determine whether the strength of do-not-resuscitate (DNR) recommendations varies with medical specialty and experience. Their conclusion, that the strength of DNR order recommendations varies with different internal medicine specialties and with different levels of experience, is not supported by their data.

None of the seven groups in the study varied significantly in the number of DNR orders recommended, so that all groups demonstrated a similar approach to this end-of-life issue. Only three findings were statistically significant, each in only one group of physicians, and these involved only strength of opinion, not the number of DNR orders recommended. One of the three significant findings, that the more senior house staff recommended DNR more strongly than did the younger interns and junior residents, may reflect increased confidence with increased length of training.

The authors’ use of statistics may have misled them. Statistics, which is concerned with correlations, can be applied to any problem but is not sufficient to show causation, which is the cardinal function of scientific research. The improper use of statistics often results in what has been termed “statistical malpractice.” Findings that are not statistically significant should not be reported as a trend.

Cultural influences are important when dealing with end-of-life issues. The new field of bioethics has created an ethics that places the needs of society and third parties above those of the individual patient. Because of this, the attitudes and behaviors of physicians toward the terminally ill that were reported in the 1970s (references 10 and 11 in the article by Kelly et al) may not be comparable to those from recent years.

Finally, how this study will “help to target educational interventions and . . . ensure effective collaboration with colleagues and communication with patients,” as the authors claim in their conclusions, is not explained.

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REFERENCES

To the Editor:

Dr. Arnett’s interest in our publication is appreciated. We again acknowledge that the number of do-not-resuscitate recommendations was not different between subspecialist groups. However, the purpose of the study, as stated in the introduction, was to determine whether the strength of do-not-resuscitate order recommendations, not the absolute number of decisions, varied with medical subspecialty and years of training. Our results did indeed find statistically significant differences in the degree of these convictions. This is important and is of interest to internists in general and chest physicians in particular. We believe that the strength of physicians’ convictions affects their guidance to patients who are making end-of-life decisions.

Dr. Arnett charges statistical malpractice by the confusion of correlation with causation. In our study, we never claim to show any causation. We only report observations from our limited database. Our statistical significance does add greater clarity to these findings by suggesting they are not a result of chance. Additional findings that approached but did not meet significance are so disclosed with p values and statistical methods.

The specific differences that we found among medical subspecialties are consistent with the results of other reports in the medical literature. Dr. Arnett suggests that such references may be out of date (ie, references 10 and 11) but fails to note our citation of this same subspecialty bias in physician actions (reference 9) and in end-of-life publications over the subsequent 20 years (reference 18).

We propose that understanding and respecting subspecialty differences in end-of-life opinions may advance us toward more effective collaboration with colleagues and more effective communication with our patients. We hope that we have shed some light on these differences and invite readers to generate their own hypotheses about causation.

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How To Blow Your Defense

To the Editor:

I was recently consulted by a medical malpractice attorney who asked for assistance in the defense of his client, a board-certified pulmonologist who had been managing a patient with very difficult steroid-dependent asthma. The patient also smoked cigarettes. The man, age 41, had acquired aseptic necrosis in both femoral heads requiring total hip replacements.

The patient had suffered from asthma since the age of 6 months. He had had several hospitalizations for asthma and frequent trips to the emergency department for life-threatening attacks. He had been appropriately managed by this pulmonologist, with the use of inhaled short-acting as well as long-acting agonists, inhaled corticosteroids, leukotriene modifiers and, at times, bursts of systemic steroids to deal with exacerbations of asthma and/or associated acute and chronic sinusitis.

The major issue in the plaintiff’s strategy was the fact that this pulmonologist had never done spirometry at any time during the management of this patient. Accordingly, the plaintiff argued that the patient never had asthma, which was one of the contentions of the medical expert hired by the plaintiff, also a board-certified pulmonologist. Fortunately, however, numerous measurements of peak flow during exacerbations, which demonstrated increases from low values up to the “personal best” level of approximately 450 to 500 L/min while in remission following corticosteroid treatment had been recorded. But why a simple spirogram was not done by the pulmonologist, as well as other pulmonary function tests, is beyond me. It certainly would have helped in this physician’s defense. Later, an allergist did perform spirometry, which showed severe airflow obstruction and air trapping with a normal diffusion test result.

This is the fourth or fifth time I have been asked to defend a
board-certified pulmonologist or internist in a similar malpractice action. The simple use of spirometry would have made the defense much easier.

John Hutchinson introduced spirometry in 1846. Some time ago, noted physiologist Joseph Milic-Emili wrote on 150 years of blowing, citing the work of Hutchinson, who coined the term vital capacity, and Tiffeneau of Paris, who added the timed vital capacity (ie, FEV1) to spirometry.2

Today, the National Lung Health Education Program recommends spirometry for all smokers ≥ 45 years old and anyone with dyspnea on exertion, chronic cough, mucus hypersecretion, or wheeze.3 Certainly the patient had all of these. The National Asthma Education and Prevention Program has recommended spirometry in the evaluation of asthmatics for more than a decade.4 Thus, spirometry has become the standard of care.

Physicians who treat asthma, COPD, and other pulmonary disorders for which steroids may be required will be well advised to “blow their defense” in the form of doing spirometry in conjunction with the initial patient assessment and for documentation of responses to therapy.

The issue of aseptic necrosis of the femoral head has been commented on for some time.5–7 It is not clear, however, if aseptic necrosis in patients treated with corticosteroids represents a drug complication, a complication of the disease process, or both.5–7 It is interesting that in 1965, a Massachusetts Supreme Court ruling (Frecket vs Frederic, 355 Mass 679) held that the risk of acquiring aseptic necrosis from long-term prednisone use was so negligible that the “informed consent” issue should not be used.

Simple spirometry is a requirement for the initial evaluation of patients with both obstructive and restrictive ventilatory disorders. It is key to monitoring responses to therapy. The use of spirometry will also help avoid trips to the courthouse. So always remember to blow your defense!

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**REFERENCES**

1. Hutchinson J. On the capacity of the lungs, and on the respiratory functions, with a view of establishing a precise and easy method of detecting disease by the spirometer. Medico-Chirurgical Transactions (London) 1846; 29:137–161


**What About the Role of the US Food and Drug Administration?**

To the Editor:

As a professional couple with one half in the world of human subjects’ protection and the other half in the world of academic pulmonary medicine, we read the article by Miller and Shorr1 and the accompanying editorial by Perkins2 with great interest. The article, in the April 2002 issue of CHEST, elucidated the many challenges faced by all of us who conduct research involving human subjects. The authors have brought us into focus the ethical challenges presented to the investigator, the institutional review board (IRB), and the sponsor. Although we agree with the authors regarding the problems that they have identified, we suggest that the responsibility for the problems is not limited to the three groups they have identified. We would like to point out some of the inherent and fundamental problems of industry-sponsored randomized clinical trials as they are currently conducted.

The current practice is that industry (with some input from expert consultants) designs clinical trials, the US Food and Drug Administration (FDA) reviews them, and then the sponsor then seeks sites for these trials. As Miller and Shorr’s point out, clinical trials have seen a tremendous change in recent times, moving away from academic medical centers and toward private practice settings. The scrutiny of IRB applications for these trials is different given the context of an independent IRB relative to the academic IRB. There is a potential and very real problem of “IRB shopping” with the obvious benefit that sponsors can have clinical trials conducted, unopposed and without modification. IRBs, both local and independent, are under extreme pressure to review protocols quickly and without requesting modification. By contrast, there is a strong tradeoff and clear need for local control of IRBs so that their actions reflect the communities that they serve. However, Miller and Shorr have pointed out the universal nature of the ethical dilemma confronting the investigators, the IRB, and the sponsor. Obviously, these groups did not meet this ethical challenge in the mometasone trial.

In this context, such review standards and, in fact, this level of review would be more appropriate at the level of the FDA. At the present time, the role that the FDA plays in the risk/benefit analysis for the subject is ambiguous. This realization leads to a variety of troubling questions. What was the role of the FDA in allowing a study such as the mometasone trial to proceed? In general, what kind of review does an investigational new drug application undergo? Is it reviewed by experts in the area of study? Does the FDA consider whether the protocol meets current guidelines for the treatment of the condition under study, or does the FDA see this as the responsibility of the sponsor or the local IRB?

Our local IRB is frequently told by sponsors that we are the only IRB that has issues with a particular protocol. These issues usually relate to our concerns with including a placebo arm, or with withholding or withholding proven treatment. Industry-sponsored clinical trials that do not pass ethical muster or put patients at unjustifiable risk should be stopped at the FDA review. They should be rewritten according to currently accepted guidelines for the treatment of the condition under study, and according to regulations meant to protect any vulnerable subjects who might be included.

At national IRB meetings last year (Public Responsibility in Medicine & Research), Robert Temple, MD, of the FDA...