Balancing Self and Patient in the Physician-Patient Relationship

In this issue of CHEST (see page 1337), Miller and Shorr examine the ethics of clinical trials funded by pharmaceutical companies and performed by practicing physicians. The authors describe a seven-point framework for evaluating the ethical soundness of any clinical trial. Then they use that framework to critique a recent company-sponsored study comparing a new inhaled corticosteroid, a proven inhaled corticosteroid, and a placebo for treating moderate persistent asthma. Miller and Shorr argue convincingly that, by withdrawing patients with stable asthma from proven treatment and randomizing some to placebo this study risked patients' serious clinical deterioration.

So why was the study ever approved? Miller and Shorr speculate that self-interest was the driving force: the sponsoring company may have expected marketing advantages from the results; the participating physicians, fees for subject recruitment.

To be sure, self-interest motivates everyone at times. It is an indelible part of human nature. Especially in capitalistic cultures, self-interest rules the marketplace and is expected of companies. Business pursues profit, and customers know to protect their own interests. But physicians are held to a different standard.

Certain sensitive relationships involving unequal parties demand a higher motivation than self-interest. The stronger party has a special duty to ignore natural self-interest and serve the interests of the weaker party. Such relationships are called fiduciary because the weaker party must trust the stronger. Physician power and patient vulnerability make the physician-patient relationship necessarily a fiduciary one. The physician must promote the patient’s legitimate medical interests—sometimes at a cost to the physician’s own interests. The rationale for such a fiduciary duty is clear: a patient will not come for care without trusting the physician to promote the patient’s interests.

Disagreements inevitably arise over when and to what degree physicians must sacrifice their own interests for the patient. While others may disagree, Miller, Shorr, and, I suspect, the physicians in this asthma study failed in their fiduciary duty to patients.

How can physicians balance natural self-interest and fiduciary duty in everyday practice? I believe three tests, used sequentially, can help.

The “golden-rule” test states the familiar tenet: treat others as you want to be treated. With this test, the moral agent identifies the different stakeholders in a decision. Then the agent uses his or her own values to judge the possible choices from each stakeholder’s perspective. Consider the practicing physician as a moral agent deciding whether to recruit patients into this asthma study. Using his or her actual values, the physician judges such recruitment from the perspectives, say, of the participating physician, a company official, a subject receiving active drug, a subject receiving placebo, and other asthmatics. The stakeholders most likely to be harmed deserve careful consideration. This asthma study obviously risked most harm to the subjects receiving placebo. As the study report attests, the harm turned out to be significant. Compared to subjects receiving any active drug, subjects receiving placebo had four or more times the risk of intervention failure (4 to 11% vs 44%, respectively) and more than twice the risk for adverse events (2 to 4% vs 9%). And clinical deterioration on placebo occurred quickly—in a median time of just 40 days. A physician’s values, based on the fiduciary duty to patients, typically include continuity of effective therapy and avoidance of unnecessary medical risks. Such values applied from the perspective of a subject receiving placebo argue strongly against the physician’s recruiting patients into this study.

The golden-rule test helps the moral agent recognize other stakeholders in the decision and know when the agent’s own values are at risk from different stakeholders’ perspectives. But the golden-rule test is also mired in the agent’s values. Unique combinations of personality and experience make each person’s values somewhat idiosyncratic. For instance, the physician’s particular abilities, aspirations, training, and experiences can make his or her values different from patients’. So how can the physician learn patients’ real values and incorporate them into decisions such as the one about recruiting subjects for this asthma study?

The publicity test provides a way. With this test, the moral agent seeks feedback by “publicizing” any tentative decision before implementing it. A weaker version of the test requires the agent simply to imagine the values and feedback of others. (The American College of Physicians advocates such a
version when it urges the physician to imagine what the public would think about the acceptance of pharmaceutical company gifts.5) A stronger version of the publicity test requires actual feedback from others. Because personal biases limit one’s ability to imagine other people’s thinking, I favor the stronger version. The most important feedback comes from people who differ most from the agent. Because these people may be hard to identify or may hesitate to speak honestly, the agent must seek them out and encourage them to express any objections.

The institutional review board (IRB)—the local body charged with protecting human subjects—poses a publicity test for research protocols. Using the perspective of subjects, the IRB must scrutinize protocols for risks and ensure proper subject protections before the studies may begin.

While I cannot know the actual IRB deliberations over this asthma study, three concerns (besides the medical risks to placebo-treated subjects) suggest inadequate subject protections. First, the consistent references in the study report to subjects as “patients” and to research interventions as “treatments” suggest the study blurred the critical distinction between research and therapy. Research subjects should expect no benefit and possibly some harm from research interventions. Furthermore, research physicians owe subjects only the few services detailed in consent forms. In contrast, patients can expect benefit from therapy, and treating physicians owe them extensive, often unwritten fiduciary services. Not grasping this distinction, many patients mistakenly expect therapeutic benefit from research, and physicians often do not think to correct the misunderstanding.

Second, Miller and Shorr raise the possibility that physicians received bounties for recruiting their patients to this study. If so, these bounties created a serious conflict of interest. The profit motive might have tempted physicians to recruit their patients despite the medical risks involved. And third, the study report describes the approving IRB as “responsible for the study center.” The pharmaceutical company surely hired the center to conduct this study. The IRB likely included study center employees as members or support staff. Either way, the employees had an interest in study approval and might have biased the IRB—even unintentionally—that way.

While no IRB can completely escape conflicts of interests, they can be minimized. The IRB must see its foremost duty as protecting research subjects. All members must scrutinize research protocols for subject risks and protections. Members without vested medical or business interests bear a special duty to identify potential subject concerns, to voice them, and to advocate vigorously for remedies. When serious conflicts of interests arise, the IRB should seek independent review of protocols. If this asthma study offered recruitment bounties, the IRB should have required the consent forms to divulge them. If the study misrepresented its research as therapy, the IRB should have required the consent forms and the participating physicians to clarify the point to potential subjects. Without such conditions—the minimum consistent with a fiduciary duty to patients—the physicians should have refused to participate.

The publicity test reminds the moral agent that the opinions of others may differ from his or her own over particular decisions and encourages the agent to take seriously such differing opinions. But neither the golden-rule test nor the publicity test explores the implications of adopting a particular decision as widespread practice.

The generalizability test serves this function. With this test, the moral agent extrapolates the tentative decision from one case to all similar cases. The agent imagines the decision as a generalized practice or precedent and anticipates any resulting threats to the fabric of society’s shared values. A decision that works well in a few cases might prove disastrous on a wide scale. For example, widespread adoption of market-driven medical science, recruitment bounties for physicians, and the use of placebos when safe, effective treatments already exist would surely threaten the public’s trust in medical science to pursue benefits with impartiality and in physicians to protect vulnerable patients.

These three tests offer a disciplined, rational way for physicians to balance self-interest against fiduciary duty. Used sequentially, the tests can systematically weed out many unacceptable decisions. But the tests are not perfect. They offer neither absolute protection against excessive self-interest nor a single “right” decision in every case.

Nonetheless, medicine must have safeguards against all-too-human self-interest. While self-interest rules the capitalistic marketplace and customers must beware, medicine is not a mere marketplace and patients are not mere customers. Patients often enter the medical care system unsophisticated about medical technology, hampered by disease in pressing their interests, and awed by physician authority. Those vulnerabilities create for physicians a fiduciary duty far more stringent than marketplace morality.

The golden-rule, publicity, and generalizability tests can help physicians fulfill that duty. These tests encourage physicians to identify all others affected by a professional decision, to learn their own and others’ values at stake in it, and to consider the consequences of widespread adoption of a particular decision. In the case of this asthma study, I believe...
all three tests would have argued against physician participation. However contrary to self-interested human nature, these tests in the service of the fiduciary duty should guide physicians’ professional conduct. Genuine care for patients demands no less.

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Prevention and Management of Hypoxemia During Fiberoptic Bronchoscopy

Generally, hypoxemia is very common with diagnostic fiberoptic bronchoscopy. Hypoxemia occurs with insertion of the bronchoscope through the glottis into the trachea, and becomes worse when local anesthetics or saline solution are instilled into the lower airways. BAL is associated with greater levels of oxygen desaturation than when lavage is not done. This has led physicians routinely to monitor oxygen saturation during and after bronchoscopy, and to the nearly universal use of supplemental oxygen to prevent severe hypoxemia during bronchoscopy.1,2 A more parsimonious approach, providing supplemental oxygen only to those patients who actually do exhibit desaturation, was the subject of a recent report.3 At times, the fall in oxygen saturation can be sufficiently profound or sustained as to require aborting the procedure, or taking some measure to correct it in order to complete what is intended. While the hypoxemia is associated with cardiac arrhythmias in 11 to 40% of patients who undergo fiberoptic bronchoscopy, the cardiac rhythm disturbances are rarely important clinically.4,5

In the current issue of CHEST, Chhajed and colleagues (see page 1350) report a simple and novel approach (inserting a nasopharyngeal tube) for managing or preventing hypoxemia in lung transplant recipients as they underwent bronchoscopy as part of their posttransplant management. Most patients (88%) had relief of bronchoscopy-related hypoxemia with insertion of a nasopharyngeal tube.

Snoring with upper-airway obstruction and desaturation were the initial observations in this population of lung transplant recipients undergoing bronchoscopy. The authors then developed a stepwise approach for such patients. When snoring in association with saturation fell to ≤ 90%, the jaw was supported and oxygen flow via nasal prongs was increased from 4 to 6 L/min. If desaturation persisted, a nasopharyngeal tube was inserted and the bronchoscope was withdrawn to the trachea. If desaturation still persisted, additional oxygen was administered with a 7F catheter passed nasally to a position just above the larynx or in the proximal trachea. By utilizing these maneuvers, only 5 of 714 procedures required termination with withdrawal of the bronchoscope, reversal of the sedating agents, and bag and mask ventilation of the patient.

The patients in this study received larger doses of sedating agents than most bronchoscopists find it necessary to administer. (For a 70-kg person, the preprocedure morphine dose was 2.5 to 5 mg, followed by an average IV dose of midazolam of 10.5 mg, along with 125 μg of fentanyl.) Like the authors, we have found that larger doses of conscious sedating medications may be needed in lung transplant recipients than other groups of patients undergoing bronchoscopy. While these sedating agents are central respiratory depressants, another mechanism is needed to account for more than transient hypoxemia after boluses of these drugs are administered carefully. For example, the degree of airflow obstruction as judged by FEV1, is a predictor of clinically significant bronchoscopy-related hypoxemia.3,6 Inserting a flexible bronchoscope into the airway by the transnasal route causes a 17% rise in the functional residual capacity of the lungs, altering gas exchange.7 Instillation of local anesthetic solutions or saline solution, and especially high-volume BAL, causes changes in ventilation/perfusion relationships. This leads to a right-to-left shunt-like phenomenon, with systemic arterial hypoxemia.