EVALUATIONS OF AI APPLICATIONS IN HEALTHCARE

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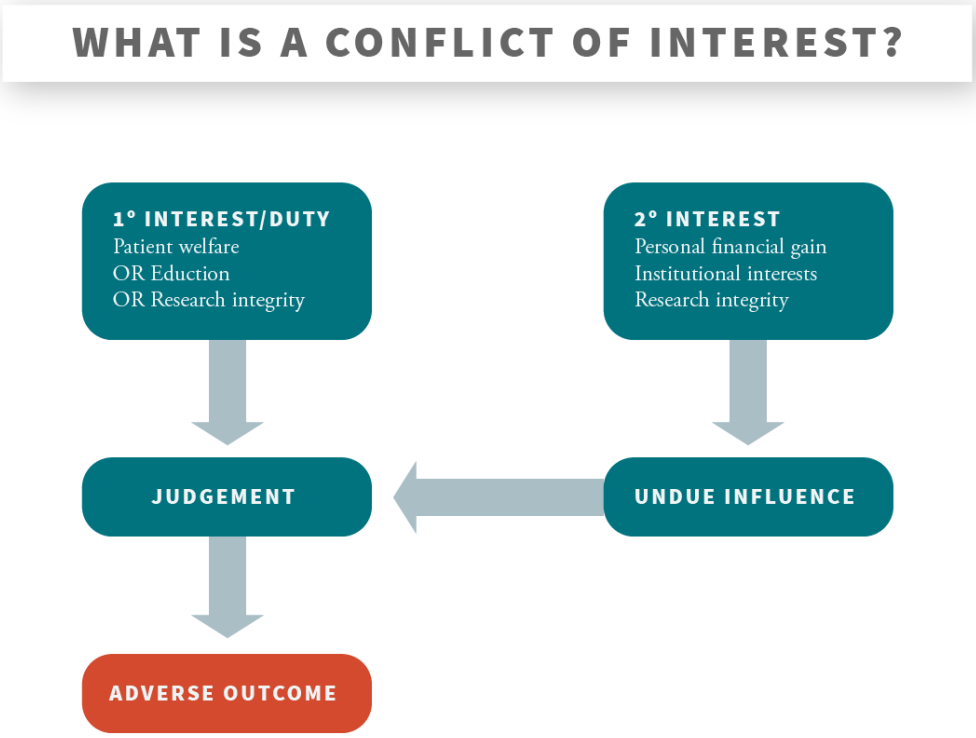
BEST ETHICAL PRACTICES – IDENTIFYING CONFLICTS OF INTEREST

In this section, I want to talk about best ethical practices that address the issue of conflicts of interest. In medicine and biomedical research, we deal with conflicts of interest all the time, and have developed ways of mitigating their negative effects. So, how is that done, and how can we apply those strategies to the development and deployment of AI in health care settings?

First, what is a **conflict of interest**? For our purposes, they exist only when there is a primary interest that is a duty. An example of a primary interest is the clinician's or hospital's duty to care for their patients. However, we all have multiple interests, some of which can compete or conflict with these interests. These other interests are called secondary interests, and can include, for example personal or institutional financial interests, duties to others such as people who are not the clinician's or hospital's own patients, or reputational interests, either positive or negative.



So, why are these secondary interests a problem? In the health care setting, the problem arises because in the course of carrying out duties, many decisions have to be made on behalf of patients, and decisions are often based on individual judgement. And judgement can be influenced by all of these secondary interests, in such a way as to subvert from the primary duty and cause harm to patients.

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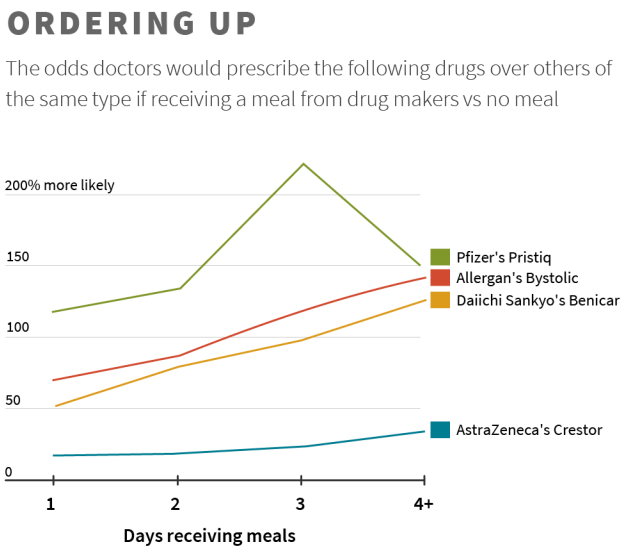
An example of this in clinical care is the influence of pharmaceutical sales representatives who try to persuade doctors to use their drugs instead of the competitor's drugs, when in some cases the competitor's drug might be better for the patient. Influence might be exerted in the form of financial incentives or gifts. These secondary interests have been linked to significant changes to prescribing practices, so they have real effects.

Although physicians think it is impossible to be influenced by accepting a slice of pizza paid for by a pharmaceutical company, there is a study demonstrating that prescriptions can be more than doubled specifically for drugs sold by the providers of meals over other similar drugs, with increases in prescribing seen even after just one meal and rising with every additional day of meals provided. So, part of the problem is that these secondary interests have effects without our being aware of them.

In biomedical research, secondary interests can also include financial factors such as the promise of obtaining research grants or consulting fees from sponsors, or stock or royalties from companies whose products are being studied. Secondary interests can also be reputational or ideological, for example, a strong desire to gain fame or promote a specific hypothesis. In the case of research, the primary interest is usually the integrity of the research, although for research involving human subjects, the health and welfare of individual research participants is also of high priority. But what are the possible



Source: DeJong C, Aguilar T, Tseng C, Lin GA, Boscardin WJ, Dudley RA. Pharmaceutical Industry–Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries. *JAMA Intern Med.* 2016;176(8)

negative effects of influences of secondary interests?

Again, let's look at all the **decisions** that are made in the course of research that could be subverted away from serving the primary interest of the integrity of the research. One is the **formulation of the research question**. Is the question in service of corporate interests or meeting a real patient need? For example, is a clinical trial designed to test a drug in order to serve patients who have no other therapeutic options, or a reformulation of an existing drug that will extend patent protection and a company's market position?

Another way that secondary influences can have effects is through creating unconscious bias, leading to inaccurate **measures of treatment effects**. We know that, in general, systematic error tends to inflate effect sizes. Clinical researchers have long recognized this, and therefore use techniques such as randomization and blinding to reduce bias, or systematic error. Choosing to use such techniques represent design decisions. Other important design decisions that could be influenced by secondary interests are what populations and data you choose to study, and **how you choose to analyze, report or share data and findings**.

Ways to Mitigate Conflicts of Interest:

Disclosure	• Publicizing the secondary interest
Mediation	• Putting financial (secondary) interest in blind trust • Putting some decisions about the primary interest in the hands of an independent body
Recusal	• Removing financial (secondary) interest or replacing the person with the primary interest

So, what do we do to mitigate potential effects of conflicts of interest? We can focus mitigation strategies on protecting the primary interest, eliminating or reducing the secondary interest, or both. The most common strategy, which you have probably employed or been asked to employ, is disclosure, which entails making public your secondary interests, such as disclosing speaking fees or research sponsorships from companies whose products are related to the primary interests. Although it is the most common strategy, it is also the weakest because it does nothing to reduce or remove the secondary interest, but relies on those to whom the interest is disclosed to understand the implications of the disclosure and act in some way to counteract possible negative effects. Other strategies that are more robust involve mediation of the primary or secondary interest, such as placing a financial interest in a blind trust, or having an independent oversight committee such as a

Data Safety Monitoring Board in place to oversee or make important decisions, essentially taking them out of the control of the person who has the conflict of interests. The strongest strategies are recusal from secondary interests, such as selling one's stock, or even recusal from the primary interests, such as replacing an investigator with another person who does not have conflicting interests.