Virtual Mentor
American Medical Association Journal of Ethics
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The Clinician-Researcher

From the Editor

Case and Commentary

In the Literature

Medical Education

Viewpoint

Personal Narrative

Upcoming Issues of *Virtual Mentor*

November: When Patients Can't Afford Drugs
December: Taking Responsibility for One's Own Health
January: Do No Harm: End-of-Life Care
February: Emergency Medicine

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FROM THE EDITOR

Apples and Zebras

Audiey Kao, MD, PhD

As children, all of us were taught that 2 plus 2 equals 4. None of us questioned the simple truth of this mathematical equivalence. The concept that one thing is equal to another, whether that thing is a number, an action, or a group of people, is appealing in its simplicity, but can go disturbingly awry. For example, this country was founded on the principle that "all men are created equal." But at the time of the signing of the Declaration of Independence, slaves were not considered by most to be equal to their masters; they were, in fact, equated more with livestock than with humans. Nor were women considered to be the equal of men; they were denied many of the fundamental rights and opportunities enjoyed in contemporary America. Currently debate rages about the nature of certain acts of violence and destruction. Some argue vehemently that suicide bombings and other acts of violence are the moral equivalent of actions by yesterday's revolutionary colonists or today's freedom fighters. Others take offense when these violent acts are equated with political martyrdom. In the minds of these observers, they are simply acts of terror and barbarism. Judging moral equivalency is not as easy as comparing 2 plus 2 with 4.

In medicine, the concept of equivalence manifests in various forms and circumstances. Many scientific advances in medicine have emerged from our increasing ability to assess the relative efficacy of medical treatments. Randomized clinical trials are designed to compare the efficacy of a new drug against that of a conventional therapy. Rarely, however, do published reports on industry-funded studies find the new drug equivalent to the conventional treatment in all respects.[1-4] Published reports of industry-funded studies are more likely to find that the newer (more expensive) drug is better than the older (cheaper) medication. Given that the market for a new drug that is "equivalent" to an old drug would be small, the lack of peer-reviewed articles attesting to such equivalence is not all that surprising, but raises serious concerns about the integrity of the biomedical research and reporting enterprise.

The concept of equivalence has also been used to analyze vexing ethical dilemmas in medicine including the issue of physician-assisted suicide (PAS). Going back as far as the Hippocratic Oath ("I will give no deadly medicine to anyone if asked, nor suggest any such counsel"), the idea that a physician would act with the intent of ending a patient's life has been considered antithetical to the role of a physician-healer. While the ethical prohibition of PAS is not universally shared (Oregon, for

example, permits assisted suicide), most physicians and professional organizations do not support PAS. At the same time, driven largely by respect for patient autonomy, withholding or withdrawing potentially life-sustaining treatment is considered by most to be acceptable professional conduct.

For those uninitiated in the longstanding PAS debate, the general rejection of PAS, on the one hand, and acceptance of withholding/withdrawing life-sustaining treatment, on the other, appears inconsistent. Some argue that if withholding/withdrawing treatment is deemed ethical, then, under the moral equivalence hypothesis, PAS (active euthanasia in which a physician administers the lethal drug) should be considered no less ethical because both lead to the death of the patient.[5] Others reason that the 2 acts are not equivalent because in withholding/withdrawing treatment, the intent is to remove painful interventions and relieve prolonged suffering, even if the action has the unintended, yet foreseeable, effect of causing a patient's death. Is intent sufficient to render these 2 acts morally unequal? Put another way, can a physician's intended end justify the means even when he or she is aware of the possibility of unintended ends? In medicine (as in law and life in general), intent does matter and, for many physicians, serves to distinguish between ethical and unethical actions taken in the course of caring for patients.

Finally, patients are not created equal. Some have family histories that predispose them to heart disease; others do not. Some are genetically predisposed to develop cancer; others are not. That patient health burdens are unequal, however, does not justify disparities in health associated with race and ethnicity that persist even when clinical factors are equal. Some elements that contribute to such disparities are not modifiable by the medical care system. But, one modifiable contributing factor to racial and ethnic disparities in care may be physician bias. As physicians, we have a professional responsibility to treat like patients equally, basing treatment on relevant clinical considerations. Which brings up the case of so-called "zebras"—patients who present with rare and interesting diseases. While these patient presentations are clinically fascinating to physicians, we should remember that, though patients are not created equal, they are never as different as apples and zebras.

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CASE AND COMMENTARY
Clinician and Researcher, Commentary 1
Commentary by Timothy F. Murphy, PhD

Case
Internist Michael Hoover has been in practice in a mid-sized city for 12 years. He is a member of an internal medicine group practice, so he frequently sees patients of his partners when their own physician is unavailable. The group's patients range in age from early 30s to late 80s, the majority in the 40- to 75-year range. Those whom Dr. Hoover sees on a regular basis have hypertension, heart disease, headaches, arthritis, or respiratory and other organ system complaints, often related to aging. Some have cancers; a few have chronic conditions such as diabetes and lupus. Most of the group's patients have some health insurance or Medicare; 8 to 10 percent of care is uncompensated.

Dr. Hoover is prompted to think about the illnesses and demographics of his patients in this way when he receives a letter from a contract research organization that matches pharmaceutical companies that are conducting clinical research to physicians. One of the contract organization's current client companies has an anti-depressant drug in Phase III randomized clinical trials and is looking for physicians who can participate. The company is particularly interested in testing the drug's effectiveness on men. They would like Dr. Hoover to enroll 25 participants.

Initially, Dr. Hoover is eager to participate. He has a significant number of male patients who, he thinks, suffer from depression of various kinds—some because they are aging and losing abilities they once had or have chronic illness that brings increasing disability with it. Others because they have lost a wife, or a job, or their rights to see their children. Still others seem depressed regardless of their current life circumstances. Most have been reluctant to try medication or to see counselors of any sort. "If only I could get a good night's sleep," they say, or "had a little more energy," or "had a job," or "could see my kids." They rarely entertain the notion that treating depression might enable them to get more sleep, or a job, or have more energy, because they don't think they're depressed.

Dr. Hoover reckons that, given the good relationship he has with his patients, and by offering them the opportunity to do their part for medical science, he could persuade many of his depressed male patients to participate in the study. As the decision time draws close, however, Dr. Hoover begins to have second thoughts. The pharmaceutical company will pay him $3,000 for each patient he enrolls in the study. He will follow the participating patients for 2 years. These visits that will be

free to the participants. Is it taking advantage of his patients' trust that he can probably "persuade" them to participate, he wonders? Does the offer of a free visit every 3 months constitute financial pressure for his jobless patients with depression? Is the $3,000 per subject an incentive for him to participate? Will the clinician and researcher roles conflict?

The study is double-blind, so Dr. Hoover will not know which patients are receiving the trial drug and which are not. Dr. Hoover has no financial interest in the company that is conducting the trials, and believes that a good anti-depressant with limited side effects would be a therapeutic advantage over what is currently available. If he doesn't participate, will the doctor who the contract organization ends up recruiting handle the patient trust and conflicts of interest issues better than he can?

Under what conditions, if at all, should Dr. Hoover agree to be a clinician-researcher for the pharmaceutical company testing its anti-depressant drug?

Commentary 1

Capitation fees are financial incentives that sponsors of clinical trials offer to physicians who help identify and enroll subjects in studies of medical drugs and devices. In the case here, Dr. Hoover might enroll as many as 25 subjects over the course of 2 years. At $3,000 per subject, he could take in $75,000. The purposes for which this money can be used depend on the rules of his group practice. One use would be to cover the costs of running the study. For example, Dr. Hoover could use the money to hire an assistant to coordinate the study and make sure that appointments are kept and data are sent to the pharmaceutical corporation as appropriate. Some medical practices might allow Dr. Hoover to use any money left over for professional purposes. For example, he could use the money to attend medical conferences and seminars or to buy medical equipment. Depending on the rules of his group practice, he might even be able to use the money as part of his salary or for personal purposes.

Dr. Hoover wonders whether it is ethical to involve his patients in this study or whether he has conflicts of interest, both medical and financial. A conflict of interest involves a situation in which someone has a private or personal interest that could influence the way in which professional decisions are made. In conflicts of interest, people could make decisions that serve their own interests rather than the interests of the people they have an obligation to serve.

The notion of *equipoise* should be helpful to Dr. Hoover in coming to a decision about whether it is appropriate to enroll his patients in this trial. *Equipoise* refers to indeterminacy about whether one medical drug or device is better than another. A clinical trial is designed to resolve this uncertainty. Before such studies begin, there should be good reasons for thinking that a new drug should be tested: it has shown strong promise in animals; there are scientific reasons for expecting it to offer superior therapy; or it might be an improvement in that it could be taken only once

a day rather than 4 times a day. It is this expectation that the new intervention is superior in some way and uncertainty about that superiority that justify asking people to enroll in clinical trials. If Dr. Hoover is convinced *that* there are good reasons to expect this drug to be better in some way than other drugs *and that* it is unclear whether this new drug is in fact superior, he is justified in asking patients to enroll in the study. In other words, he has no reason to think that he is depriving a patient of a clear benefit by offering that patient the opportunity to take a new—and possibly better—drug.

Enrolling patients will bring money to Dr. Hoover, and he therefore wonders whether capitation fees generate a financial conflict of interest. One danger arising from capitation fees is that Dr. Hoover might be tempted to enroll patients who are not appropriate for this study. The way to control this temptation is to ensure that the study in question has very clearly identified inclusion and exclusion criteria. These criteria spell out the subjects of interest to the research, and when defined in a precise way they can work against dubious enrollment practices. Dr. Hoover should also remember that it is not his decision to enroll patients in the study; that decision belongs to them. In order to minimize any conflict of interest he should make sure that the patients receive thorough information about the study in a way that lets them decide free from any possible bias from him about the importance of enrolling.

Federal regulations governing clinical research require that researchers disclose certain financial aspects of subjects' involvement: whether they will receive any free care, compensation, or treatment in the case of an emergency. For some people, free medical care—even experimental medical care—can influence decisions about enrolling in clinical trials. To be sure, some people might not get medical care except for their participation in clinical trials. It is not unethical to offer free medical services as part of a clinical trial. If those services cross the line to the point where they have a undue influence in decisions to enter the trials, Dr. Hoover would be right to wonder how free his patients were to make their own decisions about enrolling. Free services should not force people to accept risks they would not otherwise accept.

Federal regulations *do not* require researchers to disclose capitation fees to subjects, and the vast majority of researchers make no such disclosures. Dr. Hoover is not alone in wondering whether there are ethical concerns here. Good practices in study design and informed consent should work to prevent any lapses of judgment on Dr. Hoover's part. However, potential subjects could be in a better position to evaluate *for themselves* whether the offer of enrollment is disinterested if they knew what benefits the researcher would receive. If Dr. Hoover is worried that capitation fees might influence his judgment in some way, or if Dr. Hoover wanted to avoid even the appearance of a conflict of interest, he could exceed federal requirements and disclose the terms of his own financial arrangements with the sponsors of the research.

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CASE AND COMMENTARY
Clinician and Researcher, Commentary 2
Commentary by Matthew Wynia, MD, MPH

Case
Internist Michael Hoover has been in practice in a mid-sized city for 12 years. He is a member of an internal medicine group practice, so he frequently sees patients of his partners when their own physician is unavailable. The group's patients range in age from early 30s to late 80s, the majority in the 40- to 75-year range. Those whom Dr. Hoover sees on a regular basis have hypertension, heart disease, headaches, arthritis, or respiratory and other organ system complaints, often related to aging. Some have cancers; a few have chronic conditions such as diabetes and lupus. Most of the group's patients have some health insurance or Medicare; 8 to 10 percent of care is uncompensated.

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Initially, Dr. Hoover is eager to participate. He has a significant number of male patients who, he thinks, suffer from depression of various kinds—some because they are aging and losing abilities they once had or have chronic illness that brings increasing disability with it. Others because they have lost a wife, or a job, or their rights to see their children. Still others seem depressed regardless of their current life circumstances. Most have been reluctant to try medication or to see counselors of any sort. "If only I could get a good night's sleep," they say, or "had a little more energy," or "had a job," or "could see my kids." They rarely entertain the notion that treating depression might enable them to get more sleep, or a job, or have more energy, because they don't think they're depressed.

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The study is double-blind, so Dr. Hoover will not know which patients are receiving the trial drug and which are not. Dr. Hoover has no financial interest in the company that is conducting the trials, and believes that a good anti-depressant with limited side effects would be a therapeutic advantage over what is currently available. If he doesn't participate, will the doctor who the contract organization ends up recruiting handle the patient trust and conflicts of interest issues better than he can?

Under what conditions, if at all, should Dr. Hoover agree to be a clinician-researcher for the pharmaceutical company testing its anti-depressant drug?

Commentary 2

Doctor Hoover faces a situation that is becoming increasingly common. In the more than 20 years since the Belmont Commission issued its landmark report that laid out ethical considerations for research on humans, and which resulted in greater government regulation of federally funded research, clinical research has become increasingly commercialized. More clinical research is now performed by private industry than is funded by the government. And more clinical research is moving into individual doctors' offices, away from large academic medical centers. There are many reasons for this, and the trends carry some benefits and some risks.

Clinical trials, wherein real patients affected by an illness agree to try an experimental therapy, provide the clearest and quickest route to demonstrating that a new treatment is safe and effective. Phase III trials, like the one Dr. Hoover is considering, are designed to demonstrate that a new treatment works better than a placebo, or better than standard therapy, and they are required for approval of new drugs by the FDA. Because clinical trials are necessary for regulatory approval, and because the number of potential new treatments under development continues to balloon, demand for clinical trial participants will continue to rise. Clinicians like Dr. Hoover, who does not practice in an academic medical center and has not previously been a clinical researcher, hold the key to enrolling new patients into these trials. Therefore, it is to be expected that future physicians practicing outside of academic medicine will face even more requests to participate, along with their patients, in clinical trials.

In many ways, bringing traditionally "non-academic" clinicians and their patients into the research enterprise represents a potentially healthy democratization of the process. In the past, clinical trials often involved only large academic institutions. But being involved in clinical trials is a useful way for physician participants to keep abreast of new developments. Patients may see the opportunity to enroll in

clinical trials as a way to "do their part" for medical science, and they may benefit if the new treatment ends up being better than existing options. Enrolling in clinical trials has been an important avenue to obtain new therapies among patients with HIV infection, for example. For researchers and drug developers, clinical trials that include a broader cross-section of patients may better assess the real-life effectiveness of the treatment under study.

But there are also risks associated with bringing clinicians inexperienced in conducting clinical trials into the clinical trials enterprise. And some of these risks are increased when for-profit corporations are ultimately running the trials.

One risk is that inexperienced clinicians, like their patients, will fall into a "therapeutic misconception" about the trial. That is, they may, perhaps subconsciously, believe that the trial drug being given is already known to be better than existing options. Dr. Hoover might believe this; why else would he believe he could convince his depressed patients to try a new experimental treatment, where he has been unable to convince them to try existing therapies that are already known to be somewhat effective?

As for patients, they are especially likely to mistake an experiment for a therapy when the person asking them to enter the experiment is the same one that usually offers them proven therapies. Patients facing a physician-researcher may not be able to distinguish these different roles. Large academic medical centers are in a better position to address this by having another doctor or nurse who has not been involved in the patient's care help to ensure informed consent when patients are deciding whether to enroll in a trial. But in a small clinic, this may not be an option. Therapeutic misconceptions, especially when they are eventually proven wrong, can have serious negative consequences, both on health and on the patient-doctor relationship.

Industry-sponsored trials are prone to additional problems. Bringing a new drug to market is expensive, often costing upwards of $500 million. It is also time consuming, and many drugs spend years of their limited patent protections awaiting the results of clinical trials before they can finally go on the market. By the time a drug reaches the Phase III clinical trial stage, the company will already have made an extremely large investment, all of which is at risk based on the performance of the drug in the trial. At the same time, good performance in a trial by a new drug to treat a common illness, such as depression, could be worth hundreds of millions or even billions of dollars in profit for the company. Thus, while pharmaceutical companies have clear incentives to produce newer and better treatments, since new and improved products sell, they also have clear incentives to rapidly convince regulators, doctors, and patients that their new and improved drug really is new and improved, perhaps even when it is not.

The pressure to recruit patients quickly and demonstrate good results can lead to inappropriate incentives to recruit trial participants and to designing trials that

optimize the chance of a positive results. For instance, a large payment to the physician for recruiting patients may tempt the physician to recruit inappropriate candidates. A rough calculation shows that Dr. Hoover will receive $3,000 up front for seeing each patient 8 times – a payment of more than $300 per visit. Presuming that very ill patients will be excluded from the trial, many of these visits should be fairly routine and in some cases the visits might also be billed to, and covered by, insurance. If this is the case, then this payment seems much more than generous – it seems more like a kickback. On the other hand, if Dr. Hoover must establish a new system for following these patients, hire new staff, and so on, then perhaps this level of payment is appropriate. In fact, since this would be his first involvement in a clinical trial, Dr. Hoover probably has little information with which to determine whether the amount is appropriate. He would do well to have his attorney or business manager evaluate the proposed research contract.

Dr. Hoover's inexperience might also lead him to participate in a trial that is methodologically or ethically unsound. Industry sponsored trials, since they are not federally funded, may not have undergone review by an Institutional Review Board, for example. While we do not know enough about the trial at issue to make a judgment as to its ethical and practical merits, an inexperienced physician might not know what questions to ask. Medical researchers should demand that clinical trials be designed ethically and to provide meaningful new information – not simply to information that will allow a new drug to make it to market.

Finally, Dr. Hoover should not be concerned whether another physician might take the contract and be even less prepared to handle these issues. He should be concerned about his own ethical and legal standing, and his relations with his patients. Clinicians outside of academic medical centers can and ought to be involved in clinical trials – but Dr. Hoover should receive training in both the ethics and the practicalities of conducting clinical trials before he signs up to be an investigator.

Matthew Wynia, MD, MPH is a clinical associate professor of medicine at the University of Chicago and the director of The Institute for Ethics at the American Medical Association.

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CASE AND COMMENTARY
Patient Confidentiality and Overriding Social Considerations
Commentary by Faith Lagay, PhD

Kathleen Wills visited a private clinic and learned that she was nearly 2 months pregnant. She and her husband were delighted to discover that they were expecting a child, their first, and shared the news with friends. About 6 weeks later, on her first regular prenatal visit, an ultrasound examination revealed that the fetus had no heartbeat. The Wills were greatly saddened by the loss. Kathleen underwent surgery for removal of the fetus.

Eight months later, Mrs. Wills received a subpoena issued by a county judge demanding that she report to the county attorney's office for questioning in a criminal investigation. The body of a 24- to 48-hour-old baby had been found abandoned in a garbage dumpster, and the clinic where Mrs. Wills received her pregnancy test had been subpoenaed for medical record information on all patients whose pregnancy tests were positive during a 9-month period that included the date of Mrs. Wills' test. The clinic had complied. It pained Mrs. Wills to recollect the facts and feelings associated with her miscarriage. But it angered her also. Why had the clinic violated patient confidentiality? Why did she have to prove, of all things, that she had not abandoned a living baby?

Questions for Discussion

1. Did the clinic act ethically in handing medical record information to the county attorney's office?[1]
2. Did Mrs. Wills have a right to expect that the information about her positive pregnancy test would be kept confidential?
3. What, if anything, was mishandled here? Is anyone at fault in the breaching of Mrs. Wills' confidentiality?
4. Is the harm to Mrs. Wills and other innocent women whose names are given to the county attorney's office in this case balanced by "overriding social considerations," ie, the public's interest in finding the woman who abandoned her infant?

Analyses
This case is based on events in Buena Vista County, Iowa in 2001-2002. After receiving information on patients who had positive pregnancy tests from several private clinics in the county where the dead infant was found, the county attorney's office sought the same information from a clinic operated by Planned Parenthood of Greater Iowa, Inc. (PPGI). The PPGI president refused to release the information,

calling the subpoena an unwarranted invasion of privacy and of confidential medical information. She petitioned the judge to quash the subpoena.

The court overruled PPGI's motion to quash, holding that the subpoena violated neither federal laws nor Iowa statutes regarding physician-client privilege because no physicians or other health professionals were being asked to testify to the validity of the records. The court did limit the information that the county attorney's office could demand to names, addresses, and birth dates of women with positive pregnancy tests during the 9-month period of inquiry.

PPGI appealed to the Iowa Supreme Court for a stay of the lower court's subpoena, which the higher court granted. The Iowa Supreme Court later granted PPGI's petition to appeal its medical records privacy case.[2] Argument is scheduled to begin in the Iowa Supreme Court in December 2002.

The American Civil Liberties Union has filed a friend-of-the-court brief in the case, arguing that irreparable harm and suffering will come to those like the Wills who have lost a fetus or newborn and will be questioned by the attorney's office about that pregnancy. The ACLU also argues that trust in the medical profession and, hence, in people's willingness to consult physicians when necessary, will be eroded as a result of the breach of patient confidentiality that the attorney's office intends to carry out. Moreover, there is no evidence that the mother of the dead infant sought any type of care during her pregnancy, or even lived in the community or county where the infant was found.

The county attorney's office contends "that pregnancy-test information is not protected by doctor-patient privilege because it isn't 'medical' information and the test could be performed and interpreted by non-medical personnel."

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2. *Planned Parenthood of Greater Iowa, Inc. v The Iowa District Court of Buena Vista County*. The ACLU brief is available at https://www.aclu.org/FilesPDFs?pp_iowa-amicus.pdf. Accessed January 30, 2009.

Faith Lagay, PhD is the managing editor of *Virtual Mentor*.

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IN THE LITERATURE

Should Clinician-Researchers Disclose Financial Incentives to Patients?

Jeremy Spevick

Rao JN, Sant Cassia LJ. Ethics of undisclosed payments to doctors recruiting patients in clinical trials. *BMJ*. 2002;325:36-37.

It is common practice for British doctors, like their US counterparts, to receive payments for enrolling their patients in clinical studies. In some instances doctors may follow their patients throughout the trial, while in others patients are recruited for studies in which the doctor is not personally involved. Regardless of the nature of recruiting, doctors in the UK, as is the case in the US, are under no obligation to disclose potential earnings for recruitment to their patients. While reimbursement of physicians is needed to ensure that important clinical research gets done, randomized clinical trials sponsored by pharmaceutical companies sometimes offer significant financial incentives to physicians. Jammi N. Rao and L. J. Sant Cassia question the ethics behind this current practice in their July 6, 2002 article, "Ethics of Undisclosed Payments to Doctors Recruiting Patients in Clinical Trials," in the *British Medical Journal*.[1]

Concerns about clinical equipoise, informed consent, and trust in the patient-physician relationship are brought to the forefront. A state of equipoise must be present during a clinical trial. The state exists when there is "genuine uncertainty within the expert medical community about the preferred treatment."[2] Many of the most lucrative clinical trials sponsored by pharmaceutical companies make no attempt to address areas of clinical uncertainty. Doctors who offer their services to these trials have very little control over the specifics of the study such as the research question, or the design and methods to be used. Rao and Cassia contend that oftentimes, it is "the size of the payment and not the buzz of research" that motivates doctors To join such trials.[3] One concern is that trials seeking to answer clinically important questions, which are designed by non-commercial sponsors, may not have the funding necessary to attract doctors.

Physicians are required to give their patients all the relevant information before a treatment decision is made. This allows patients to give their informed consent to a doctor's actions. Rao and Cassia assert that by not disclosing their potential gain from participating in clinical research, physicians are not allowing their patients to be truly informed before making their decisions. The authors cite an American survey,[4] for example, which found that 80 percent of patients feel they have a right to know that their doctor would be paid for enrolling them in a study and that over

half of those surveyed felt that payments to clinicians were unacceptable. These surveys suggest that patients are concerned about the financial interest their doctors may have in recruiting them for a clinical study.

Doctors must be trusted to put the interests of the patient above their own personal gain. Rao and Cassia stress that it is not enough to just disclose payment information to an ethics committee, a measure that the Royal College of Physicians does require. The authors are concerned that the current practice of financial disclosure requires patients to have "blind and unquestioning trust"[5] in their physicians.

Many of the studies sponsored by pharmaceutical companies are postmarketing research, or Phase IV studies, designed to familiarize physicians with new and recently licensed drugs. The commercial interests of such studies often outweigh their scientific interests. Rao and Cassia assert that postmarketing studies can sometimes be, "marketing thinly disguised as research," that probably would not be possible, "without a system of undisclosed payments."[3]

An interesting question raised in the article is why governing bodies do not require the disclosure of payments to patients at the present time. There is a widespread belief in the medical community that nothing prevents patients from asking their physicians about payments if they feel this is important to them. Yet, it is somewhat naïve to expect patients to inquire about something that they may not be aware is taking place.

The authors believe that most doctors and trial sponsors will not object to changes in regulations requiring doctors to disclose financial information to their patients.

Questions for Discussion

1. Do you agree with Rao and Cassia that money is a greater enticement to doctors for participation in clinical trials than the opportunity to answer important clinical questions?
2. Are the ideals of clinical equipoise and informed consent threatened when doctors do not inform their patients of their potential financial earnings?
3. Do you agree with Rao and Cassia that physicians should be required to tell their patients about money they will receive for enrolling the patient in a clinical trial?

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IN THE LITERATURE

Questioning the Voluntary Nature of Informed Consent

Michelle Lim

Are voluntary informed consents truly *voluntary*? How well informed are individuals recruited for clinical trials of their choices to refuse participation or withdraw at any time during the study? Clinical researchers have an obligation to abide by codes of ethics that protect the interests of human research subjects and are under careful evaluation by Institutional Review Boards to fulfill that obligation. Drs Robert M. Nelson and Jon F. Merz, however, argue in their recent *Medical Care* article, "Voluntariness of Consent for Research: An Empirical and Conceptual Review,"[1] that despite all the emphasis placed on the importance of voluntariness in clinical trials, various recruitment and consent practices may undermine the possibility of informed voluntary consent.

Nelson and Merz describe *voluntariness* as "an exercise of free will or choice—an act being done volitionally or with intent and deliberateness, and one that is free from coercion and undue influence."[2] After reviewing the relevant literature, the authors conclude that the scarcity of information specifically addressing voluntariness in research studies reflects a lack of a coherent model or adequate tool for measuring voluntariness in informed consents. This lack of a measuring standard compromises the researcher's ability to ensure the voluntary nature of the patient's consent to participate. The authors investigate the voluntariness issue by exploring characteristics of potential research subjects and behaviors of clinical researchers in the research setting.

Nelson and Merz cite diminished cognitive or other capacities, socioeconomic status, disease status, and the patient's family position as factors that may constrain prospective research subjects' ability to make voluntary decisions. They describe the elderly, children, prisoners, minorities, and those with low income and little education as populations most vulnerable to undue influence and coercion by the researcher's behavior and the practices of recruitment and consent. These populations are considered vulnerable despite their practical reasons for desiring to enroll in the clinical trials, which range from, "altruism, a sense of duty to others, the chance for personal medical benefits, financial gain, and trust in the health care provider."[3]

Physicians are ethically and legally bound to protect the best interest of their patients. While the clinical researcher may believe that participating in the study is in the best interest of the patient, Nelson and Merz question researchers' ability to

"look out" for their patients' interest, believing that certain researcher behaviors can persuade, manipulate, or coerce potential research subjects. The authors demand further exploration of the physician's role as a researcher and the possible impact of the physician's role on voluntariness.

The clinical researcher's status as a physician alone may carry strong influence in swaying the decision to participate. The authors consider patient "trust" as "power" physicians have over their patients. Such trust can be problematic in that it may be used (unconsciously or not) to persuade or manipulate.

Manipulation, according to Nelson and Merz, "seeks to influence a person's decision through altering the available choices or the perception of those choices."[4] The study identified three forms of manipulation: manipulating options, manipulating information, or psychological manipulation. For instance, researchers may withhold information about all the treatment options available in the clinical trial except for the one trial option they want the subject to enroll in.

Coercion, on the other hand, involves the use of credible threat or harm to force participation. A result of coercive researcher behavior, for instance, may be the patient's fear of loss of health care benefits or of retribution for refusing to participate. Individuals with the age-, socioeconomic-, and cognitive-characteristics mentioned above may be vulnerable to such a threat of harm that could be resisted under other circumstances or by other people.

Nelson and Merz do recognize the gray areas in determining whether "trust" (or power) creates undue influence. They also admit that there is a fine line between what is appropriate influence and what is inappropriate or coercive influence. They contend that while defining and determining the fine lines are difficult, these tasks can be accomplished with further study of the characteristics of potential research participants and behaviors of clinical researchers. They offer prescriptive solutions to addressing voluntariness, recommending, first, that careful attention be given to the content of and process by which information is relayed to potential research subjects. Nelson and Merz conclude that the evident lack of empirical measures for voluntariness calls for a reasonable public policy that will hold researchers accountable by placing on them the burden of proof to demonstrate the absence of undue influence or coercion.

Questions for Discussion

1. Do you think that any decision is made completely voluntarily?
2. Provide your own definition of "voluntariness."
3. Do you agree with Nelson and Merz that a standard measurement for voluntariness is feasible? Is it necessary?
4. What factors would you consider when crafting a "reasonable" public policy to determine the voluntariness of research subjects, as suggested by Nelson and Merz?

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MEDICAL EDUCATION
Cultural Impasse
Akshara Meran

Name of patient: Lee, Lia
Ethnic group: Hmong
Principal language: Hmong
Western diagnosis: Severe epilepsy
Hmong diagnosis: Soul loss
Cause of death: CULTURAL IMPASSE

By now the tale told in *The Spirit Catches You and You Fall Down* by Anne Fadiman[1] is familiar to many students of cultural competence in medical schools and residency programs. The novel captures the tragic story of Hmong immigrant parents, Foua Yang and Nao Kao, and their clash with Merced Community Medical Center over the care of their daughter Lia Lee. Fadiman demonstrates how profound cultural differences and linguistic miscommunication cause an increasing rift between Lia's loving parents and her well-intentioned doctors, eventually resulting in her death.

The novel is remarkable in that it does not seek to blame either Lia's parents or the medical professionals for Lia's death, but rather advocates that the medical establishment overcome linguistic barriers and bridge the cultural gap with its immigrant patients. As one review said, "It has no heroes or villains, but it has an abundance of innocent suffering, and it most certainly does have a moral."[2]

A reflection of the colliding worlds of Western medicine and Hmong culture, Lia's story represents the situation faced by immigrants who do not speak English and hold different cultural values about health care.

In addressing the culture gap present in the health care setting, Fadiman presents an approach put forward by Arthur Kleinman, which entails colloquy between the patient and health care professionals. Kleinman proposes a model of mediation and urges physicians and other health professionals to recognize that biomedicine has its own cultural biases that also influence each medical case.

Apart from cultural differences, language is a problem for immigrants trying to communicate with nurses and physicians. Foua, the mother in the novel, cannot read English. Yet, she is asked for her signature so many times that she masters

writing her name. Foua signs forms she does not comprehend, which is the case for many immigrants who do so to satisfy the abhorrent unfilled blanks.

America is a land of diverse people, and, as the number of minority communities increases, some ask whether we need to impose a multilingual requirement on our health care professionals in addition to our expectations of medical competence. At the same time, they know it is unreasonable to expect every doctor to be proficient in Wolof, Tswana, Hmong, and Queche, in the off chance that one of their many patients speaks one of these languages. The need for translators/interpreters to bridge the language gulf between immigrant patients and their doctors is evident. While health care professionals accept this solution, it is now a matter of who should pay for translation services.

In August 2000, the Department of Health and Human Services' Office of Civil Rights issued a mandate that all physicians who receive federal financial assistance, including payments under the Medicaid program, should provide, at their own expense, a trained clinical interpreter for all their limited English proficiency (LEP) patients.[3] This has caused heated debate. Many physicians claim that the financial burden of providing written and oral translation services to LEP patients would cause them great economic loss. The cost of hiring an interpreter ranges from $30-$400 per patient visit, significantly higher than the $30 to $50 Medicaid reimbursement for an office visit.[3] To reduce the financial burden on physicians, several options have been promoted and even adopted in some states, such as "I speak" cards that list the languages a patient speaks and provide the phone number of interpreters.[4] The idea of telephone interpretation services, allowing physicians to access state-funded, trained clinical interpreters also has appeal. Others argue that if the federal government is serious in its mandate for interpretation services for LEP patients, it should increase its funding so as to cover the costs.

While payment issues need to be resolved, it is necessary that interpretation services are made available to LEP patients as a first step in dealing with cultural differences in health care like the ones that resulted in Lia's death. Then, Anne Fadiman's wish will come true; the voices of immigrants and voices of American doctors will be heard on the same tape, speaking a common language.

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VIEWPOINT
The State of Emergency
Colleen Danz

- There were 108 million visits to ERs in 2000 – a 14 percent increase from the 95 million ER patients in 1997.[1]
- Average patient wait time is 41 minutes for an emergency and 1 hour for a non-urgent visit, while the average total visit time is 2 hours and 40 minutes.[2]
- Most visits occur between 4:00 PM – 7:59 PM; Monday is the ER's busiest day.[2]
- According to a study by the Center for Disease Control and Prevention, waiting time for non-urgent emergencies has increased 33 percent.[1]

What is an emergency condition?

- According to the Emergency Medical Treatment and Labor Act an emergency condition is defined by the presence of acute symptoms, including severe pain, of sufficient severity that the absence of immediate medical attention could reasonably be expected to result in:
    - Placing the health of the individual in serious jeopardy,
    - Serious impairment to bodily functions or,
    - Serious dysfunction of any bodily organ or part[4]
    - Uninsured Americans, who now number close to 40 million, are likely to use emergency departments for routine care.[1]

In light of the health care shortages and overcrowding in ERs, some hospitals have found a way to guarantee shorter waits without compromising quality of care.

- Oakwood Health Care in southeast Michigan guarantees patients are seen by a doctor in 30 minutes or they will receive free movie tickets and a personal apology.
    - They have seen a 50 percent increase in patient volume.[2] Average wait to see an ER physician decreased from several hours to 22 minutes at the Oakwood center.[4]
- Northern Nevada Medical Center gives a 15-minute guarantee or your ER visit is free. They have seen a 54 percent increase in patient volume.[2]
    - The success of this campaign has prompted an expansion that will double the size of the department by June 2003.[5]

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VIEWPOINT
Running in First Place
Faith Lagay, PhD

Media stories this past August that used such terms as "unbelievable," "competitive," and "a good role model" in describing President Bush were reporting not on his handling of international affairs, running of the country, or even his approval rating among voters.[1] The superlatives referred to Mr. Bush's health and physical condition. The reports appeared following Mr. Bush's annual medical exam at the National Naval Medical Center in Bethesda, Md. Readers were informed of the President's height (6 ft), weight (189 lbs), blood pressure (106/70), heart rate when resting (44 beats per minute) and after running on the treadmill for 27:03 minutes (169 beats per minute), his body fat (14.4 percent), his high- and low-density lipoprotein, the latter, "near optimal."[2] On and on the report went, listing triglycerides, C-reactive protein, thyroid tests, and PSA level. It concluded by stating that Mr. Bush's TB skin test "showed no evidence that he has been infected by the bacterium."[2] Given the privacy of the patient-physician relationship, the presence of so much medical information in the news means that, first, the media figured the American public wanted to know, and, second, the patient—President Bush—consented to release of the information.

Such disclosure is a recent phenomenon. After a long tradition of silence about the health of our presidents, the public was told about Dwight Eisenhower's heart attack in the 1950s and Lyndon Johnson's gall bladder surgery in the '60s. The '70s brought presidential candidate George McGovern's replacement of his running mate Thomas Eagleton when it came to light that Eagleton had been hospitalized for depression. After that, disclosure of medical records became a sign that one had nothing to hide. Law professor George J Annas, who has written about the role of political candidates' medical records in their campaigns for office, points out that the releasing of medical information started to resemble a competitive sport after Senator Paul Tsongas's 1992 candidacy.[3, 4] The first presidential candidate to announce that he had had cancer, Tsongas offered to submit to examination by an independent panel of physicians if the public wanted proof of his cancer-free state. Tsongas believed he was setting a precedent for the level of health information disclosure by candidates. "To the extent that Tsongas was right," Annas says, "presidential candidates wind up playing a public game of chicken with their medical records and thus their medical privacy."[5]

And "to the extent that Tsongas was right," President Bush has set the bar at a height not many presidents or candidates will be willing to challenge. *The New York*

Times article that recounted all the levels and measurements noted above also informed readers of Mr. Bush's "high frequency hearing loss in both ears from 4,000 to 8,000 kilohertz" and told us that "the small harmless red blotches that appear on Mr. Bush's nose are due to widened capillaries resulting from sun exposure."[2] Imagine a president of 60-something years; how long would a thorough description of hearing and sight losses, and of "harmless" discolorations (A.K.A. liver spots) be? Who would consent to such disclosure? If the level of medical record disclosure were to discourage a qualified candidate from pursuing office, it would be acting against public interest.

There may be another motive for the disclosure of medical records. Writing about "the health of the president and presidential candidates" in 1995 (long before George W's stats were published) Annas says, ". . . to the extent that cholesterol levels and weight are used as measures of virtue, all this is nonsense and is likely to distract us from focusing on the substantive policy differences between the candidates."[6] There is evidence that some people, at least, are making the equation between good health and virtue in President Bush's case. The "unbelievable physician condition" attributed to the president by one his examining doctors, is not an objective evaluation in the same way that "desirable/near optimal level" is.[2] The 7-page photo-essay on Mr. Bush entitled "Leader of the Pack" in the October 2002 *Runner's World* would suggest that the President's health, physical condition, and work-out schedule are being offered up as praiseworthy models.[7] They are praiseworthy, no question. Moreover, by demonstrating his commitment to a regular work-out regime, the article bolsters the President's health and fitness initiative, a program that challenges teachers, principles, youth camp and club leaders to improve the physical fitness and reduce the obesity of young people in the US.[8] On the other hand, the magazine article carries postage-stamp drawings or photos of 22 U.S. presidents and lists their body-mass indexes under the heading "Fit to Be President?" And White House officials admit that they "provided extraordinary access" to the President for the article because, "they believe it will burnish Bush's image with Americans who don't follow politics."[9] These White House officials, then, must think (or believe that *Runner's World* readers will think) that George W. Bush's "unbelievable" physical condition and competitive running times improve his qualifications for leading the country.

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PERSONAL NARRATIVE

Through the Caregiver's Eyes: Darkness

FR Burdett

"I hope they don't admit me. I hate this ... hospital."

"I hope they do. I can't blame you for hating the hospital but you've been ... dying in your ... apartment."

We were waiting in the Emergency Room for the doctor to come back. It wasn't easy for Bob to go back to the hospital. He kept putting it off hoping he'd feel better the next day or so or in a couple days. Maybe the fever would go down and the shaking stop; maybe the diarrhea would slow down; maybe the breathing would get easier.

"For the first time I feel like one doctor knows everything you're going through." I had done my best to tell the ER doctor everything. "Now, maybe, they'll be able to do something." It sounded like a no-brainer at the time.

It was New Year's Eve. It had been a tough year. In the spring, they had discovered a fistula, a connection between his colon and bladder. Fecal matter was entering the bladder and mixing with his urine. He had diarrhea and ran a fever.

The doctor finally walked in and told him, "We're going to admit you for a couple days until we can get you to feeling better." I wanted to get out of there before anybody changed their mind.

Five months later, Bob receives his oxygen from a ventilator, his nourishment from a bag of white liquid that drips into his chest just below his shoulder. He has a tube through the side of his neck, in his nose and mouth. Other tubes hang down beneath the sheets that drain body fluids and there is a bag on his stomach for solids. He cannot swallow, cough, or talk. He has a new lung infection—pneumonia, maybe. He thinks he may or may not need more surgery again when he is stronger. Sometimes he says they tell him he does; sometimes he says they tell him he doesn't. I don't think he knows. I don't think it matters.

This isn't the way he wanted it last summer. He had completed his "Living Will" and "Power of Attorney for Health Care" and intended to sign a "Do-Not-Resuscitate" order before the first surgery. He had black trash bags and masking tape sitting on his dining table at home. Although I didn't like his choice of exit

plan, we both agreed that plastic bags were preferable to tubes and machines. He asked, "Would you rather have white bags with happy faces on them?"

I would have. I'm the designated body discoverer.

There was no joking about the desire to die before becoming dependent, incompetent, incontinent, bankrupt—before being hooked up to machines.

In July he had the first surgery to remove part of his colon and the fistula which attached it to his bladder, a temporary colostomy to give time for the colon and bladder to heal. It appeared successful. He had an epidural and morphine on demand. He felt little pain. He looked forward to the second surgery to reverse the colostomy.

The second surgery was everything the first wasn't. New fistulas were discovered. More of the colon had to be removed before the colostomy was reversed. There was no epidural and recovery (such as it was to be) was painful. The doctors hadn't prepared him for this and he was angry. He quit trusting them. He stopped paying attention to what they said and he answered their repetitive questions angrily telling them they didn't have to talk so loud; he wasn't deaf. Not all of it was Bob's fault; different doctors voiced different opinions daily.

He had to return to Intensive Care several times. He told me he had to go back the first time because a new nurse had pulled out a drainage tube by mistake. Staff said it was because of a heart attack. He was angry when he denied having a heart attack so I left it as a tube story. The tube story eventually became that he might have pulled it out himself; he couldn't remember.

I began to suspect that I couldn't depend on what he remembered. I might know more about what was going on with him than he did because I wasn't sharing the morphine.

They sent him home to get built up for more surgery but his condition deteriorated. There were still more fistulas. He experienced diarrhea every 10 or 15 minutes 24 hours a day 7 days a week. He ran a fever, chilled and shook. Antibiotics didn't seem to work. He had trouble breathing. He was losing strength, wasting away. He wasn't well enough to make a lot of his follow-up doctors' appointments.

He was hanging on to the counter waiting to sign in for a urologist's appointment. I told him to go sit down and I would sign in for him. When I got back to him he told me, "If I didn't know better, I'd swear I was having a heart attack"

"When did it start?"

"In the shower this morning."

"Shall I tell them at the counter?"

"No, they'll be calling me soon."

Then he gave me a piece of paper with some phone numbers on it. "I think they'll be keeping me. Call these people for me."

"When did you write this?"

"After my shower. Maybe you should tell the lady at the counter."

Later, before his angioplasty, he told me: "The black bags are looking better all the time."

The angioplasty seemed to help his strength and breathing for a while. He went home. In about a week he resumed dying his slow miserable death.

On December 30, he called me and asked me to take him to the Emergency Room the next day. He would tell them that he thought he was having a heart attack so they would be sure to admit him. He wasn't. I guess he didn't think they'd admit him if he just recited his "regular" symptoms.

They performed heroic emergency surgery twice within the next week. Presumably he would have died after 3 more days at home. They took more colon and did another colostomy. He was on life support—puffed up with his mouth open and face distorted like road-kill on the shoulder of the road except with sterile plastic tubes everywhere. The only sign of life for the next week was the occasional shaking of his head from side to side; the nurse said it was because of the tubes in his throat but I wondered if he were shaking it "No," trying to tell me to start pulling plugs.

"Are you here to see Mr. Harvey? We moved him after he came back from his CAT scan. He's over there now." I looked behind me. He was still tangled up in a mass of wires and tubes but it looked like his eyes were half-open. As I got closer, I could see his eyes really were open and they looked up at me. Unbelievable!

I mumbled something perfunctory. I really hadn't expected this—ever. When I left him in the Emergency Room he had asked me to pick up some items for when he went home; I'd already returned them. Now he was smiling at me. I felt giddy. I laughed, "I can't believe . . . ." I had to search for something to say, ". . . how much progress you've made . . . how much better you look."

"I mean you still look like hell . . . but it's better." By now he was laughing. No sounds were coming out but I could tell he was laughing and that it hurt.

I didn't stay long. I brushed my hand over his head and told him I'd be back, "Tomorrow." I couldn't wait to call friends. I'd been telling it like it was; I needed to tell it like it had become.

Unbelievable! In fact, a nagging doubt that maybe it should have turned out otherwise.

He hasn't been free of tubes and machines the past 5 months. There have been times when he improved followed by times when another heart attack or high fever took him back to Intensive Care. When he could still talk, he'd ask, "Am I taking 2 steps forward and 1 step back or 1 step forward and 2 steps back?"

Nobody can find the Living Will or Power of Attorney now; he hasn't filled in the new forms I got for him.

Not going to the hospital New Year's Eve would have saved a lot of suffering. What had changed for him by then for him go back?

I always try to ask him if he's okay with what they're doing. So far he nods his head yes. I don't understand why; I don't see any future for him. But I can't hope for him to die when he nods his head that he is okay with what they're doing. I can't hope for him to live either; when others do I get angry. Then I have to remember that just as ending it would have been, going on is his choice and I have to respect it.

Meanwhile, someone has used the bags for trash.

FR Burdett lives, writes, and walks the seawall in Galveston, an island off Texas, in the Gulf of Mexico.