Furthermore, most of the patients were not concerned about such potential conflicts. This attitude was not an indication that these patients were naive, unsophisticated, or uneducated. Actually, they were socioeconomically privileged members of American society who should have been knowledgeable regarding financial interests. Only among patients with graduate training were the majority worried about or wanted to prohibit such financial ties.

At least among patients in cancer trials, finan-

cial links between researchers or cancer centers and drug companies were not particularly salient or worrisome. Why not? For these patients with cancer, concerns about health and getting the "best" care seemed to predominate. More than 70% of the patients would still have enrolled in their trial even if they had known about any financial ties. In addition, it is probably psychologically essential for such patients to trust that their doctors and cancer centers would not let financial ties compromise their medical care.

Unlike the findings in previous studies,¹⁸⁻²⁰ our data reflect the views of patients who were actually enrolled in trials. Substantiation of these findings comes from focus groups conducted by senior NIH officials, in which patients who did not have cancer and patient advocates indicated that they were minimally concerned about researchers' financial conflicts of interest. They were more concerned about making progress in curing major diseases and thought collaboration

Table 5. Disclosure of Financial Ties between Researchers or Cancer Centers and Drug Companies.*

Question and Response	Financial Ties of Researcher (N=253)	Financial Ties of Cancer Center (N=253)
	<i>percent of patients</i>	
To whom should the disclosure of financial ties be made?		
Patients in research trials	35	NA
Cancer center administration	19	NA
Independent oversight committee	32	NA
Government agency	3	NA
Persons designated by researcher or cancer center	6	NA
No one	2	NA
Other	2	NA
What should be disclosed to patients?		
No disclosure required	17	16
Disclosure of financial ties if they are above a monetary threshold	9	6
Disclosure of all financial ties, regardless of amount	31	33
Disclosure of the oversight system for monitoring financial ties	40	43
Other	2	1

* Percentages may not total 100 because of rounding. NA denotes that a question was not asked.

between academic researchers and pharmaceutical companies was necessary for making such progress.²⁸

Almost half of the patients in our study did not seriously consider any treatment options other than the experimental therapy in their research trial, and more than 70% reported that disclosure of financial ties would not have changed their decision to participate. For these patients, the desire to receive what they viewed as the best treatment option may have outweighed worries about financial ties. Although 13 to 34% of the patients thought various financial ties should be prohibited, less than 15% would not have enrolled in their trial if they had known about the ties. This discrepancy merits additional exploration, but it suggests that for seriously ill patients, disclosure is unlikely to provide protection against the potential harm of financial interests.

Most patients thought that the common financial ties between researchers or cancer centers and drug companies should be permitted. They

had a more favorable view of researchers' receipt of consulting fees than they did of researchers' ownership of stock. Similarly, institutional receipt of per capita payments was viewed more favorably than was stock ownership. The reasons for these views are unclear, but patients may feel that some types of ties, such as consulting, are necessary to facilitate the conduct of research and to make progress against diseases.^{20,28,29}

There was wide variation in the views of patients about what should be disclosed and to whom. Seventeen percent thought there was no need for any type of disclosure, 9% preferred disclosure of any financial ties over disclosure of a particular monetary value, 40% preferred disclosure of the oversight system, and 31% wanted disclosure of all financial ties. How to handle the minority of patients who want disclosure of all financial interests is challenging.^{8,13-15} Some observers have argued that if 30% of patients in research trials want disclosure, then there should be mandatory disclosure in consent documents. Others argue that disclosure is time-consuming and potentially confusing and worrisome and is of little concern to the majority of patients. A majority of patients believed that an oversight system was in place to monitor and manage potential conflicts of interest, even though most of them could not specify what that system was. The establishment and disclosure of such oversight boards would provide an opportunity to preserve the confidence of patients without the burden of presenting detailed financial information.

Our study had several limitations. First, data from patients who were already enrolled in cancer trials might not be relevant for patients with other illnesses, patients considering participation in such trials, or patients who have refused to participate in research. Second, typical of patients in cancer research trials, the patients in our study tended to be well educated, financially secure, older, and white.³⁰ Their views might not apply to other populations, such as various minority groups, who may be more suspicious of research and financial ties.³¹ However, this hypothesis was not borne out by the patients from minority groups who participated in our study. Furthermore, since more educated people seem to be less tolerant of financial conflicts of interest, the bias in our study should have been toward an overestimation of concern about financial ties, rather than an underestimation of such concern.

Supported by the National Institute of Health's Department of Clinical Bioethics and Evaluation Branch, Division of Evaluation and Systematic Assessments, Office of the Director.

No potential conflict of interest relevant to this article was reported.

The ideas and opinions expressed are the authors' views, and do not represent any official position or policy of the National Institutes of Health, the Public Health Service, or the Department of Health and Human Services.

We thank the investigators and interviewers at the National Cancer Institute, the Dana–Farber Cancer Institute, the Fred Hutchinson Cancer Research Center, the University of Colorado Cancer Center, and the Yale–New Haven Medical Center for their recruitment and interviewing of patients; and Frank Miller and David Wendler for their critical reviews of this article.

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