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"Can You Handle the Truth?"

Conflict of Interest as a Disease

By Norman M. Goldfarb

Ethical misconduct is relatively likely to occur when a person has a conflict of interest. A conflict of interest exists when a person has a motive to advance his or her own interests at the expense of someone for whom the person has a role of responsibility. For example, if a study sponsor pays the investigator bonuses to enroll study subjects, the investigator may coerce a patient to enroll in the study in order to earn the bonuses. Financial conflicts of interest are relatively easy to measure because there is money involved. However, their effect in specific circumstances is much more difficult to determine – did the investigator coerce the patient for the money, or because he or she truly believed it was the right thing for the patient? The investigator may not even know his or her motives. Further complicating the analysis is that, even without the enrollment bonus, the investigator in this scenario benefits financially from the enrollment through other study fees. Unfortunately, eliminating all compensation or making compensation independent of performance is impractical. Further, the problematic conflict of interest may relate to career advancement, publication, reputation, time savings, or one of many other non-financial benefits.

Eliminating all conflicts of interest is impossible. We can police some of them, but they are an unavoidable fact of life. We can also educate people to be aware of their own conflicts and how to deal with them ethically. Just because a conflict of interest exists does not mean it will cause improper behavior.

One way to understand conflicts of interest is to look them as ethical diseases, with related pathologies, treatments and public health considerations. Just as there are many different medical diseases, there are many different conflicts of interest. Some are more serious than others. Diseases affect different people differently: some people are immune, while others experience mild to severe symptoms. Different people can display different symptoms for the same disease. They can be contagious to differing degrees.

For example, a study sponsor might offer an enrollment bonus to an investigator. The infectious agent may be mild (e.g., \$50) or virulent (e.g., \$5,000). The investigator may be immune because he or she has a very low level of financial motivation or can make more money by not enrolling patients. Or, the investigator may need the money desperately to pay off loan sharks. Once the investigator is infected with a conflict of interest, his or her ethical immune system may cause him or her to exhibit mild symptoms, such as offering patients sample drugs, or severe symptoms, such as lying to patients about the risks of the study. The investigator may be infected, but asymptomatic, because a nurse coordinator handles most interactions with potential subjects.

Once infected, the investigator may infect others. For example, he or she may offer a share of the bonuses to the nurse coordinator. He or she may tell other physicians about the opportunity. People exposed to the investigator may be susceptible, or they may be immune because they were vaccinated by a previous experience. Education may have strengthened their ethical immune systems. They may have access to an ethics professional who can counsel them on how to protect their ethical health. An institution may get a reputation for flexible ethics, thereby generating more dubious offers from study sponsors.

In public health, a population has "herd immunity" when most, but not necessarily all, of its members are immune to a disease. In this circumstance, the chance of an infected person making contact with a susceptible person is very low, so transmission of the disease is

uncommon. Similarly, if most people at a hospital have high ethical standards, an ethically infected investigator will soon recognize the disadvantages of telling colleagues about the advantages of his or her ethical disease. In contrast, if many members of a population are susceptible to a disease, an epidemic can quickly spread. If some members of the population are susceptible to one disease and other members to another, herd immunity still applies. In other words, as long as most members of a group are immune to each specific ethical disease, a relatively large number can be susceptible to some ethical disease without causing an ethical epidemic. However, to the extent that the diseases weaken the basic immune system, they increase the population's susceptibility. For example, trivial gifts from pharmaceutical companies may not, in and of themselves, create meaningful conflicts of interest, but they can make larger conflicts seem more acceptable.

Public Health Measures

Government officials can take numerous measures to protect the public's health, such as:

- Identify infected individuals, e.g., with rapid identification and notification systems.
- Isolate infected individuals so they cannot infect others, e.g., in hospital rooms.
- Cure infected individuals so they cannot infect others, e.g., with pharmaceuticals.
- Identify and deal with sources of the contagion outside the population, e.g., with travel warnings.
- Immunize as many people as possible, e.g., through vaccination programs.
- Improve public health in general (e.g., through nutrition and education programs), so people are less susceptible in general.
- Develop and implement effective standards of care, e.g., for treating polio.
- Increase the number of trained healthcare professionals, e.g., doctors and nurses.
- Prioritize the use of public health resources to address the most serious, common and treatable diseases, e.g., influenza.

Similarly, institutional officials can take numerous measures to protect their employees' ethical health, such as:

- Identify infected individuals, e.g., by auditing informed consent processes and surveying study subjects.
- Isolate infected individuals so they cannot infect others, e.g., outside of clinical research.
- Cure infected individuals so they cannot infect others, e.g., with education and perhaps disciplinary action.
- Identify and deal with sources of the contagion outside the population, e.g., by communicating with compliance professionals in other organizations.
- Immunize as many people as possible, e.g., through training programs.
- Improve public health in general (e.g., by publishing ethical guidelines), so people are less susceptible in general.
- Develop and implement effective standards of care, e.g., for reporting and investigating ethical incidents.
- Increase the number of trained ethical healthcare professionals, e.g., regulatory specialists.
- Prioritize the use of public ethical health resources to address the most serious, common and treatable ethical diseases, e.g., financial and political.

Conclusion

A public health approach to managing public ethical health can leverage proven methodologies for developing programs, allocating resources, and measuring progress. Most healthcare institutions have access to public health professionals. Many are familiar with the concepts. Most importantly, most healthcare professionals understand that public health is everyone's responsibility.

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