

GUEST EDITORIAL

Stop Excluding the Elderly From Clinical Trials

We desperately need more and better data on how to manage cardiovascular diseases in elderly patients, and in particular in the advanced elderly.

Most studies that assessed diagnostic methods of treatments for cardiovascular diseases systematically excluded elderly patients, starting with those aged at least 65 years but especially the oldest elderly, those 80 or older. The irony is that these "oldest old" patients have both the highest prevalence of cardiovascular disease and constitute the fastest-growing segment of the U.S. population. Every effort should be made to include in clinical trials patients older than 75-80 years as long as they are stable and willing to participate.

In some ways, excluding the elderly had some rationale. Because of their multiple comorbidities and their polypharmacy, elderly patients introduced a heterogeneity that made studies harder to conduct and interpret. While comorbidities in elderly patients can complicate the analysis of a trial's results, inclusion of these patients helps to ground a trial in real-world concerns. It's important to study the interaction of a new treatment with comorbidities and to assess a treatment's im-

act on functional status, quality of life, and cost effectiveness. Elderly patients present issues of impaired cognitive function and frailty, which can lead to study dropout. The risk of dropout is magnified when transportation issues are not appropriately addressed.

But these variables are counterbalanced by the demographic imperative of including the elderly. Cardiovascular disease is primarily a disease of the elderly, and among the elderly cardiovascular disease is the primary illness. Elderly patients can also benefit from the group dynamics that participation in a trial offers. Social isolation is a major problem for the elderly. Being in a trial can bring an elderly patient in contact with like-minded peers, offer the social support of trial staff members, and may improve their quality of life.

We need more information on how to treat our burgeoning elderly population. For example, almost 85% of pacemakers implanted in the United States are in patients aged 65 or older. The elderly also receive about half of the defibrillators that are now implanted. When a broad spectrum of age groups is enrolled in a trial, medicine gains important additional insights into how a treatment can be applied

in everyday practice. The Food and Drug Administration encourages pharmaceutical companies to include in their studies patients who match the profile of the people expected to use the new agent once it is approved and on the market.

Cardiovascular therapies are currently not as widely used in elderly patients as at younger ages. For example, in the CRUSADE (Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes With Early Implementation of the American College of Cardiology/American Heart Association Guidelines?) national quality improvement initiative registry, which involved patients with acute coronary syndrome, lipid-lowering therapy was given to half of the patients older than 75, compared with 70% of those younger than 75. Data from the Framingham Heart Study, collected during the 1990s, showed that among patients with hypertension aged 80 or older, only 38% of men and 23% of women had blood pressure control to recommended levels of less than 140/90 mm Hg.

In 1992, I chaired a workshop at the American College of Cardiology that summarized several of the then-pressing issues on how to manage cardiovascular disease in elderly patients. Our list included the following questions:

► **What is the efficacy of preventive interventions in the elderly?** We noted that

the potential benefit of prevention was likely magnified in the elderly because of the high attributable risk in this subgroup.

► **What is the efficacy of diagnostic testing?** Use of diagnostic testing tends to decrease in older patients. Is this appropriate? Does early testing that leads to interventions produce improved outcomes?

► **Is the current practice of treating cardiovascular disease in elderly patients only when symptoms occur appropriate?** Do outcomes improve if the high-risk yet asymptomatic elderly are also treated?

► **What drug regimens for cardiovascular disease are optimal in the elderly?** For example, isolated systolic hypertension and diastolic dysfunction are major problems in the elderly. What are the optimal treatment regimens for this?

► **For the burgeoning interventional procedures—is there different risk or benefit for patients at an advanced age?**

Despite the challenges identified at the workshop, none of these questions has been adequately answered. And these issues are as important today as they were 14 years ago. ■

DR. WENGER is a professor of medicine (cardiology) at Emory University and chief of cardiology at Grady Memorial Hospital in Atlanta. This editorial is based on a keynote address at the annual scientific sessions of the Society of Geriatric Cardiology in Atlanta.



BY NANETTE K. WENGER, M.D.

LETTERS

Diabetes Registry Not a Solution

Dr. Lynn Silver and others have decided that collecting patients' data on diabetes and then sending them letters will help control diabetes, and they maintain that "the potential benefit in light of the epidemic condition outweighs any risk to privacy." They also argue that doctors can't take care of patients without an electronic medical record ("NY Diabetes Monitoring Program Raises Privacy Concerns," February 2006, p. 6). Wrong on all counts.

Sending patients letters is not going to make a difference in management. As for dietician counseling and diabetes education, physicians are already doing that. Why pay for a duplicative system?

Also, nothing in an electronic database is confidential, and it will lead to discrimination and data brokering. Others don't have the right to decide for the patient that the benefits outweigh the risks.

Finally, medical management takes cognition, conscientiousness, knowledge, and experience. Recording it on paper or in a computer doesn't indicate quality of care.

It's time for doctors, patients, and taxpayers to nip this one in the bud.

Frances Parisi, M.D.
Lancaster, N.Y.

'Cookbook' vs. Real-World Medicine

As commonly occurs, an academic physician discussing the medical system as it exists comes forth with a simplistic response to an infinitely complicated envi-

ronment ("Crossing the Quality Chasm in Health Care," February 2006, p. 36.).

In his Guest Editorial, Dr. Harvey V. Fineberg described multiple methods whereby improvement in the medical health care system could produce a decrease in errors.

As a pulmonary critical care physician, I see innumerable uncommon presentations for common diseases that do not lend themselves to diagnoses with a "cookbook" or "practice guideline" method. Proper diagnosis and subsequent therapeutic planning require a thoughtful and appropriate evaluation in an individually designed logical and stepwise fashion.

This is not something that will be supplanted by guidelines which ignore the input of highly trained physicians.

The concept that you can create guidelines that allow hospital-based physicians or outpatient physicians to avoid errors simply by following a stepwise/cookbook model is facetious, and, again, one that is commonly promoted by academic physicians who do not live in the real world of medicine.

I agree that the model that Dr. Fineberg recommends to address some of these issues, such as giving physicians time to evaluate their patients appropriately, is good.

However, the current financial environment, with its increasing demands on physicians, does not help promote that model.

My recommendation is that Dr. Fineberg advocate for physicians to be "adequately protected" in terms of time constraints, legal constraints, and third-party payer constraints.

This may be a more effective mechanism to reduce hospital or office errors.

Gary R. Schafer, M.D.
Forest City, N.C.

Dr. Fineberg replies:

Dr. Schafer seems to regard my call for greater reliance on standards and guidelines in medical practice as a replacement for expert clinical judgment.

To the contrary, well-framed guidelines do not supplant expert medical judgment, nor are they a cookbook that treats every patient the same. Rather, guidelines informed by the best medical expertise can aid clinical decision making, match diagnostic and treatment strategies to the individual circumstances of each patient, avoid errors, and save lives.

In Dr. Schafer's field of pulmonary medicine, the American College of Chest Physicians has issued evidence-based guidelines on managing patients with problems ranging from cough to lung cancer (see www.chestnet.org/education/guidelines/currentGuidelines.php).

Dividing the House of Medicine

I am outraged that the American Medical Association has conducted secret negotiations with members of Congress, which end up being "on behalf" of all U.S. physicians ("AMA Pay-for-Performance Agreement Stirs Debate," April 2006, p. 39).

I am very troubled by the concept of performance measures. The mere fact that Congress wishes to develop performance measures implies that Medicare is not getting its money's worth from American physicians. What a joke!

All of us are working harder, documenting more, and providing better care for our patients due to the advances in medical science. We have been rewarded by declining reimbursements compared with the cost of living and malpractice expenses.

Performance goals will be a tool to divide the house of medicine, separate the "good" physicians from the "bad" physicians, and further decrease reimbursement to the profession as a whole. And there will be even more documentation requirements.

I wish the AMA and the American College of Physicians were taking these messages to Congress, instead of selling us out.

Eric Frankenfeld, M.D.
Bellingham, Wash.

LETTERS

Letters in response to articles in CARDIOLOGY NEWS and its supplements should include your name and address, affiliation, and conflicts of interest in regard to the topic discussed. Letters may be edited for space and clarity.

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