I recently encountered the term, “shared decision making” (SDM) for the first time. It was in a paper that stated that a doctor needs to use SDM before instituting an antipsychotic drug with a “black box warning” to treat psychotic symptoms in people with dementia with Lewy bodies (DLB).

DLB is a variant of Parkinson’s disease (PD) in which dementia precedes motor signs, whereas PD with dementia starts with motor features, followed by dementia, which occurs in about 80% of PD patients. The rationale for SDM lies in the observation made in several distinct studies of demented elderly, that all antipsychotics are associated with an increased mortality rate, although in none of the studies is it clear what the cause of the increase is. In some of the reports the increase is clinically significant, but not in all.

What was striking in the paper was that SDM was invoked for trying the antipsychotics because they have “black box” warnings, but SDM was not invoked for trying dementia drugs, or reducing the medications that treat the PD motor symptoms, but which contribute to the psychotic symptoms. This sounds reasonable. One type of drug is associated with black box warnings while the other approaches are not. This got me to thinking about how I approach decision-making in cases of PD psychosis and found that I do the exact opposite. I can’t recall ever introducing the topic of the black box warning. These drugs have the mortality risk only over the course of several months. The problems are not immediate. It is unknown if the mortality is a result of the drugs or an associated effect, and, in my extensive experience, the benefits so far outweigh the risk that there is really no choice. But, of course, the patients and the families lack the experience to make the choice.

In treating people with PD, I use a SDM paradigm for everything but psychosis. If I introduce L-Dopa or a dopamine agonist, I discuss side effects and benefits and weigh this against the no-treatment option. I always reassure my patients that I do not subscribe to the “my way or the highway” approach to compliance with my recommendations. I always tell patients that I view my role as being similar to that of a financial advisor. I make educated recommendations, but that doesn’t mean they must be followed.

In reflecting on my approach, using SDM for medications considered benign, but not for the only drugs I use that have black box warnings, I realize that there is an element of legal risk taking, and a larger element of paternalism. If my patient dies unexpectedly, which, of course, would raise no eyebrows, because all my patients are ill, many are elderly and most are frail, there will be no statement in the chart that we discussed the increased mortality, that the drug I introduced had a “black box” warning, and that it was not FDA approved for the indication. I would also have to admit that I was biased by my extensive use of the drugs for over 30 years, and that I am quite expert in this area. In my mind, a patient can decide whether to take L-Dopa or not. It is not life saving and may be associated with long-term side effects. It improves quality of life, but who am I to judge where the proper balance lies? If a patient would prefer to be slow and stiff rather than to take a medication, because of concern for side effects or for whatever reason, that is their choice. But to choose to remain psychotic, to embrace paranoia, or to have a family choose that for a patient who cannot reasonably choose, is not a choice I offer.

I do not know how my colleagues discuss these drugs with patients. I think much depends on the relationship between them. In most cases I know my patients and their families fairly well. This is unlike the situation where psychiatrists use the same drugs on patients they have only recently met, or when the drugs are used in nursing homes. These doctors are usually involved only when the patient is in extremis. They
Letter to the Editor

Regarding the Idiopathic Intracranial Hypertension Treatment Trial

June 24, 2016

We read the article by Thakore and colleagues concerning the Idiopathic Intracranial Hypertension Treatment Trial (IIHTT), published in your journal in May 2016, and were surprised at the comments. By design, both the acetazolamide and placebo groups received the same low sodium, weight reduction dietary intervention. The fact that the acetazolamide group lost more weight on average than the placebo group does not account for the positive results concerning acetazolamide on vision outcome. As we explained in the original trial report, we used mediation analysis to determine that the effect of acetazolamide was independent of its effect on weight. In other words, while acetazolamide had a significant effect on weight [acetazolamide – placebo difference of approximately 4 kg, p < 0.001], the effect of acetazolamide on the visual field PMD was independent of its effect on weight loss. This strongly suggests that the mechanism of the effect of acetazolamide on vision outcome is not through its effect on weight reduction. We note that the IIHTT findings are not inconsistent with the theory that a weight loss intervention would be an effective therapy in IHI – Indeed, there was improvement observed over time in both the acetazolamide and placebo groups on most outcome measures. The IIHTT, however, was not designed to evaluate the effect of a weight loss intervention because all subjects received such an intervention delivered by an expert obesity nutrition research center.

We sincerely hope that this clarifies, and prevents any further misperceptions about, the results of the IIHTT.

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References


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When you (or I) are patients and go to doctors we assume that all their advice is directed to our well-being and that it will not be compromised to enhance the doctor’s welfare. But there are economic issues and time constraints that conspire to thwart this expectation.

The moral concept that doctors should always act in the best interests of their patients, even if it may be detrimental to their own interests, is rooted in antiquity. “No…physician considers his own good in what he prescribes, but the good of his patient.” [Plato c.428 BC–c.348 BC]. This obligation to always put our patients’ interests first continues as a core principle of the current AMA Code of Medical Ethics, the authoritative reference for US medical ethics.

A fiduciary has a statutory legal obligation to place the client’s interests above his own. Examples include, among others, attorneys, members of corporate boards, independent financial advisors and, recently, stockbrokers [under protest].

The concept of a legal fiduciary responsibility for doctors was introduced in a 1969 judicial opinion: “The relationship between a physician and his patient is fiduciary, which, like all such relationships, imposes a duty of full disclosure.”

And in 1986 a CT court stated: “The fiducial nature of the physician-patient relationship flows not from the physician’s ethical duties, but rather as a result of the physician’s unique role in society….we believe that our society has an established and beneficial interest in the fiduciary quality of the physician-patient relationship.”

However, doctors are at little risk of being charged with a breach of fiduciary duty to patients since the facts of the case almost always also involve violating a standard of professional care and the Supreme Court has disallowed the charge of violating one’s fiduciary responsibility when it is duplicative of the malpractice action. That case questioned whether a doctor who altered treatment due to financial incentives could be sued for a breach of fiduciary duty.

In one exception in 1997 in CA, Dr. Nokuzola Ntshona was convicted of Medicare fraud for prescribing unnecessary medical devices. Her sentence was “enhanced” because she profited by making her patients liable for co-payments. This constituted a breach of fiduciary duty in addition to her criminal activities and her malpractice [negligence]. She suffered very real consequences for violating her fiduciary responsibilities.

Alabama, Minnesota and Delaware courts have held that doctors do not have a fiduciary duty to their patients. Ten other states admit the existence of a fiduciary duty but prohibit it as a cause for legal action against doctors, restricting actions to malpractice claims.

As medical care is morphing from an interpersonal interaction into an impersonal commodity, we must be aware that restrictions on care imposed by third parties such as payers, large medical “systems,” institutions, etc. may thwart the intent of doctors making medical decisions in accordance with their ethical and fiduciary responsibilities. Frustrating disincentives [prior authorizations, denials of costly treatments, exclusion from the system, etc.] may impede zealous physician advocacy for indicated medical treatment. However, hospitals and other institutions also may be considered fiduciaries and thus be required to formulate and enforce policies that protect patients. Thus doctors and institutions may be “co-fiduciaries.”

A CA court has opined: “The physician who complies without protest with the limitations imposed by a third party payor, when his medical judgment dictates otherwise, cannot avoid his ultimate responsibility for his patient’s care. He cannot point to the health care payer as the liability scapegoat when the consequences of his own determinative medical decisions go sour.”

A recent review notes that, “Fiduciary law principles have been applied to physicians only for very limited purposes” such as patient abandonment,
confidentiality, informed consent and disclosure of a financial interest in clinical research.

Additional conflicts that might be contrary to fiduciary duties [and not duplicate malpractice claims] include, but are not limited to, not advocating for indicated diagnostic and therapeutic actions when third party decisions may preclude their implementation, accepting gifts from industry, referring patients to physician-owned ancillary facilities, accepting kickbacks from non-physician-owned facilities, conditioning too great a proportion of physician income on bedside rationing, and “gag clauses” that prohibit physicians from giving patients information that might be adverse to the patient’s health plan.

So what to do?

What if all doctors and medical institutions were fiduciaries [though jurisdictional variations would make this difficult]? If this were the case, the doctor, citing his fiduciary obligation to provide medically appropriate treatment, would enhance patient advocacy. A third party that contravened such an order would risk being liable for interfering with the doctor’s fiduciary duty as well as possibly not fulfilling its own fiduciary duties.

The financial limitations of our health care system are real and constructive approaches are needed to ensure that patients receive the best possible care.

Doctors play two roles, but not simultaneously, in the maintenance of a financially healthy, efficient and high quality medical system. As administrators and members of committees, task forces, etc. we participate actively in formulating the rules and policies that are necessary to keep our medical system efficient and financially healthy. In addition to local efforts, state and national medical societies, are well suited for this effort. Transparency is critically important. Patients must be told about the rules and policies in terms they can understand. For example: patients should know if treatment for hepatitis C is restricted to those with defined complications and if referrals to specialists and institutions are limited.

But when actually caring for a patient, we zealously advocate for that patient’s health. Ethical and moral imperatives mandate this approach. A fiduciary obligation for doctors and institutions to advocate for the welfare of patients can only strengthen this advocacy. This patient-centered approach is similar to the dedicated advocacy provided by lawyers to their clients within the constraints of the legal system.

This approach will benefit us both when we are patients, as well as when we are doctors.

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