ORIGINAL ARTICLES

Views of Potential Research Participants on Financial Conflicts of Interest

Barriers and Opportunities for Effective Disclosure

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BACKGROUND: There is little guidance regarding how to disclose researchers' financial interests to potential research participants.

OBJECTIVE: To determine what potential research participants want to know about financial interests, their capacity to understand disclosed information and its implications, and the reactions of potential research participants to a proposed disclosure statement.

DESIGN AND PARTICIPANTS: Sixteen focus groups in 3 cities, including 6 groups of healthy adults, 6 groups of adults with mild chronic illness, 1 group of parents of healthy children, 1 group of parents of children with leukemia or brain tumor, 1 group of adults with heart failure, and 1 group of adults with cancer.

APPROACH: Focus group discussions covered a range of topics including financial relationships in clinical research, whether people should be told about them, and how they should be told. Audio-recordings of focus groups were transcribed, verified, and coded for analysis.

RESULTS: Participants wanted to know about financial interests, whether or not those interests would affect their participation. However, they varied in their desire and ability to understand the nature and implications of financial interests. Whether disclosure was deemed important depended upon the risk of the research. Trust in clinicians was also related to views regarding disclosure. If given the opportunity to ask questions during the consent process, some participants would not have known what to ask; however, after the focus group sessions, participants could identify information they would want to know.

CONCLUSIONS: Financial interests are important to potential research participants, but obstacles to effective disclosure exist.

KEY WORDS: conflict of interest; disclosure; human experimentation.

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Concerns about financial conflicts of interest in clinical research have led professional societies and governmental bodies to issue recommendations for managing conflicts of interest.¹⁻⁷ Many of the guidelines call for disclosure of investigators' or institutions' relevant financial interests to potential research participants. However, there is little guidance regarding precisely how to disclose financial interests to potential research participants, and little is known about the likely ef-

fects such disclosures might have on potential research participants⁸ and the research enterprise as a whole. However, to be effective, policies and practices regarding disclosure must address a number of important issues, including what information potential research participants want to know, the capacity of potential research participants to understand disclosed information and its implications, and the reactions of potential research participants to proposed approaches to disclosure. Therefore, we sought to elicit the perspectives of potential research participants to help inform the development of appropriate guidance on disclosure of financial interests in research.

METHODS

Participants

We conducted 16 focus groups in 3 cities (Durham, NC; New York, NY; and Chicago, IL) between October 2004 and April 2005. Six groups consisted of healthy adults, and 6 groups consisted of adults with mild chronic illness (including arthritis, allergies, and hypertension). In each city, 1 of each of these groups was composed of participants who indicated that they were white, and 1 was composed of participants who indicated that they were a race other than white. The remaining groups were racially mixed but consisted of participants with different disease characteristics, specifically parents of healthy children, parents of children with leukemia or brain tumor, adults with heart failure, and adults with cancer.

A market research firm recruited the healthy adults and the adults with mild chronic illness from a panel of people who agreed to be contacted for participation in focus groups. Physicians at Duke University Medical Center recruited the parents of pediatric patients. Both the market research firm and the physicians recruited adults with heart failure or cancer. Persons who had participated in another focus group within the previous 6 months or were working or had worked for an organization involved in the conduct of clinical trials were excluded from the study. Ten people were recruited for each group with the goal of recruiting 6 to 8 participants per group. Final group sizes ranged from 7 to 10. Table 1 shows the demographic characteristics of the participants.

None of the authors have any conflicts of interest to declare.

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Table 1. Sociodemographic Characteristics of Participants (N=139)

Characteristic	Participants, n (%)
Age	
18–29 y	17 (12)
30–49 y	71 (51)
≥ 50 y	51 (37)
Race/ethnicity	
White	78 (56)
African American	47 (34)
Other	14 (10)
Female sex	80 (58)
Income level	
< \$20,000	12 (9)
\$20,000 to \$49,999	55 (40)
\$50,000 to \$79,999	48 (35)
≥ \$80,000	24 (17)
Education level	
High school diploma or less	23 (17)
Some college/college degree/technical	94 (68)
Some graduate school/graduate degree	22 (16)
Never participated in clinical research	114 (82)

The institutional review boards of the Duke University Health System and the Johns Hopkins Medical Institutions approved this study.

Focus Group Sessions

All participants provided written informed consent and received compensation for their time and effort. One African American woman moderated all of the focus groups. Each session lasted 2 hours and was audiotaped. Members of the study team observed the sessions via 2-way mirrors or teleconference.

Participants were initially asked to describe their experiences with clinical research. They were then asked to explain “medical research” and the role of the principal investigator. The moderator explained the various levels of risk associated with clinical research, illustrating these levels with brief scenarios describing hypothetical research studies (i.e., a focus group, an exercise intervention for heart failure, and bone marrow transplantation for cancer).

Participants were then asked to comment on each of 9 financial relationships that could occur in clinical research: salary support, money received outside of the study, per capita payments covering research costs, finder’s fees restricted to professional uses, unrestricted finder’s fees, patent ownership by the researcher, patent ownership by the university, equity holdings by the researcher, and equity holdings by the university. (For a description of each, see Table W1 [Web link material].) Discussion then concentrated on whether it was important for potential research participants to know about these financial relationships and whether this depended on the level of medical risk, as described by the risk scenarios.

A discussion about disclosure of financial relationships in research ensued. The moderator asked the following questions: Would knowing this information affect your decision to participate? Would it affect the trust you had in the researcher? What effect do you think these financial relationships could have on a researcher? What level of detail would you want to know about these relationships? When do you want to be informed about these relationships? Would you need help understanding the potential consequences of the relationships?

The participants in most focus group sessions were then asked for their reactions to a sample disclosure statement, which included elements proposed by the Association of American Medical Colleges (AAMC)^{9,10} and the National Human Research Protections Advisory Commission (NHRPAC)⁷:

I have been informed that [a member of the study team] has a personal financial interest in [the sponsor company or other interested entity]. I have also been informed that the nature of this financial interest and the design of the study have been reviewed by the Conflict of Interest Oversight Committee, and that this Committee has determined that the investigator’s financial interest would not compromise the quality or reliability of the study. Furthermore, the Institutional Review Board has determined that the investigator’s financial interest will not adversely affect the subject’s welfare.

The discussion format was essentially the same across focus group sessions, but was modified somewhat over the course of the study to ensure comprehensive coverage of relevant information.

Data Analysis

Audiotapes of the focus group sessions were transcribed verbatim and verified for accuracy. We developed an initial set of content codes based on the interview script. The researchers summarized and dual-coded the transcripts and reconciled coding discrepancies. They added codes and refined the coding dictionary during the coding process. Another researcher reviewed the summaries and content codes, identifying the main themes discussed in the focus group sessions. Other members of the research team independently verified these themes.

RESULTS

Several domains of interest emerged during the analysis: motivations for conducting medical research, awareness of financial interests, understanding financial interests, understanding implications of financial interests, desire to know about financial interests, and what people want to know. We discuss these in turn, and then discuss participants’ reactions to the generic disclosure statement.

Motivations for Conducting Medical Research

When asked why medical research is conducted, almost all groups responded initially by citing a desire to improve people’s health or gain new scientific knowledge. Some participants volunteered that researchers might benefit financially or acquire prestige, promotion, and fame by conducting medical research. After the moderator introduced the idea that researchers might benefit financially or in terms of prestige, no participant disagreed that these motivations could be present.

Awareness of Financial Interests

Many participants reported that they did not know about or had not thought about investigators’ financial interests in research before the focus group session. Several participants who had been (or whose children had been) involved in clinical research expressed surprise about the existence of such financial interests. One participant explained this finding in terms of the trust that many people have in medical institu-

tions: "No, I just don't think I've really ever thought about it, because I think that when you're talking about big major medical centers you think that—you know what?—they believe in this. They think it's going to help patients. They are vested in it for the patient's sake."

Participants' awareness of the potential for financial conflicts of interest in research were influenced somewhat by concurrent news media's coverage of how financial interests of pharmaceutical companies might compromise patient safety. Indeed, in 10 groups, at least 1 participant made reference to recent media attention to drug safety such as rofecoxib (Vioxx)¹¹ and fenfluramine and dexfenfluramine (Fen-Phen).¹²

Understanding Financial Interests

Substantial work was needed to educate participants to a level at which they might form and express opinions about financial interests in clinical research. These efforts, however, were not always successful. For almost all of the groups, presenting a simple description (e.g., "researcher owns equity") was not sufficient to convey the nature of the financial interest. Especially difficult to understand were patent rights, equity, and various types of finder's fees, but some participants also had difficulty understanding salary support and money received outside of the study.

Implications of Financial Interests

There was a broad range of attitudes regarding potential implications of financial interests in clinical research. Some participants were quite naïve, while others were more savvy, such as this participant:

[O]bviously a patent is worthless if what you have it on doesn't work. So you've got a clear conflict of interest there. The researcher is going to have a very natural desire for the results to come out a certain way, I would think. It would seem to me that you would want separate entities or persons to be doing the actual research, just to keep it objective.

In contrast to the views expressed in much of the literature on financial interests in research, several participants felt that a greater financial interest would make the investigator do a better job. As 1 participant understood it, this would translate into more ethical conduct:

I think it's probably a pretty good idea, because if they get paid they'll be a little more ethical about what they're doing. . . . Yes, they'd be on track with what they're supposed to be doing. . . . What I'm saying is that they're getting paid enough to do the work. . . . That will keep them from just going through the motion, I would say. . . . [I]f you know that you have the money, you won't cut corners or try to do it the easy way instead of doing it the way it should be done.

Desire to Know About Financial Interests

Participants varied in their desire to know about financial interests and their reasons for wanting or not wanting to know (see Table W2 [Web link material]). Among those who wanted to know about financial interests, some indicated that such information would affect their decision about participating in research. Others said they would want to know about financial interests, even though it would not affect their participation. The justifications given by such respondents were often vague,

but seemed to make reference to a general desire to have the information available for consideration.

Many participants who expressed a desire to know about financial interests said that a disclosure would lead them to trust the researcher or physician more. They would appreciate the physician being "up front" with them, and they would interpret a disclosure as an indication of the integrity of the study or researcher. Several participants noted that they would be upset if they later found out about an undisclosed financial interest. Implicit in many comments was the notion that the researcher who discloses a financial interest will be more likely to conduct the study in an ethical fashion.

Some participants did not want to know about financial interests, some because they felt such information would not affect their decision about participating in a research study. These participants tended to be more concerned about how the research might affect their health. Other participants did not think financial interests needed to be disclosed because they already assumed that financial interests are involved. Especially in the context of other concerns about one's health, financial information seemed trivial.

In several groups, participants who did not want to know about financial interests seemed to assume that "ignorance is bliss." That is, these participants acknowledged that there might be something upsetting to them about the financial interest, but they would rather not know. Some participants' comments reflected a tension between wanting information that might be pertinent and wanting to preserve the image, if not the reality, of the trustworthy physician or researcher.

Risk and the Desire to Know

An important consideration for many participants in deciding whether they wanted to know about financial interests was the level of risk involved. Risk could be associated with the type of study (e.g., focus group research compared with a bone marrow transplantation study) or with the severity of the person's illness. Some participants remarked that they would require more information about the study, including financial interests, as the study procedures became more invasive. Other participants thought that the severity of their illness would affect their desire to know. In particular, some felt that if they were extremely ill and desperate for a cure, they would not care about financial interests:

Participant: With [a focus group study] and [an exercise intervention], I'd have the luxury of time to consider all of this. If I am [a participant in a bone marrow transplantation study], I'm probably vulnerable and probably not going to consider this. Moderator: So if you're vulnerable, does that mean I need to make sure you know about it? Participant: As long as there is someone else out there looking out for it, on [the focus group study] and [the exercise intervention] I can protect my own interests. [For the bone marrow transplantation study], my judgment might be clouded. A million other things might be going on. But there still need to be global systems in place to ensure that what's being done to me is being done in my best interest and in the best interest of society.

The group composed of parents of children with leukemia or brain tumors was particularly vocal about knowing about financial interests in clinical research. In contrast to the other groups, the discussion in this group was emotionally charged:

And it seems to me, with this kind of thing, there ought to be disclosure. I've never even thought of these kinds of scenarios until you brought them up here this evening, and it's opened my eyes to the possibilities of things that can be going on that we have no idea of. We've got little folks with lives on the line, and I think we deserve and ought to know.

What People Want to Know

When asked to indicate what information they would want to know, most groups mentioned a description of the financial interest and the name of the sponsor. Regarding the magnitude of the financial interest, there was great variability across the groups. Some participants felt the amount of money would be important to know, whereas others felt they would not want to know the amount. Of those who did not want to know the amount, some indicated that they did not need to know because they believed that the same risk applied to the financial relationship regardless of the amount. Many participants felt that no specific dollar amount should be specified, because the value of any given amount of money depended a great deal on the person with the interest and on the person assessing the value.

Given that many participants had trouble identifying the potential implications of some financial interests, participants were asked whether they would want help understanding the potential consequences of financial interests in clinical research. Some clearly did want help and others clearly did not.

Reactions to a Generic Disclosure Statement

When presented with a generic disclosure statement (see Methods section), participants reacted in a number of ways. Many wanted to know more details. Participants differed, however, in whether they thought additional details should be included in the disclosure statement itself or in a separate document or pamphlet, or whether it sufficed to provide an opportunity to ask questions.

While many participants did not have difficulty with the reference to administrative oversight (e.g., the institutional review board), some did have concerns:

Participant: I would be wondering what the Institutional Review Board is. They're the ones that have the belief that it wouldn't affect my safety, and I would really want to know who those people are.

Participants in several groups found the generic disclosure acceptable, even though they had earlier said they would need more information disclosed than was provided in the generic disclosure. To understand this better, the focus group discussion guide was modified for the later groups to encourage the moderator to explore such inconsistencies when they arose. When presented with the inconsistency in preferences that were articulated, members of 1 group in turn responded that the opportunity to ask questions would satisfy their need for additional details. Importantly, however, members of this group indicated that, before their participation in the focus group, they would not have known enough about the funding of clinical research to know what questions to ask. For another group, once the moderator pointed out that the participants apparently accepted a generic disclosure statement that did not contain the information they earlier identified as important, these participants changed their minds to declare the

disclosure insufficient. Their proposed remedy was to include additional information.

DISCUSSION

Consistent with previous work involving an internet survey,⁸ we found that many participants want to know about financial interests in research, whether or not they report that such knowledge would affect their decision to participate. However, we documented great variability in participants' desire and aptitude to understand the nature and implications of financial interests in clinical research. Many participants had difficulty understanding why financial interests might be troubling in clinical research. For example, contrary to most commentators on conflict of interest, some participants felt that financial interests would help investigators conduct ethical research. Furthermore, many participants had difficulty appreciating how financial interests might actually affect research participants or the quality of the science. This suggests that some people may not have the baseline understanding necessary to judge the risks posed by financial interests, calling into question whether simple disclosure to prospective research participants is an effective strategy, standing alone, for managing conflicts of interest in research.

One frequently discussed approach to disclosure is to describe a core of basic information and give the potential research participant an opportunity to ask questions.^{7,13} Presumably, this approach would satisfy differing needs for information without appreciably lengthening the consent process and document. This approach assumes that people know whether they should be concerned about financial interests at the time of consent and that they will know what questions to ask to learn more about the details and implications of such financial interests. However, we found that many participants' thoughts regarding conflicts of interest and their disclosure evolved over the course of the focus groups. It was clear that if some of these people had engaged in a consent process without the experience of the focus groups, they would not have viewed a core disclosure of financial interest as important enough to ask more questions and would not have known what questions to ask. This presents a challenge for developing strategies to manage financial conflicts of interests in clinical research. Furthermore, the observation that people's thoughts regarding financial interests evolved as a result of discussion and education raises an interesting question: What is the responsibility of the research community to educate those being recruited for clinical research and the general public about the conduct and funding of clinical research?

Our findings also shed light on the complex and variable role of risk in potential research participants' perceptions of financial interests. Many participants felt that disclosure of financial interests was more important for riskier or more invasive studies than for less risky ones. At the same time, several participants expressed that if they were very ill, financial interests would not play a role in their decision as compared with information about possible medical benefits. Complicating matters further, when participants' health was at stake, they suggested that they might not be in a good position to evaluate risks that might arise as a result of a financial interest. An important insight from these findings is that

when risks are high and/or the clinical situation is dire, a person might be less able to evaluate the risks posed by a financial disclosure, even though they generally believe that such risks are important to consider.

We also found interesting and paradoxical findings regarding the role of potential research participants' trust in researchers and clinicians. Some participants expressed the view that disclosure of financial interests was important in preserving trust in doctors or researchers. For these participants, it would violate their trust to learn about a financial interest that had not been disclosed. On the other hand, a minority of participants appeared motivated to preserve the image of the trusted clinician or researcher. They indicated that they would be upset by information about financial interests, and so would rather not be told about them. This finding suggests that some participants would choose to deny or selectively not attend to disclosed financial interests. Still others wanted to know this information because they considered it relevant to deciding whether to participate, presumably because it might affect their trust. Additional work is clearly needed to better understand the role of trust in decision making about participation in clinical research.

Despite these important insights, our findings should be interpreted with several limitations in mind. First, although the use of a single moderator promoted consistency in how the sessions were conducted, it is possible that different data might have emerged with another moderator. Second, there are methodological complexities in asking about people's preferences for information and how they would use that information to make a decision. The focus on this single factor in a complex calculus, and the implicit assumption that rational decision making is expected, may have led some participants to overstate how much information they would want about financial interests. Also, people may make decisions differently from how they report that they will make them. Third, our sample in aggregate was more educated than the U.S. population average. Fourth, our study did not allow a comparison of the views of those with and without previous clinical trial experience.

In conclusion, if the goal of disclosing financial interests is to allow the research subject to assess the risk of harm, either to self or to science, our data present several cautions. Consistent with research about informed consent and consumer disclosure practices in other medical and nonmedical arenas,^{13,14} there are high barriers to achieving the goals of rational decision-making models. For example, to formulate properly their thoughts about financial interests in clinical research, some people will need considerable time, reflection, and assistance during the informed consent process. Nevertheless, even after such assistance, some will not understand the potential implications of financial interests and might even see them as mitigating the risks associated with participating in clinical research. Furthermore, some people will not be in a position to ask questions about financial interests even if given the chance. Finally, some people might avoid or deny information about their doctor or the clinical investigator that compromises the image of the trustworthy physician.

This does not necessarily mean, however, that disclosures should not be made. Many focus group participants thought this information was important to know, even though they could not articulate or understand very well what difference it

might make. In at least 1 model of informed consent,¹⁵ information can be "material" information even though it does not affect a person's decision. Also supporting disclosure is the suggestion from our data that disclosures would increase some people's trust in clinicians, investigators, and research institutions.

On balance, those charged with protecting research participants should consider what might be a realistic goal of disclosing to potential research participants. Our data suggest that allowing potential research participants to weigh the risks of financial interests might not be as realistic a goal as the more general goal of honoring patients' right to know and avoiding harms to trust if they learn of undisclosed incentives at a later time.¹⁶

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Supplementary Material

The following supplementary material is available for this article online at www.blackwell-synergy.com

Table W1. Types of Financial Interest Discussed in the Focus Groups.

Table W2. Justifications Regarding Desire to Know or Not Know About Financial Interests in Clinical Research.