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Our Conflicted Views on Conflict of Interest in Healthcare

By Chuck Dinerstein — May 15, 2017

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“Patients have long been aware that many unseen dollars drive medical decisions and events.”

Introduction

Since the first time exchange of a chicken for medical care, there have been conflicts of interest, real or imagined, between “self-interest" and "altruism.” Recently JAMA devoted an entire issue [2] to conflicts of interest (COI) in healthcare, within the healthcare community as well as for physicians facing outward, towards our patients.

Before summarizing those outward facing articles [1], consider the underlying problem of the dilemma between patient and doctor.

The patient, the person with a need, employs another person, the physician, with more expertise or ability to fulfill their need. But a dilemma is inherent because of the needs of the patient and the actions of the doctor, and this can be categorized as “self-interest and altruism.” How is that conflict of interest resolved? Primarily by trust. In the marketplace, reputation - trust - and the concept of fiduciary obligation resolve those concerns. Fiduciaries are required, by law, to place the interests of the principal above their own. In medical care, the ethical standards of professionalism also guide physician obligations to their patients.

The origins of self-interest

A minority of doctors receive direct payments that can influence or manipulate care. There is

usually no smoking gun. But physicians, through their choices of procedures and prescribing, influence health care spending. The typical primary care physician will provide care for perhaps two thousand distinct patients in a year. And each patient generates about $5,000 dollars in healthcare expenditures. [2] Yes, that is about $10 million that primary care physicians direct spending for in networks, even if they are not recipients. It is within the strands of these networks that COI can arise.

Fee for service (FFS), payments to physicians for providing a particular service remains the primary source of physician payment. It is easy to see how *increasing the volume* of services will increase doctor's income. Surgeons and other physicians performing procedures clearly can be more subject to this dilemma, especially when two methods are equally efficacious but one pays better. The choice of using [3] one eye drop over another for age-related macular degeneration represented an aggregate income difference of $1.5 million versus $62.3 million to physician prescribers. [3] But surgeons and other 'proceduralists' are not the only physicians faced with this dilemma. For physicians providing long-term care for chronically ill patients, increased frequency of follow-up visits and 'intensity' of service enhances their income.

The most common alternative to FFS is capitation, a methodology going back to the push for Health Maintenance Organizations (HMOs) in the 1980's. Providers receive a set fee irrespective of how many services are provided. More services actually result in less profitability. The COI for health systems using capitation instead involves identifying and caring for patients who need *less service* - choosing well rather than ill patients. Pre-existing conditions are a risk. A more updated form of capitation, that spreads the risk across health systems rather than a doctor, is called *gainsharing*. In this model, physicians and health systems join to provide care for a set payment and the savings are shared. Bundled care and medical homes use this financial model, sharing savings and losses. But ultimately, there can still be the same COI, because less expensive care, medications or devices enhance profitability.

Gainsharing does account for the outcomes of the care, poor quality at any price is not rewarded; equal quality at low prices is rewarded. But no matter how you slice it, these business models address economic inefficiencies in a manner reminiscent of eliminating inefficiencies in any factory. Gain sharing creates highly efficient factory operations.

Seeking solutions

> *"Medical care involves significant uncertainty and heterogeneity in treatment efficacy, and patients also vary in their needs and preferences. These complexities make it difficult or impossible to identify specific cases in which payments influence decisions which both increases the potential for COI to occur and makes it impossible to address the problem with remedies such as the threat of malpractice suits for unwarranted procedures."*

A multiplicity of factors make medical care difficult to research. It is hard to create randomization when multiple factors change simultaneously. Care choices may involve different risks. PSA and

mammography are two great examples where the ‘cost’ of surveillance to find cancers has the unintended consequence in those patients found to have false positives, elevated PSAs or ‘changes’ on mammograms resulting in more, with hindsight, unnecessary biopsies. More importantly, medical care cannot be measured just in dollars. What about the emotional ‘cost’ to these patients from increased anxiety and concern?

The routine disclaimer on mammograms that ‘dense breast tissue makes finding areas of concern more difficult' is a perfect example. Often these unintended consequences are difficult to quantify even though we know that they place an increased burden on patients.

Let me be clear, overwhelmingly physicians act responsibly about COI. There are few examples of gross disregard for these issues; doctors work in the best interest of their patients, it is a hallmark of their professionalism. But our increasing understanding of behavior has shown unconscious bias in our decisions. The most frequently cited example, and the one driving concern around physician’s COI is receiving a gift – most often in the form of a meal. There is a large body of literature that shows that getting a gift confers an unstated, unconscious favoring of the gift giver. Makes sense, I am always happy to get a gift, aren’t you?

There are any number of studies that suggest that physicians having been ‘detailed’ by a drug representative, and given a free lunch, is more inclined to prescribe their drug. But these studies are difficult to interpret because we have little information on the physician’s prescribing behavior before the lunch, and is a different cognitive bias, the availability bias, where you are more inclined to remember a recent event than a distant event, actually driving the prescription rather than the Subway sandwich and Coke?

Few people would disagree that giving a doctor a dinner in return for listening to a product explanation at night is better than omnipresent direct-to-consumer advertising like we have now.

Two additional circumstances affect patient’s perception of physician’s COI. First, there is a disconnect between ‘my’ doctor and ‘doctors’ – between the familiar and the faceless. In general, I am not fond of lawyers as a group, but I love my attorney and my friends who happen to be attorneys. And to be honest, some days I have the same feelings about physicians. Second, when patients need physician expertise, they are often not in a position to concern themselves with issues like COI.

> *“…healthy patients and patients with acute illness or chronic disease are likely to think very differently about medical conflicts of interest. When people get sick, all they really want is to get well again, and even the enlightened 21st-century patient undoubtedly cares much less and how that happens than that it happens at all.”*

Disclosure is the solution

In the marketplace, the simplest means to counteract conflicts of interest is to disclose them. Once I am aware of your bias I can take it into account in making my decision to follow your advice, etc. But “research on disclosure of conflict of interest shows that transparency confers benefits, it

seldom mitigates and in some situations exacerbates problems caused by conflicts."

That's because we have been taught by media that money is the only conflict of interest. If you are an environmentalist and work on a government environmental panel, you do not have to declare a conflict of interest. If you have consulted for industry, however, you are assumed to have a COI. Clearly neither may have a conflict of interest, or both could, but the environmentalist is free from disclosure rules.

Therefore the simple belief is that personal and institutional financial interests should be disclosed to the patient. The 2010 Physician Sunshine law requires all vendors to report to the government any payments to physicians - meals, speaking fees, royalties, grants, etc. You can find that information here [4] or perhaps in a more accessible form here [5]. But how often these sources of sunshine used by patients rather than the media? And when patients do consider this information, how can they separate the signal from the noise? After all, what is a 'significant' financial gift? Lunch, a $2,000 grant for research, a million dollar royalty payment? When faced with the plethora of information these sites provide increasing information may be mistaken for noise and discarded, leaving little information to signal COI.

With the increasing employment of physicians by groups or healthcare systems fee-for-service, COIs diminish – these physicians have employment contracts that stipulate how they are paid and increasingly impact physician payment and subsequent COI. Employment contracts formalize gainsharing and may also reward productivity and outcomes. Oddly, you do not hear the need to disclose these payment arrangements with anywhere near the frequency of the calls for physician information.

Another suggestion is that patients "should be educated" about how to discuss the risks and benefits of physician compensation with their doctors. There are a few problems here, not the least of which is that the onus in determining trust now lies solely with the patient – a new version of 'let the buyer beware.' But the payment system for physicians and healthcare systems is a difficult system to comprehend. "Up to 57% [of patients] do not know how to interpret additional sunshine information from practices."

Another problem with the patient trying to inform themselves is the effect on their relationship with the physician. If I disclose my financial interest when I say I am a surgeon and get paid more to operate, what is the patient to do? Should they punish my honesty by choosing another physician? Or do they feel even more pressure to accept my recommendations to 'signal trust' in my professionalism? If the goal of disclosure is to increase trust and prevent COI, are the effects of disclosure helpful?

Reputation - trust - is a frequent alternative to ‘buyer beware’ but reputation is partially driven by professional societies in their credentialing/branding of competency. Being a Fellow of the American College of Surgeons has reputational credence and comes with ethical obligations. But to what degree do professional societies monitor COI instead of relying on the legal system to identify fraud? And to what extent do professional organizations hold their members accountable? There is a conflict of interest here, professional societies are supported by dues, and fewer members reduces money.

Practice Guidelines – a special case

In the growing effort to standardize and provide the best quality care for patients, professional societies and regulatory agencies develop practice guidelines - statements on the consensus of experts for standards of care, an important exercise and role. But practice guidelines, like all medicine, are collections of judgments, subjective judgments. Many of the media’s health headlines come from the latest practice guidelines. Much of the confusion among patients about what to eat, how to behave or when to be checked originate from the changing practice guidelines. Evidence-based medicine is great, except the evidence keeps changing.

Practice guidelines are based on evidence found in literature reviews, either specific articles or meta-analysis reviews. Often the evidence is inadequate It is necessary to demonstrate causality linking evidence and recommendations. But many studies placed into evidence are at best associations, rarely causal and often statistical findings unable to explain the ‘causal’ relationship. Strong recommendations are based on weak evidence. Finally, even when harm and benefit can be identified and quantified, they are measured in differing ways. For example, carotid endarterectomy, where we remove blockages in the artery supplying the brain with blood to prevent a stroke is associated with an unintended perioperative stroke rate of 2-3%. But stroke is all encompassing, numbness in your thumb and a complete inability to use your arm are both strokes. In the end, guidelines for all their attempts at objectivity remained biased judgment.

One conflict of guideline panels is their composition, the experts.While experts have the knowledge, they are most frequently the physicians that receive grants, speaker and consultation fees or that make a living from the procedures the guidelines are addressing – therefore the most susceptible to our beliefs about COI. Guidelines are expensive to develop, where is the source of their funding? Industry will frequently offer ‘unrestricted’ grants, to be used as physicians wish, no strings attached. But isn’t an unrestricted grant still a gift? What about government grants? The NIH and other agencies fund research they consider important, but that decision is made up of panels of people who have their own COI; what is their vested interest, if any? [4]

Professional organizations have national meetings where industry rents exhibit space to inform physicians and financially support their meetings. Health systems are also susceptible as they rent space for medical education presentations. Are there conflicts of interest here?

The Institute of Medicine (IOM) has advanced several standards for practice guideline workgroups.

- Prior to selection, candidates for panel provide COI disclosures
- Panels should discuss members COI before guideline development work starts
- Each member with a conflict should describe how it might affect the guidelines

- Guideline panel members should divest any investments that cause a COI with the guideline topic
- When possible, no panel member should have a conflict
- Members with a conflict should comprise a minority of panel members
- Chairs or co-chairs should be conflict free

The IOMs recommendations fall into one of three approaches. First, remove experts with conflicts – as we have said that's hard if not impossible, meaning panels could be composed of people who are just not great at their jobs. Second, minimize their influence by reducing their number and not assigning them leadership roles. The same issue; the most prominent people are blocked out by default.Finally, redact their input when COI looms large – but this is often the time when expert opinion is the most necessary.

This is because money is considered the only conflict, when that just isn't so.

Finally, some have suggested that a firewall is constructed between the advisors and their advice. Two problems here, using consultants without real world expertise creates guidelines that may be objective but are not particularly useful. Imagine if we said a bridge could only be built by engineers who had only used a computer to make one, none who had ever been paid to build a bridge. We could get guidelines for rivets that are optimal - but at 1.7867676 inches could never be manufactured.

There were a lot of firewalls were separating banking from investment activity but the housing bubble and the mortgage debacle of 2008 still happened.

Dr. Abagail Zuger summarizes the situation around conflicts of interest as well as can be done, even if it only makes the issue as clear as mud, "…whether the modern decision to reveal some of these relationships preemptively will make any real difference to the average patient is still unclear."

NOTES:

[1] The following articles were used in this summary Conflict of Interest in Practice Guidelines, Challenges/Opportunities in Disclosing Financial Interests to Patients [6], Business model-Related Conflict of Interests in Medicine [7] and What do Patients think about Physicians' Conflicts of Interest? [8]. While I read the entire issue and am writing about one specific aspect, the article on what patients are thinking by Dr. Abagail Zuger, was to my mind, the best overall summary. All quotations are taken from these papers.

[2] These cost estimates include professional services, payments to hospitals, spending on medications or ancillary services (i.e. physical therapy). This is not the income of the primary care physician, just the expenses their choices influence.

[3] Actual CMS payments were $27 million versus $1.1 billion. The figures cited represent the 6% physicians receive for administering the medication. For more information, consider this previous article [9].

[4] Senator Wyden recently questioned [10] the conflict of interest regarding national opioid policy.

Links
[1] http://www.shutterstock.com
[2] http://jamanetwork.com/journals/jama/issue/317/17
[3] https://oig.hhs.gov/oei/reports/oei-03-10-00360.pdf
[4] https://www.cms.gov/openpayments/
[5] https://projects.propublica.org/docdollars/
[6] http://jamanetwork.com/journals/jama/fullarticle/2623625?amp;utm_source=JAMALatestIssue&utm_campaign=02-05-2017
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[9] http://www.acsh.org/news/2016/09/13/paying-drug-administration-medicares-crumbs-make-gigantic-cake-10146
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