

Virtual Mentor

American Medical Association Journal of Ethics
November 2013, Volume 15, Number 11: 926-931.

ETHICS CASE

Responding to Patients' Requests for Nontraditional or Unproven Treatments

Commentary by T. Forcht Dagi, MD, DMedSc, MPH

Dr. Jeffries is a neurologist in private practice in a Virginia suburb. One day Ms. Ballard, a patient with a history of recurrent migraines, comes to his office in the midst of another splitting, pulsing headache centered on her right forehead and typical of her previous migraines. This is her third episode in the past month.

Ms. Ballard is frustrated and discouraged that her migraine regimen has been so ineffective. While reasonably well controlled for the past 3 years with beta blockers, her migraines have increased in frequency and severity over the past 6 months. They have been somewhat relieved but not eliminated with a variety of pain-relieving medications including nonsteroidal anti-inflammatories and triptans.

On this visit, Ms. Ballard brings up “feverfew,” a supplement from the sunflower family that she says has been shown to be effective in preventing migraines. She first found out about feverfew from *The Dr. Oz Show*, a popular daytime television show whose host is a surgeon. “Dr. Jeffries,” she explains, “I saw on *Dr. Oz* that feverfew has been tested in clinical trials and helps prevent migraines. And you can get it online for \$12!”

Dr. Jeffries has no idea what feverfew is. After quickly stepping out to conduct a quick online search, he finds one published clinical trial that suggests that feverfew compares reasonably well with beta blockers as preventive therapy. However, its side effects include allergic reaction and painful rebound headaches, and it is not known whether it interacts with the antihypertensive and oral hypoglycemic that Ms. Ballard is currently taking.

Ms. Ballard is desperate to try the new medication. Furthermore, she has not had any history of medication abuse, and she and Dr. Jeffries have enjoyed a good relationship over the past 3 years.

Commentary

This case is about one of the most common, yet difficult, situations in the patient-doctor relationship: issues that arise when a patient is equipped only with poor, incomplete, or incorrect information yet seeks to change therapy on that basis.

The physician is unfamiliar with the preparation his patient is interested in, but upon preliminary review of its pharmacological properties, concludes it may be efficacious. On the other hand he has reason to be concerned about potential

interactions with other medications prescribed for the patient and about the possible side effects in her specific circumstances.

This case may not be uncommon, but it is ethically complex. It touches on patient autonomy and informed decision making, paternalism, professionalism, the effects of disparities of power and asymmetries of knowledge, implicit promise making, stereotyping, and ultimately, on trust and the patient-physician relationship. It also touches on the importance of thoughtful and effective negotiation in communicating with patients.

Clinical Context

It is useful to review briefly the subject of migraine headaches, the condition from which Ms. Ballard is said to suffer. Migraines affect some 28 million Americans. They are more common in women. Up to 25 percent of all women with migraines suffer four or more attacks per month, and 35 percent suffer between one and four severe attacks a month. Migraines can last from hours to days and take many forms [1].

The diagnosis is primarily clinical. The personal and family histories are key. There are no reliable diagnostic markers or radiological findings. Nevertheless, in the United States, almost every patient who reports migraine headaches is subject to neuroimaging studies (CT or MRI) at some point, if only to exclude an underlying vascular lesion, space-occupying mass, or other treatable pathology. Treatment is aimed at preventing attacks, breaking the cycle leading to debilitating pain once the aura sets in, and relieving the headache if all else fails.

Treatment typically includes dietary and environmental modification, prophylactic medications, analgesics, and, more invasively, chemical or surgical denervation procedures. The combination of diet, prophylaxis, and analgesic is reasonably effective for the majority of patients, but not for all [2-4]. Patients often turn to nutritional supplements, over-the-counter medications, herbal preparations, and folk remedies to supplement conventional measures. Some of these substances may have analgesic or anti-inflammatory properties, but most are of questionable value [5-6].

Many migraine sufferers experience periods of inadequate headache management. Episodic or not, these can be debilitating. A particularly unfortunate few never seem to find adequate relief. Ms. Ballard exemplifies the kind of patient for whom good solutions seem particularly elusive.

Patients who have migraines are at risk for being stereotyped, once the diagnosis has been given. They are often perceived to be and described as “difficult” personalities, whether or not they are, because their condition is difficult or impossible to treat. It is all too easy to disregard new or changing symptoms and to dismiss potentially important and portentous clinical signals.

The dynamic of a call or visit to the physician in the course of a migraine attack is complicated. From the physician's perspective, there are two challenges. The first is to determine whether the current (or any other) episode of headache is different enough from the norm to warrant investigation. The purpose of the investigation (which in practice generally starts with neuroimaging and goes on from there) is to prove that the headache is "only" a migraine by means of a negative study. The second challenge is to find an effective treatment acceptable to the patient. It takes an open mind and keen clinical judgment to meet these two challenges.

It is critical to think through the meaning of the patient's complaints. Do they signal a new and potentially serious event such as an intracranial hemorrhage? The key is to ascertain that the event may be discontinuous with (it does not quite "fit" or "match") earlier events in the patient's history. Should they throw into question existing assumptions about diagnosis? For example, a patient with migraine headaches may develop temporal arteritis and experience headaches from that cause. Temporal arteritis is an autoimmune disease with potentially serious consequences, but one that has nothing to do with migraine headaches. Both can occur in the same patient, but they are treated very differently. Or are the symptoms communicating something altogether different, such as emotional stress or depression?

From the patient's perspective, the conscious dynamic is usually simpler. Many patients hope that, miraculously, each headache will be the last, which means each recurring headache gives rise to an emotional storm that includes disappointment, frustration, anxiety, anger, and fear. It goes without saying that patients look not only for ways to prevent and relieve attacks, but also for control. They would rather not need a doctor. The call to the doctor is an appeal for care because the means available to them have failed. For that reason, somewhere in the background, there not infrequently resides the fear that the physician too might fail. Psychologically, that is a terrifying prospect.

Physicians are generally more focused on diseases and conditions. Patients, however, will be focused on how they feel and, subconsciously if not overtly, on what they fear. This difference may be narrowed by skilled practitioners, but it almost never disappears entirely.

Ethical Context

On the surface, this is about the management of a patient who comes with questionable health information. When we start to look at all the elements of the case, it becomes much more nuanced.

Autonomy and risk. Let us start with the matter of patient autonomy and informed decision making. Autonomy and informed decision making are usually invoked in the context of positive coercion—an attempt on the doctor's part to persuade a patient to agree to a certain course of action or to act in a certain way. Patient autonomy and informed decision making are protective principles. Patients are permitted to decide what to do with, and what may be done to their bodies. The

corresponding obligation on the part of the physician is to obtain voluntary informed consent when a patient is to be subjected to surgery and, increasingly, to some nonsurgical interventions as well.

There is no real broad parallel with respect to protecting a patient of sound mind from risky activities undertaken voluntarily, at his or her own discretion and on his or her own initiative. Physicians have an inconsistent record on that score, leaving aside suicide and other forms of self-destructive behavior associated with emotional illness. Substance abuse and smoking prevention are diligently opposed by most physicians, but less so extreme sports, even though the risk of injury is very high. Even boxing, whose purpose is to create concussion, and football, whose injuries have begun to attract critical attention, have not been the object of consistent and concerted medical protest. How then can one object to an herbal preparation which has presumably passed some regulatory scrutiny by the U.S. Food and Drug Administration (FDA), may be classified by the FDA as GRAS (“generally regarded as safe”), is sold over the counter without prescription and has been endorsed by celebrities? One can only begin to formulate an answer to that question by looking at each patient and each drug separately.

Communication. It is not necessary, nor is it necessarily helpful, to disparage the preparation. It is important, however, for the physician to consciously focus on the patient and to communicate as much. It makes more sense for Dr. Jeffries to spend more time educating Mrs. Ballard about why he is concerned for her and less time about why he is concerned about the preparation. Time is better spent in creating a trusting relationship than in giving an immediate and categorical reply.

Dr. Jeffries should not be shy about admitting to Ms. Ballard that he needs more time to study the drug in the light of her personal situation and medications. Patients do not generally mind when physicians confess that they want to know more in order to help them. The physician may want to compliment her for her wisdom, thank her for consulting with him and express appreciation for her trust. He should probably spend time acknowledging her frustration with medications that do not work adequately, and express to her his interest in a collaboration that will optimize *her* control of the pain. Dr. Jeffries’s interest should be Ms. Ballard’s well-being, not the drug.

It is entirely fruitless (not to mention antagonistic) to criticize Ms. Ballard for coming with incomplete or inaccurate information. After all, she has relied on national authority figures’ endorsements and turned to her physician for more advice. The power of marketing to create confidence and product demand cannot be overestimated. Dr. Jeffries might find the advertising fatuous, but Ms. Ballard does not.

We are not informed in this case of the relative social standing of the physician and the patient or of Ms. Ballard’s level of education. Nevertheless, there is always the risk that disparities of power and asymmetries of knowledge may affect the tenor of the patient-physician relationship by hampering autonomy or encouraging

paternalism. By the same token, it is important to guard against making promises about prevention and relief that are difficult or impossible to fulfill. Finally, Dr. Jeffries's perception of Ms. Ballard is vulnerable to stereotyping, both because of her diagnosis, and because she is asking to act independently outside of conventional therapeutic practice. This must be guarded against. If he thinks she is vulnerable, he should try to engage her, not protect her.

This situation presents the perfect temptation to engage in a form of well-meaning and seemingly benign paternalism. After all, the patient *did* come to Dr. Jeffries and ask for his opinion. It would be easy for him to say, "I wouldn't take this drug and you shouldn't either." And yet, that kind of response does not serve the patient. Next time, she won't come for advice and the preparation she chooses might be unsafe. The objective must be not only to prevent the patient from trying potentially unsafe medications, it must be to educate the patient about the risks of such preparations.

Next steps. If Dr. Jeffries's research indicates that this is less of a risk for Ms. Ballard than he initially imagined, he might decide to test it with her if, after learning about the potential side effects, risks, and alternatives, she continues to request and consent to a trial. (Formal informed consent in this case might be advisable not only for ethical reasons but in order to transmit to the patient the seriousness of the physician's concerns.) By working with her to explain his concerns and what he was looking for, Dr. Jeffries would educate her both about the drug and the process by which he would determine whether the drug was safe and effective in her particular case. Communication is paramount.

It is essential that Dr. Jeffries remain professional and objective, however strongly he advises against taking the drug (assuming that's where his opinion lands). He might think about referring Ms. Ballard to a migraine specialist for a second opinion. Whether it confirms his therapeutic approach or suggests a modification, and whether it allows or dismisses the herbal preparation, the consultation will help fulfill Dr. Jeffries's ethical duties of both beneficence and respect for persons and is likely to further improve the patient-physician relationship.

Conclusion

The ethics of this case cannot be cleanly separated from the clinical issues in the management of Ms. Ballard. That is not an unusual situation. What makes this case important and interesting is how clearly the elements of clinical decision making and the elements of ethical decision making dovetail and overlap. The successful ethical management of this case depends on Dr. Jeffries's interest in optimizing communication and investing in a trusting patient-physician relationship. How that relationship is negotiated for the long run will be what matters.

References

1. WebMD. Migraines and headaches health center: migraines and headaches. <http://www.webmd.com/migraines-headaches/guide/migraines-headaches-migraines>. Accessed July 30, 2013.

2. Loder E, Biondi D. General principles of migraine management: the changing role of prevention. *Headache*. 2005;45(Suppl 1):S33-47.
3. Dowson AJ, Sender J, Lipscombe S, et al. Establishing principles for migraine management in primary care. *Int J Clin Pract*. 2003;57(6):493-507.
4. Latimer KM. Chronic headache: stop the pain before it starts. *J Fam Pract*. 2013;62(3):126-133.
5. Bigal ME, Lipton RB. Overuse of acute migraine medications and migraine chronification. *Curr Pain Headache Rep*. 2009;13(4):301-307.
6. Landy SH, Turner IM, Runken MC, Lee M, Sulcs E, Bell CF. A cross-sectional survey to assess the migraineur's medication decision-making beliefs: determining when a migraine is triptan-worthy. *Headache*. 2013;53(7):1134-1146.

T. Forcht Dagi, MD, DMedSc, MPH, is distinguished scholar and professor at the School of Medicine, Dentistry and Biomedical Sciences at Queen's University Belfast and holds an appointment in the Division of Medical Ethics in the Department of Global Health and Social Medicine at Harvard Medical School in Boston. Dr. Dagi is an editor of *Neurosurgery* and of the *Journal of Clinical Ethics*. He is a neurosurgeon, medical educator, and medical ethicist with particular interests in the ethics of uncertainty, diversity, and international disaster assistance.

Related in VM

[Herbal Supplements as Placebos](#), June 2011

[Physician-Rating Websites](#), November 2013

[Physicians' Responsibility to Understand Patients' Pain](#), May 2013

The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental.

The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.

Copyright 2013 American Medical Association. All rights reserved.