prudent to demonstrate the utility of cerebral SPECT imaging as it impacts on clinical management decisions. Although our studies were one of several in the patients' workup, if a change in clinical management decisions resulted, it was specifically due to the results of the cerebral SPECT scan. This was confirmed during the follow-up interview.

Although MRI and CT will continue to be useful tools, cerebral SPECT imaging will be a critical part of the workup in patients with neurologic and psychiatric disorders. We identified a significant impact of cerebral SPECT imaging in clinical management decisions. Although preliminary evaluation of the effect of these management decisions on patient morbidity, mortality and cost containment appears to be favorable, long-term follow-up is needed to confirm these initial results.

REFERENCES

1. Van Heertum RL, Miller SH, Mosesson RE. SPECT imaging in neurologic disease. *Radiol Clin North Am* 1993;31:881–908.
2. Matsuda H, Tsuji S, Sumiya H, et al. Acetazolamide effect on vascular response in areas with diaschisis as measured by ^{99m}Tc-HMPAO brain SPECT. *Clin Nucl Med* 1992;17:581–586.
3. Yudd AP, Van Heertum RL, Masdeu JC. Interventions and functional brain imaging. *Semin Nucl Med* 1991;21:153–158.
4. Mountz JM, Modell JG, Foster NL, et al. Prognostication of recovery following stroke using the comparison of CT and technetium-99m-HMPAO SPECT. *J Nucl Med* 1990;31:161–166.
5. De Roo M, Mortelmans L, Devous P, et al. Clinical experience with Tc-99m-HMPAO high resolution SPECT of the brain with cerebrovascular accidents. *Eur J Nucl Med* 1989;15:9–15.
6. Podreka I, Suess E, Goldenberg G, et al. Initial experience with technetium-99m-HMPAO brain SPECT. *J Nucl Med* 1987;28:1657–1666.
7. Yeh SH, Liu RS, Hu HH, et al. Brain SPECT Imaging with ^{99m}Tc-hexamethylpropyleneamineoxime in the early detection of cerebral infarction: comparison with transmission computed tomography. *Nucl Med Commun* 1986;7:873–878.
8. Jagust WJ, Reed BR, Seab JP, et al. Alzheimer's disease: age at onset and single-photon emission computed tomographic patterns of regional cerebral blood flow. *Arch Neurol* 1990;47:628–633.
9. Johnson KA, Holman BL, Rosen TJ, et al. Iofetamine ^{123}I single-photon emission computed tomography is accurate in the diagnosis of Alzheimer's disease. *Arch Intern Med* 1990;150:752–756.
10. O'Connell RA, Van Heertum RL et al. Single-photon emission computed tomography (SPECT) with ^{123}IMP in the differential diagnosis of psychiatric disorders. *J Neuropsychiatry* 1989;1:145–153.
11. Hunter R, McLuskie R, Wyper D, et al. The pattern of function-related regional cerebral blood flow investigated by single-photon emission tomography with 99m-HMPAO in patients with presenile Alzheimer's disease and Korsakoff's psychosis. *Psychol Med* 1989;19:847–855.
12. Launes J, Sulkava R, Erkinjuntti T, et al. Technetium-99m-HMPAO SPECT in suspected dementia. *Nucl Med Commun* 1991;12:757–765.
13. Miller BL, Cummings JL, Villanueva-Meyer J, et al. Frontal lobe degeneration: clinical neuropsychological and SPECT characterizations. *Neurology* 1991;41:1374–1382.
14. Bonte FJ, Stokely EM, Devous MD, et al. Single-photon tomographic study of regional cerebral blood flow in epilepsy. *Arch Neurol* 1983;40:267.
15. Abdel-Dayem HM, Sadek SA, Kouris K, et al. Changes in cerebral perfusion after acute head injury: comparison of CT with ^{99m}Tc-HMPAO SPECT. *Radiology* 1987;165:221–226.
16. Choksey MS, Costa DC, Iannotti F, et al. Technetium-99m-HMPAO SPECT studies in traumatic intracerebral hematoma. *J Neurol Neurosurg Psych* 1991;54:6–11.
17. Masdeu JC, Van Heertum RL, Kleiman A, et al. Early SPECT in mild head trauma: a controlled study. *J Neuroimaging* 1994;4:177–181.
18. Roper SN, Mena I, King WA, et al. An analysis of cerebral blood flow in acute closed-head injury using technetium-99m-HMPAO SPECT and computed tomography. *J Nucl Med* 1987;32:1684–1687.
19. Batjer HH, Devous MD. The use of acetazolamide-enhanced regional cerebral flow measurement to predict risk to arterio venous malformation patients. *Neurosurgery* 1992;31:213.
20. Toyama H, Takeshita G, Takeuchi A, et al. Cerebral hemodynamics in patients with chronic obstructive carotid disease by rCBF, rCBV and rCBV/rCBF ratio using SPECT. *J Nucl Med* 1990;31:55–60.
21. Pohl P, Vogl G, Fill H, et al. Single-photon emission computed tomography in AIDS dementia complex. *J Nucl Med* 1988;29:1382–1386.
22. Tatsch K, Schielke E, Bauer WM, et al. Functional and morphological findings in early and advanced stages of HIV infection: a comparison of ^{99m}Tc-HMPAO SPECT with CT and MRI studies. *Nucl Med* 1990;29:252–258.
23. Masdeu JC, Yudd A, Van Heertum RL, et al. Single-photon emission computed tomography in human immunodeficiency virus encephalopathy: a preliminary report. *J Nucl Med* 1991;32:1471–1475.
24. Mayberg HS, Lewis PJ, Regenold W, et al. Paralimbic hypoperfusion in unipolar depression. *J Nucl Med* 1994;35:929–934.

EDITORIAL

"Frankly, My Dear, I Don't Give a Damn."

This quotation is one of the most-famous in all motion picture history. Unfortunately, it also represents the current state of advances in health care in the United States. The advocacy of new procedures or novel applications for old procedures is of little interest, except to the procedure advocates, unless costs and outcomes are clearly outlined. The medical world has become a cold, hard place where economics, not science alone, governs the diffusion of technology. The response to this change by the medical imaging community has been inadequate.

The article by Bloom et al. (*1*) in this issue represents a case in point. Let us assume that all their conclusions are valid and that the data are indeed correct. What, then, could the fault be with this report? It has passed a peer review and has been judged to be scientifically valid. Yet, by 1996 standards for publication, this report is indeed flawed.

A recent review of the appraisal of diagnostic studies in the literature indicated some of the typical problems in reporting results of diagnostic tests (*2*). That review indicated that bias was avoided in less than 50% of the studies. Reporting of indeterminate results was poorly identified, and adequate patient numbers were rarely used, so that statistical validity was uncertain, among other problems. Bloom et al. (*1*) studied very small patient groups, used subjective measures and, most significantly, failed to measure the true outcome of the study.

The measurement of what has come to be known as "outcomes" has evolved and changed over the past several years. As recently as 1990, when we spoke of outcome we were talking about the impact of a given procedure or therapy on a patient. It was the more traditional and, for the physician, a more satisfying kind of outcome. A patient got better or did not. With the coming of the health care reform initiatives, "outcomes" have become more complex. At times, it is unclear whose outcome we are even referring to. Are we talking about a given patient, a population of patients, the economic viability of a third party or a physician group? While we may bemoan these changes and wish to ignore them, we cannot.

When preparing a clinical research project or report, the investigator must bear in mind the multiple audiences it will reach. It should go without saying that the demands for a rigorous, prospective design are greater today than ever before. Both the radiology and nuclear medicine literatures are replete with articles reporting 20 cases of this or 30 cases of that, with profound conclusions drawn. Often, there are no control subjects, the pretest probability of disease is high, the

Received Feb. 21, 1996; revision accepted Feb. 21, 1996.

For correspondence or reprints contact: Robert Henkin, MD, Department of Nuclear Medicine, Loyola University Medical Center, 2160 South First St., Maywood, IL 60153.

diagnoses poorly documented, the costs lacking and the outcomes unknown. For these reasons, our clinical colleagues have become suspicious of our literature.

Several recent studies attempting to analyze nuclear medicine publications have demonstrated the lack of adherence to appropriate methodology for study design. In one of these studies, only 43 usable reports survived methodological analysis from a group of more than 4000 manuscripts (*3*). In another study, only 9 reports of more than 900 survived such analysis (Schwartz S, *personal communication,* 1995). The reasons are the same as those cited previously and basically result from faulty experimental design or incomplete reporting of findings. The stakes today, however, are too high to allow this to occur.

The two studies just cited were attempts to demonstrate that nuclear medicine procedures had acceptable degrees of accuracy in certain clinical settings. The data were supposed to show that nuclear medicine procedures were comparable to or better than other methodologies in a given clinical setting. Unfortunately, because of the poor quality of the available reports, the analysis itself was questionable. Sophisticated readers of meta-analysis data would immediately recognize the defects in such publications. It is a variant of the old saying "garbage in, garbage out."

The immediate need is for use of consulting methodologists to assist in the design and review of new clinical research projects. If we are to be credible, then we must be sure that the quality of our clinical research matches that of our basic science publications. We would never accept a basic science report in which key data are missing. We should insist on that same standard for our clinical pieces. This, however, is the easier of the problems to solve.

The most significant problem facing clinical nuclear medicine is the continued acceptance of our procedures in a world where "cost/benefit" has become dominant. We can easily compute cost data. Benefit data are much more difficult to come by and have therefore been largely ignored. Other areas of medicine are beginning to deal with this issue in publications. Abstracts and reports routinely contain information on the cost of the regimen proposed and the relative costs compared with other regimens for the same disease. Where costs for the proposed treatment course are higher, data must be included to show some offsetting benefit. Is the therapeutic proposal one that shortens hospital stay? Does it provide a measurably better outcome for the patient? Is it less expensive with the same outcome as other currently used approaches? These questions are being asked by journal reviewers and answered before manuscripts are accepted for publication.

In nuclear medicine, there are unique problems with regard to this approach. The cost of any nuclear medicine study is usually trivial compared with the overall cost of caring for the patient. We must realize, however, that advocacy of procedures that are costly and have minimal impact can represent an unacceptable cost to society. To continue to be accepted, procedures must have an impact on patient care. We must be able to show that what we do not only leads to changes in therapy (as Bloom et al. (*1*) imply), but also leads to a better outcome in terms of either cost or clinical results. In the simplest terms, what we must require is that our publications demonstrate a measurable impact on patient management and that this impact is positive. Change alone is not enough. The weather changes constantly but not always for the better. Changing the management of a patient carries with it certain risks and benefits. To which side of the balance is it tipped by what we do? On the whole, do we lead to management changes that are positive or negative for a given clinical setting?

What is required in the imaging literature is the same change as that required in imaging as whole. Our studies can no longer be reported in the vacuum to which we were accustomed. Patients need to be followed up. The change in management must be objectively documented and recorded and correlated with the short- or long-term course of the patient, as appropriate. Is the detection of a myocardial or cerebral perfusion defect a significant event in all patients? In what clinical setting does it become significant? In bone scanning, when do we reach the point of diminishing returns in metastatic disease? The simple reporting of sensitivity and specificity does not deal with the clinical impact of the examination. It gives you some feeling for whether or not results are reliable, but not whether they are useful. By omitting the cost and outcomes data from our discussions, we place ourselves in a gray area.

Many echocardiographers have challenged nuclear medicine myocardial perfusion imaging (MPI) on cost grounds. An echocardiogram often costs less than an MPI study. The sensitivity of such studies is reportedly equal, yet we believe that the cost of a nuclear study is justified by its increased prognostic value. We all know this intuitively, but where are the cost and outcome data to back this up? If we simply use sensitivity data, stress echocardiography is justified because it costs less. It is the outcome data for the patient that make the potential difference.

It would be appropriate for the *Journal* to undergo a change in editorial policy. To be accepted, clinical reports should deal with cost and outcome as well as diagnostic accuracy. Medicine has always been a combination of art and science. Today the art of medical practice includes the ability to select the appropriate diagnostic tests that yield the most useful management information at the lowest cost. If we do not provide that information for nuclear medicine procedures, who will?

Bloom et al. (*1*) have recognized this issue and have gone part of the required way. They have documented that cerebral perfusion imaging changes managing physician behavior. The challenge we now face is to see whether that change is better for the patient in terms of a positive impact on the cost of caring for the patient, or results in marked clinical benefit. We must now begin to apply standards of outcome and cost to all clinical situations as appropriate. Failure to take these steps will leave us as advocates for technology and not the patient.

Robert E. Henkin
Loyola University Medical Center
Maywood, Illinois

REFERENCES

1. Bloom M, Jacobs S, Pile-Spellman J, et al. Cerebral SPECT imaging: effect on clinical management. *J Nucl Med* 1996;37:1040–1043.
2. Reid MC, Lachs MS, Feinstein AR. Use of methodological standards in diagnostic test research: getting better but still not good. *JAMA* 1995;274:645–651.
3. Henkin RE, Kalosudian S, Kikkawa RM, Kemel A. *Myocardial perfusion imaging utilizing single-photon emission computed tomography (SPECT).* Diagnostic and Therapeutic Assessment Series (DATTA), July. Chicago: American Medical Association; 1994.