

How Should Doctors Disclose Conflicts of Interest to Patients?

A Focus Group Investigation

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Disclosure is often proposed as a strategy for handling financial conflicts of interest in medicine. Yet there has been no guidance on *how* clinicians should disclose potential conflicts of interest to patients. To discern patients' attitudes toward conflicts of interest in medicine and their opinions about how physicians should disclose possible conflicts in the clinical setting, we conducted six focus groups with patients recruited from three clinics in the Twin Cities area. Investigators reviewed audio recordings of the focus group discussions independently and identified themes. Maintaining patient-doctor trust was critical to all study participants. Most wanted to know only about conflicts of interest that were directly relevant to their care. In addition, most participants said physicians and other health care providers should offer patients an easy-to-read document about any conflict of interest during clinic check-ins and bring up the subject when discussing specific treatment plans for which the conflict of interest is relevant. Our study offers the first insights into patient attitudes toward and opinions about disclosure practices in clinical settings. More research into the practical aspects of managing conflicts of interest is needed as ineffective disclosure may undermine patients' trust in their doctors.

A great deal of attention recently has been paid to the effect of financial conflicts of interest in clinical research and practice. Scholars and practitioners have grappled with issues ranging from the ghost-writing of scientific papers to the receipt of branded ink pens. And they have questioned what patients and/or clinical research subjects should know about their doctors' relationships with drug companies and industry.^{1,2} A 2009 Institute of Medicine (IOM) report, which

offered a comprehensive review of the central issues, pointed out that conflict of interest matters not only because it may influence or affect patient care but also because it may alter biomedical research and erode the public's trust in physicians and the health care system.³

Disclosure has often been seen as a key strategy for mitigating the negative impact of conflicts of interest. The basic idea is that if physicians or researchers are transparent about potential conflicts of interest, stakeholders (peers, students, journals, patients and potential research subjects) should be able to make more sound, au-

tonomous decisions about moving forward with care, research or related activities.⁴ But physicians do not fully understand how to disclose information well. Consequently, patients and research subjects may lack the knowledge and perspective they need to assess a situation or seek care from another physician if they have concerns.^{3,5} In addition, some research suggests that disclosure produces misunderstanding and unnecessary anxiety.⁶ Nevertheless, withholding information about possible

conflicts of interest can be interpreted as being morally wrong,⁴ and evidence shows that patients and potential research subjects prefer that information about conflicts of interest be disclosed.⁷⁻¹⁰

Policymakers have tried to address conflict of interest in both the research and clinical setting. The Food and Drug Administration and the Public Health Service each have disclosure policies. In 2010, Congress passed the Physician Payments Sunshine Act, which requires manufacturers of drugs and medical devices to disclose payments made to physicians and teaching hospitals. Professional associations are similarly engaged. The Association of American Medical Colleges issued a comprehensive report in 2010 urging teaching hospitals to establish policies to manage financial relationships between physicians and industry to ensure that those relationships do not adversely affect patient care.¹¹ The authors noted, "... the research suggests that the research participant and the patient are interested in being informed of financial interests, which is consistent with the patient's right to know as a value."

Although an increasing number of institutions now have disclosure policies for those providing clinical care, there is no consensus on how to disclose conflicts of interest. In the context of clinical research, disclosure often occurs during the informed-consent process, especially after patients' misconceptions about therapies have been addressed.¹² However, much else about how to disclose conflicts of interest to patients remains unknown. Should the clinician send a letter explaining his or her potential conflict of interest? If so, should the letter be sent before or after a clinical visit? Should the discussion take place during the clinical visit? If so, when and where? Should a clinic post conflicts of interest on its website?

Answering such questions is critical for those who develop policies and practices for their institutions. It is also critical for

physicians who need to comply with those policies without needlessly alarming patients. Importantly, ineffective disclosure of conflict of interest in clinical settings may undermine the very trust patients have in their physicians.

The Study

We set out to take a first step toward understanding how patients want to learn about their physicians' conflicts of interest with the underlying goal of informing the development of optimal disclosure policies and practices. This study was motivated by difficult discussions regarding disclosure requirements in an academic health center.

Methodology

Following Weinfurt and colleagues' early work on conflict of interest in research settings,⁸ we used focus groups to gather our data. Focus groups capitalize on group dynamics so that researchers can quickly collect data on emerging or complex phenomena.¹³ This approach often serves as a prelude to, if not a springboard for, more systematic study.

In an effort to gather information from a diverse pool of patients, participants were recruited from three of the academic health center's clinics (orthopedic surgery, cardiology and dentistry). We worked with clinic administrators who had the front-desk staff hand out recruitment flyers to visiting patients. Those who were interested contacted the researchers directly. The only exclusion criteria was being younger than 18 years of age. Recruitment from the cardiology clinic proved difficult, as most of the patients were quite ill and unable to participate. As a result, we oversampled from the orthopedic surgery and dentistry clinics.

Recruitment materials indicated that the study was about conflict of interest in medicine. The ultimate purpose of the study was not revealed until after each focus group concluded. This was done to minimize the potential for bias in the selection of subjects or their responses. Participants were asked what they thought the study was about before the start of each

focus group session. No one mentioned disclosure procedures.

Over a nine-week period, a total of six focus groups were held on campus. Healthy snacks and beverages, free parking and a \$40 gift card were offered to each participant. Five out of the six focus groups were led by the same facilitator. Both focus-group leaders had years of experience with the methodology. All meetings were recorded. Recordings were independently reviewed by three of the study's investigators.

Participants were asked these questions: 1) What is a conflict of interest and when does a doctor have one? 2) Have you ever been notified by a doctor that he or she has a conflict of interest? 3) If your doctor has a conflict of interest, how would you like to be notified? Before the focus groups began, participants were asked to provide demographic information. The response rate was 100%, with no missing data.

This study was approved by our university's institutional review board for the protection of human research subjects, and informed consent was obtained prior to data collection.

Thirty-one persons participated (18, 10 and three from the orthopedic surgery, dentistry and cardiology clinics, respectively). The mean age of participants was 55 years; the youngest was 20, the oldest was 80. Twenty-six percent were male. The participants overwhelmingly self-identified as white (race/ethnicity), and 65% indicated they had completed college. It appeared the participants were quite diverse in background and world view. For example, both a college student and a self-identified new immigrant participated. One participant reported having had a long career in medical technology and another self-identified as a lawyer. There was variation in the degree to which focus group participants had interfaced with the health care system, but most had considerable experience with it.



Although there was variation of opinion within focus groups, there was little variation in collective opinion across focus groups. In other words, major themes were consistent across the focus groups.

Findings

At the start, many of the participants stated they knew what a conflict of interest was; but our assessment was that only two had a deep understanding of the issues—the lawyer and the medical technology professional. Three participants stated they had been told by a physician about a conflict of interest; those disclosures had been made in person and in an orthopedic setting. The disclosures were described as uneventful and not having had an impact on the care provided or the patient-provider relationship.

The focus group participants did not dwell on conflict of interest disclosure requirements. But during the discussions, one participant said she was certain that a federal law required physicians to disclose any and all conflicts of interest (an incorrect belief that was corrected after the group ended). In terms of clinic requirements, the participant went on to state, *“I am absolutely sure that [my doctor’s] practice already requires disclosure ... the doctor would not want his professional judgment tainted ... [the disclosure] is already out there.”*

A few participants expressed concern about the topic itself. Their feeling was that physicians and other health care providers always acted in the patient’s best interest. It seemed they could not imagine how a conflict of interest might affect patient care. When discussing the issue, one participant stated, *“I don’t want to talk down to my doctor ... or degrade his profession.”* Another said, *“I work under the assumption*

that every physician that takes care of you is doing the best they can.”

And another participant said, *“Just because [my doctor] does well [financially] does not entitle me to know.”* Further, several participants thought having a doctor with a financial interest in a new technology was a good thing because it indicated the physician was on the cutting edge of medicine.

On the other hand, most expressed cynical views about the link between conflict of interest and physician behavior. When the focus group leader pushed the issue of whether or not disclosure demeans a physician, one participant responded: *“No, it’s all about money now.”* There was almost complete agreement with this statement and similar ones across the focus groups.

The issue of trust was critical to all participants. One said, *“If I trust the doctor, the conflict is not a big deal.”* There was near unanimous agreement that when clinicians did not voluntarily disclose a conflict of interest when one existed, they put their relationships with patients in jeopardy. When discussing the issue of not disclosing a potential conflict of interest, one participant stated that even if the doctor was his long-time physician, he would wonder, *“What else didn’t he tell me?”*

With respect to disclosure procedures, participants’ opinions varied. In fact, one participant—a new immigrant to the United States—did not want his physician to be forced to disclose a conflict of interest at all because he feared the doctor might then not provide optimal care. None of the participants thought clinics should post their doctors’ conflicts of interest on clinic websites or on placards or signs. They did not think such communications were effective, and most thought they would confuse patients. One participant stated, *“I’m not going on the website if I am sick.”* Another said that a sign would be viewed as an advertisement.

Only a few of the participants liked the idea of receiving a letter at home regarding

a conflict of interest. Several agreed with the sentiment expressed by one participant who said, *“I hate stuff coming in the mail.”* Further, there was substantial discussion about whether such a letter should be sent before or after a clinical visit. And there was discussion about what should be included in such a letter. Ultimately, the idea of a mailed letter was not well-received.

Most participants, though, did think that conflict-of-interest disclosures should include a paper document. The idea was to provide the document disclosing the relevant conflict of interest during check-in. Most participants thought disclosure forms should be delivered like HIPAA forms and previsit screening surveys. Desk staff would hand out the disclosure form and be prepared to answer basic questions. One reason participants preferred a paper disclosure was because of the stress of clinic visits. Although participants generally felt empowered to ask questions during a clinic visit, they wanted a document they could examine afterward. One participant said: *“I want a piece of paper that I can see ... so I can ask the doctor if I have questions.”*

All focus group participants wanted the information presented in a simple-to-read format, perhaps using bullet points. A key point was that the disclosure form should list contact information for persons with knowledge of the issues so that patients could follow up if they wished. As is done on informed consent forms used in clinical research, listing an “out of study” contact such as a conflict of interest regulatory director was viewed as being necessary.

By far, the opinion most frequently expressed was that a physician should disclose a potential conflict of interest to a patient during any office visit specifically focused on a treatment for which the disclosure is relevant. This approach was viewed as acceptable even to those who

preferred other methods. Participants expressed a desire to hear their physician describe and explain any and all relevant conflicts.

The primary concern with verbal disclosure was that discussion about conflict of interest would distract from patient care and/or use up valuable visit time. None of the participants wanted their physician to waste time or be distracted from clinical care if the conflict of interest was not directly relevant to a specific aspect of their treatment (eg, a particular device or pharmaceutical). One participant summarized the point with the rhetorical question: “*What does your conflict have to do with me?*” Still, the vast majority of participants seemed to agree with the sentiment in the following quote: “*The extra few minutes to convey [a conflict of interest] is so worth it ... it’s much more human and ensures trust.*” Despite consensus that disclosures ought to be made in person, several participants worried about the implications of instituting systemwide policies. The following quote illustrates their concern: “*If your doctor is taking 45 minutes to discuss his stock portfolio, then the cost of health care is going to go up.*”

Conclusions and Recommendations

Conflicts of interest in health care may not necessarily be a bad thing. Entrepreneurial clinician-scientists need to break new ground and develop life-enhancing therapies and care models. The concern is to maintain both the patient’s and the public’s trust in clinical care and research.

Disclosure is often considered the paramount strategy for ensuring that trust is maintained. Previous studies have established the importance of disclosure in clinical research and practice; but until now the practical aspects of how to disclose conflicts of interest have not been empirically addressed. This study aimed to start the dialogue on disclosure procedures in the clinical setting.

Although participants’ understanding of the issues and recommendations varied, they universally stressed the importance of having trust in their doctor and in having a strong doctor-patient relationship.

The following are the two specific recommendations that emerged from our research on *how* disclosures should be made:

1) Give patients an up-to-date, easy-to-read paper document about the conflict of interest; 2) When discussing specific treatment plans for which a conflict is relevant (eg, a drug or device), take the time to discuss the conflict with the patient and offer an assessment of alternatives.

Legal and institutional concerns may need to override patient preferences as an organization develops its conflict of interest disclosure policy and practices. But in an era of patient-centered care, it seems appropriate to consider how patients prefer to learn about conflicts of interest, especially if an underlying intent of disclosure is to assist patients in making informed decisions about their care.

This research should be viewed as preliminary, if not a foundation for more rigorous future studies. Obvious limitations include its small sample size and the fact that participants were recruited from just three clinics in one academic health center. Clearly, more research into the practical aspects of conflict of interest management is needed as ineffective disclosure can negatively affect patient care and the patient-clinician relationship. **MM**

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