A medical center is not a hospital

(SEPTEMBER 2008)

TO THE EDITOR: Dr. Thomas Lansdale's provocative essay "A medical center is not a hospital" (September 2008) is, in many respects, on target. I share some of Dr. Lansdale's disenchantment, but only some. Our profession is under the gun, and everyone expects more of us. But change is the fabric of life and gives us opportunities to advance our profession and alter the fate of our patients. And I haven't changed in one respect: I am still a "hospital guy" and I still am having fun.

The pressures faced in practicing medicine are enormous. Simply put, when medicine needs a sophisticated environment such as a hospital, we need to figure out how to meet the mortgage.

This is a problem when hospital managers are not physicians and are not at the bedside enough. Their charge is different. My former chief operations officer (an MBA) used to jokingly say, "*They* (meaning the academic full-time Cleveland Clinic staff) just don't get it." And I would say, "*They* (meaning the MBA management crew) just don't get it." Well, neither group usually does. They can't. They are of different worlds—until the MBA gets sick with crushing chest pain or the physician-manager suddenly has to face the music of a Wall Street bond collapse.

We can complain all we want, but we exist in a world of profit margin and EBITDA (earnings before interest, taxes, depreciation, and amortization). The challenge is to preserve the bottom line while also protecting physician time for reasonable research and education programs.

I happen to share Dr. Lansdale's love for diagnostic challenges presented by hospitalized patients. My specialty (advanced heart failure and cardiac transplantation) certainly remains exciting and challenging because of this.

And I cannot do what I do without a hospital—no heart transplants on my kitchen table! Let's get real: for many of us the hospital is still the only place we can practice and the only place we can save lives and alter the often-dismal prognosis of our most ill patients.

Yes, our practice has changed. We no longer strain to see a glossy wet Polaroid of an m-mode echo to diagnose mitral stenosis, and we no longer have only lidocaine and a prayer for acute myocardial infarction. We don't do our own Gram stains, urinalyses, and peripheral blood smears in the middle of the night, and AIDS is no longer called "thin-man disease."

And what about safety of hospitals? Well, don't forget history. Hospitals are no longer death houses. Hospital safety and clinical outcomes have never been better. Yes, they are not yet good enough, and egregious problems exist, but never before has so much attention and expense been paid to quality improvement, patient experience, and safety initiatives throughout the industry. No, hospitals are not perfect—never will be. But I am proud of what we are doing, what we have accomplished, and what we will accomplish in the future to make ill patients better when they are sick enough to require hospitalization.

So I am proud and happy to be a hospital guy. To Dr. Lansdale I say, don't give up. Your effort to preserve the passion of our noble profession is essential. Oh, and remember that Osler of Baltimore struggled with the same issues as did Codman of Boston. The more things change, the more they stay the same—except for the fact that hospitals are better.

JAMES B. YOUNG, MD
George and Linda Kaufman Chair
Chairman, Academic Department of Medicine, and the Endocrine & Metabolism Institute
Cleveland Clinic

TO THE EDITOR: As a grateful patient of Dr. Lansdale, and as a fortunate, rather healthy soul without medical knowledge and without, up to now, much experience as a hospital inmate, I fully acknowledge that you may well deem me a dubious, uninformed, and even biased commentator on "A medical center is not a hospital." However, I deeply appreciated Dr. Lansdale's important essay, and I commend you for publishing it. The conditions he describes contrast dramatically with those of yore.

Dr. Lansdale's essay took me back many years to the time of my mother's illness, when medicine was practiced differently, and, as she suffered bravely and eventually died of cancer, I recalled myself watching warily with the keen eyes of a child.

Our experience with Mother's nurses and doctors was unforgettable, for, in nearly every case, we knew we were dealing with men and women of the profoundest dedication. Mother's nurses at the Harkness Pavilion of the Columbia-Presbyterian Medical Center treated her (she died the day JFK was elected president) with unbounded tenderness, compassion, and patience.

They moved gracefully, walked quietly in her room, spoke softly but clearly to her, and to me, a girl, they seemed like angels. Nothing was too much; they fluffed her pillows, propped the window to give her fresh air, refrained from rattling or jarring the equipment, and seemed to sense what she was feeling and to provide accordingly. Her care was a kind of devotion, I felt, and there was no sense of rush or artificial curtailment of their responses to her. They always had a kind word for me as well.

And where has this sense of vocation gone? I have no doubt there are still many who enter the health professions with a deep desire to alleviate the suffering of others, but, as Dr. Lansdale's essay shows, these people are now constrained, limited, and held back. Their care is degraded and seen as a job, a workload. What has happened to the sense of joy in alleviating even a moment of pain by administering a cold washcloth, finding a warm blanket, or holding a hand? This I saw years ago.

As for Dr. Lansdale himself, when I had the first and only major operation of my life, he appeared unexpectedly in my hospital room on a Sunday morning a couple of days later. In his arms were a container of soup he had made himself and a tiny vase of flowers grown by his wife. Tears filled my eyes after he left because he made me realize that he saw me not just as a broken body but as a human being who loved loveliness and who was on the way back to health.

The ancient Greeks understood that medicine and nursing are arts. They still are. And artists must be given the freedom, time, and chance to follow their best instincts. They deserve our honor and trust.

ELLEN HANDLER SPITZ, PhD
Honors College
Professor of Visual Arts
University of Maryland
Baltimore

The ENHANCE trial

(JULY 2008)

TO THE EDITOR: I read with great interest Dr. Davidson's commentary article[1] about the Ezetimibe and Simvastatin in Hypercholesterolemia Enhances Atherosclerosis Regression (ENHANCE) trial.[2] However, his conclusion that ezetimibe (Zetia) still has a role as an add-on to statin therapy for patients who have not achieved their low-density lipoprotein cholesterol (LDL-C) target is of great concern to me and my patients. Based on this trial, I have taken many of my patients off of ezetimibe and have wondered if this is the right decision. I also have several physician patients who have told me that ezetimibe causes muscle cramping and other symptoms often found in patients who cannot tolerate statins, and in fact one of these patients was found to have congenital cirrhosis of the liver.

Ezetimibe is mainly active in the GI tract. What relationship does this medication have in those patients who have liver disease, ie, cirrhosis? Is it safe to give ezetimibe to patients who cannot take statins? I doubt it.

Consequently, I agree with Dr. Taylor's editorial,[3] which in essence states unless you are in a clinical trial, beware of ezetimibe!

WILLIAM H. FEE, JR, MD
Chest Medicine Associates
Seneca, PA

TO THE EDITOR: Dr. Davidson concludes his article saying "we should remember [that ezetimibe] is safe and well-tolerated." Yet, he admits there is a lack of outcomes data for

the drug. So, how does he know it is safe if we don't have the mortality outcomes? The just-published Simvastatin and Ezetimibe in Aortic Stenosis (SEAS) trial indicated that there may be an increase in cancer mortality.[4] The point is that we need more data. Until we have that outcomes data we should not be saying a drug is safe as a matter of fact. Physicians need to learn the lessons we should have learned from drugs such as torcetrapib[5] or erythropoietin[6] and so many others. We often think we are doing a good thing by correcting lab values, but we often learn too late that we harmed the patient at a staggering ethical and financial cost.

Dr. Davidson also references the impressive LDL-C lowering of Senator McCain while taking ezetimibe. Senator McCain has a publicized history of melanoma. Hopefully, ezetimibe doesn't increase his cancer mortality risk because his physicians are proud of his LDL-C lowering. My advice to the senator is to use one of the many other proven methods of LDL-C lowering until there is good mortality outcome data with ezetimibe (but I'm not a Republican, so he may want to get a second opinion).

GIL PORAT, MD
Penrose Hospital
Colorado Springs, CO

IN REPLY: Both Dr. Fee and Dr. Porat recommend cautious utilization of ezetimibe until outcome studies are completed. As I stated in my article, it is unfortunate that for ezetimibe, hard outcome trials are not yet available (the SEAS trial showed a cardiovascular benefit for the combination of simvastatin/ezetimibe, but it was not the primary end point). The main point of my article is that the weight of evidence for the benefits of LDL-C lowering is one of the most proven surrogate measures in clinical medicine. The biology, epidemiology, and clinical trials with multiple LDL-C-lowering therapies (bile-acid resin, niacin, fibrates, diet, ileal bypass surgery, and statins) convincingly demonstrate the validity of this surrogate measure for regulatory approval. In fact, every drug that has been approved for the treatment of hypercholesterolemia has been based on LDL-C reduction and not on outcome trials.

If this requirement was in place, it is doubtful that statins would have been approved. Lovastatin was approved by the US Food and Drug Administration in 1987; the Scandinavian Simvastatin Survival Study (4S) trial[7] was completed in 1994. The 4S trial showed, for the first time, a reduction in total mortality with an LDL-C-lowering therapy. Millions of patients were placed on statins prior to 1994, and it is unlikely the 4S trial would have been funded unless there had been prior regulatory approval.

As a researcher, I truly believe hard outcome trials are essential, but as a clinician, I realize that most of our medical care is based on drugs approved utilizing surrogate measures. Hard outcome trials are not required for antihypertensives, oral hypoglycemics, or smoking cessation treatments prior to approval. Ezetimibe lowers LDL-C by a known mechanism and is well tolerated. The ENHANCE trial, with its well-recognized flaws, should not refute the benefits of LDL-C reduction. For patients not at goal on statin therapy, ezetimibe should remain a widely used option.

MICHAEL H. DAVIDSON, MD
Section of Cardiology
University of Chicago

REFERENCES

1. **Davidson MH**. Interpreting the ENHANCE trial. Is ezetimibe/simvastatin no better than simvastatin alone? Lessons learned and clinical implications. Cleve Clin J Med 2008; 75:479–491.
2. **Kastelein JJ, Akdim F, Stroes ES, et al: ENHANCE Investigators**. Simvastatin with or without ezetimibe in familial hypercholesterolemia. N Engl J Med 2008; 358:1431–1443.
3. **Taylor AJ**. Given the enhance trial results, ezetimibe is still unproven. Cleve Clin J Med 2008; 75:497–506.
4. **Rossebø AB, Pedersen TR, Boman K, et al, for the SEAS Investigators**. Intensive lipid lowering with simvastatin and ezetimibe in aortic stenosis. N Engl J Med 10.1056/NEJMoa0804602.
5. **Barter PJ, Caulfield M, Eriksson M, et al**. Effects of torcetrapib in patients at high risk for coronary events. N Engl J Med 2007; 357:2109–2122.
6. **Wright JR, Ung YC, Julian JA, et al**. Randomized, double-blind, placebo-controlled trial of erythropoietin in non-small-cell lung cancer with disease-related anemia. J Clin Oncol 2007; 25:1027–1032.
7. The Scandinavian Simvastatin Survival Study (4S). Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease. Lancet 1994; 344:1383–1389.