Session 18. Conflict of Interest

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Overview

Conflicts of interest arise when financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity. Conflicts of interest can surface at both an individual and institutional level, and are recognized in various disciplines such as law, medicine, journalism, academia, business, and government. In medicine, however, conflicts of interest can be particularly troubling, as they may have a direct effect on the health and well-being of patients.

In the past decade, thanks in large part to media coverage and investigative reporting, physician and researcher collaboration with the pharmaceutical and biotechnology industries has become one of the most well-known areas associated with significant potential for conflicts of interest. Real concern exists regarding physicians, researchers, and medical institutions who stand to gain financially from the development and use of industry-promoted medications and medical devices. In fact, a major study (Campbell et al, 2007) found that more than 90% of physicians have some sort of relationship with the pharmaceutical industry. Such conflicts may cloud professional judgment and jeopardize the integrity of scientific research, the quality of patient care, and the public's overall trust in medicine. Fortunately, increased awareness has also led to a dramatic increase in federal, state, and institutional oversight of the interactions between physicians/researchers and the pharmaceutical industry in recent years.

This module will review the key ethical concepts and issues related to conflict of interest by way of specific case scenarios. It will also address ways for preventing and avoiding problematic situations whereby physicians may be faced with compromising their professional and moral responsibilities.

Instructor's Guide

- Case Summary
- Alternative Cases
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Case Summary

Dr Liu is a pediatrician at the academic hospital's outpatient pediatrics clinic. Recently, 2 representatives from RD Pharma, a pharmaceutical company that develops and markets asthma medications for children, arrived at the office and asked if they can provide a catered lunch next week for the entire office staff. They also asked Dr Liu if he would be willing to speak at an upcoming medical conference sponsored by the pharmaceutical company. Before they depart, the representatives leave dozens of samples for a new asthma medication on the front office desk.

- Is it appropriate for Dr Liu to accept a "free lunch" from the pharmaceutical representatives? Does it make a difference whether or not he personally attends the lunch?
- Should Dr Liu offer the free samples of the inhalers to patients? Does it make a difference if patients who cannot otherwise afford the medication can benefit from the samples?
- Is it problematic for Dr Liu to accept a speaking engagement at a medical conference sponsored by the pharmaceutical company? Does it make a difference whether or not the company pays for his travel and accommodations?

Alternative Cases

1. Dr Smith is a physician researcher at a medical university. For the past 5 years, she has been investigating a new drug that targets a specific gene mutation implicated in the development of cystic fibrosis (CF). Although housed within the medical school, Dr Smith's laboratory receives considerable funding from CFx, a local pharmaceutical company that concentrates on novel treatments for CF. Several members from the laboratory and university happen to own some stock in CF. The university has entered into an agreement in which it is entitled to 10% of royalties from any future sales if the drug is manufactured. CFx has recently asked Dr Smith and her laboratory to enter into a nondisclosure agreement, whereby the company would be able to protect its proprietary interests and review any research manuscripts prior to submission for publication. As a new trial is commencing, Dr Smith is looking into how to best recruit patients for the study.
    - What types of conflicts of interest can you identify in this case?
    - What are the implications of the nondisclosure agreement for academic freedom?
    - Does it matter that Dr Smith and/or her staff have equity in the company?
    - Would it make a difference if someone else (without any financial stake in CFx) was responsible for clinical trial recruitment?
    - What is expected of Dr Smith and her colleagues in terms of disclosing any financial relationship they have with CFx when presenting at conferences, publishing papers, etc?

2. Dr Hernandez is a pediatrician with a busy outpatient practice. Recently, he received a letter from a contract research organization mentioning a current client company that has a new attention-deficit/hyperactivity disorder (ADHD) drug in phase III randomized controlled trials and is looking for physicians who can recruit patients to participate in a 2-year trial. They ask Dr Hernandez whether he would be willing to recruit up to 20 patients, and they offer him $2000 for each patient he enrolls in the study. All medical care received by participants in the study would be paid for by the pharmaceutical company. Dr Hernandez is puzzled as to what he should do. He believes there is a role for this new and promising ADHD medication in his practice, but wonders about the specifics of this agreement.
    - Does is make a difference that Dr Hernandez has no financial interest in the company?
    - Is it appropriate to recruit patients for whom he thinks the drug can be helpful with the knowledge that he receives a capitation fee per patient he enrolls?
    - Should there be a distinction between using the $2000 for personal uses versus investing this money in the group practice (buying medical equipment, hiring more staff, etc)?
    - Is there a role for accepting this agreement based on the premise that he might be actually be better equipped at handling any conflicts of interest than the next physician to be approached by the company?
    - Under what conditions, if at all, should Dr Hernandez agree to be a clinician-researcher for the pharmaceutical company testing its new ADHD drug?

Learning Objectives

1. Define conflict of interest in the context of health care.
2. Highlight the importance of identifying conflicts of interest.
3. Define and describe specific types and levels of conflicts of interest.
4. Articulate the underlying ethical principles associated with conflicts of interest.
5. Discuss strategies for managing and reducing conflicts of interest.

Suggested Reading for Instructor

American Academy of Pediatrics. AAP Policy on Conflict of Interest and Relationships with Industry and Other Organizations. Available at: https://www.aap.org/en-us/about-the-aap/aap-leadership/Documents/20-IndustryRelations.pdf. Accessed March 7, 2017

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Further Reading

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Case Discussion

What exactly is a conflict of interest?

Simply put, a conflict of interest is any situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity. The Institute of Medicine[1] defines conflict of interest as "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest." Primary interests include "promoting and protecting the integrity of research, the welfare of patients, and the quality of medical education," and secondary interests include "not only financial gain, but also the desire for professional advancement, recognition for personal achievement, and favors to friends and family or to students and colleagues."

What types of conflicts of interests are identified in this case?

There are several tangible, financial conflicts of interest depicted in this case. The pharmaceutical reps are offering numerous items of monetary value, including lunch, medication samples, travel/accommodation expenses, and possible speaking honoraria. There is also potentially a less tangible conflict of interest in the form of prestige or name recognition associated with speaking at a medical conference.

Why do conflicts of interest in health care matter?

Scientific research and clinical care demand integrity, objectivity, and public trust. Researchers and clinicians with secondary interests (ie, financial gain, professional promotion), however, may be unduly influenced and biased in their professional assessments of and interactions with patients. Although physicians may not think they are personally influenced by external factors, research has shown that physicians are in fact more prone to act differently (ie, change their prescribing patterns) in situations of competing interests. One large study[2], for example, found that physicians who occasionally accepted industry-sponsored meals were 2 to 3 times more likely to ask that the sponsor's drug be placed on a hospital's formulary. The study further found that physicians who accepted a free trip to a drug-company-sponsored conference were also more likely to write prescriptions of the sponsoring company's drugs. Overall, physicians who interact more frequently with the pharmaceutical industry are more likely to prescribe higher cost drugs and less likely to recommend generics or over-the-counter medications.[3]

Should medical centers permit open access to industry representatives?

Although the pharmaceutical and medical device industries are critical to scientific discovery and the delivery of patient care, industry representatives were historically permitted unrestricted access to academic medical centers, community hospitals, and private physician offices. It is not uncommon for such representatives to provide meals and various monetary gifts (ranging in value from pens to event tickets) in the hopes of influencing provider behavior. It has been estimated that the pharmaceutical industry spends around $15,000 per physician in direct marketing.[4] In working to create an environment based purely on evidence- based care and free of undue influence or bias, however, more and more academic medical centers across the country have instituted policies either banning, limiting, or regulating industry

access to physicians, residents, and students. It is often best to consult with your specific institution's policies governing if and what type of industry access is permitted.

Is it appropriate for physicians to accept and dispense free samples?

"Free" samples account for more than 60% of the $29 billion spent each year by the pharmaceutical industry to promote its products (Institute of Medicine). Several studies have shown that physicians given "free" samples to dispense to their patients are more likely to then write prescriptions for what are often more expensive – although not necessarily more effective – drugs compared with physicians without access to free samples. It is critical that prescribing physicians rely on evidence-based medicine and safe practice rather than on what is simply available and "free." At the same time, it is important to take into account any financial hardships of patients who may not otherwise be able to afford certain medications. It is also important to distinguish between what may be time-limited vs ongoing receipt of such samples. Physicians employed by a practice or institution should always refer to their institutional policy before deciding whether to accept and dispense "free" samples.

What about accepting other gifts?

Gifts may include items as small as pens and pads and as large as vacations and meals at luxury venues. Per the American Medical Association, "No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices."[5] In accordance with the Physician Payment Sunshine Act, adopted in 2010 and implemented in 2014 as part of the Affordable Care Act, medical device and pharmaceutical companies are now required to report all payments and gifts (in excess of $10) given to physicians and teaching hospitals. These data are also publicly available on a searchable federal database. Many academic medical centers now have policies that either limit or ban the acceptance of gifts of monetary value. It is the responsibility of each physician to comply with their institution's most updated policy and always keep in mind the mandate of the American College of Physicians "to assess any potential relationship with industry to assure that it enhances patient care and medical knowledge and does not compromise clinical judgment."[1] Additionally, although some physicians may be comfortable in accepting gifts of modest value in certain settings, it is nevertheless prudent to be mindful of the *perception* of conflict of interest this may entail.

What if a physician is invited to speak at an industry-sponsored medical conference?

Expert physicians play a vital role in contributing to the education of their peers and the general public. Payments for speakers and faculty at certain accredited continuing medical education (CME) events, however, may be exempt from mandatory reporting under the Sunshine Act. It is, therefore, important for speakers to explicitly disclose any financial ties they may have with a company before presenting the relevant data. It is also not uncommon for industry-sponsored events to control the content of educational modules or provide invited lecturers with prescripted presentations or slides. Physicians presenting at such events ought to carefully review the prepared materials beforehand and modify them accordingly to ensure utmost objectivity. At the very least, physician presenters must disclose the source and authorship of any materials to the audience.

What other types of conflict of interest might physicians confront in the clinical setting?
In the current health care landscape, it is routinely becoming more common—in large part because of changing payment structures—for physicians to own or have some form of business arrangements with outpatient diagnostic or treatment centers and/or specialty hospitals to which they refer patients (eg, a gastroenterologist who owns outpatient endoscopy center, a radiologist who partners with an imaging suite). This sort of partnership constitutes a potential conflict of interest. The secondary interest of physician owners (ie, increased income from increased referrals) certainly has the potential to interfere with what ought to be the primary interest of physicians (ie, patient welfare). Given the allure of increased profitability, patients may inadvertently be subject to unnecessary or extraneous procedures. Such concerns about physician self-referral have led to federal regulations ("Stark Laws"), which prohibit physicians from referring Medicare or Medicaid patients to entities for "designated health services" if the physicians or their immediate family members have ownership, investment interests, or compensation arrangements with the entities. In 2008, the Centers for Medicare and Medicaid Services issued a new rule, which requires physicians to disclose to patients any ownership of or investment in hospitals they may have.[1] As with all potential conflicts of interest, full disclosure to all parties involved is always warranted.

Conclusions and Suggestions

Conflict of interest is a very real and serious issue in health care. These conflicts can sometimes be subtle and affect even the most vigilant and well-intentioned physician. Every doctor in training should, therefore, be proactive in identifying potential sources of conflict interest and become adept in reducing or at least managing actual conflicts. Conflicts of interest overwhelmingly surface at the interplay between physicians and the health care industries. Although such collaboration cannot always be avoided—and may, in fact, be appropriate in particular settings—best practice always calls for clearly disclosing any possible conflicts of interest (financial and otherwise) to all parties involved. It is also essential that the clinician be aware that these relationships have the potential to alter their prescribing behavior in ways that may not be apparent to them. Resident physicians should consult with their institution's particular policies regarding what constitutes, and how best to manage, conflicts of interest.

References

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4. Chimonas S, Brennan TA, Rothman DJ. Physicians and drug representatives: exploring the dynamics of the relationship. *J Gen Intern Med*. 2007;22(2):184-190

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