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Cost-Effectiveness Analysis in Nuclear Medicine

Cost-effectiveness analysis (CEA) is a method for evaluating the health outcomes and resource costs of various patient management algorithms or pathways (sets of tests and interventions that explicitly describe the full management of a patient). CEA remains underutilized by nuclear medicine researchers and also continues to be misunderstood by many health care personnel. This is due in part to the nature of our profession. As nuclear medicine physicians, we often do not understand how the result of a particular imaging study fully affects a particular patient's entire medical/surgical management. This is perhaps best exemplified by oncology management, which is complex, with rapidly changing management options. Yet management is key to understanding how a given nuclear medicine study may play a cost-effective role in patient care. As an example of how serious the rest of the medical profession is about starting to formalize patient management pathways, it is significant to note that the entire November 1996 issue of *Oncology* [1996;10 (suppl)] was devoted to patient management algorithms developed by National Comprehensive Cancer Network member institutions. Updates of these guidelines are expected to be published periodically. Many management guidelines are being developed by various organizations, and nuclear medicine professionals must be careful to ensure that nuclear medicine procedures are appropriately included.

But within nuclear medicine, articles dealing with the subject often continue to use the term *cost-effective* inappropriately: Most studies simply look at the cost components of procedures without considering effectiveness, and although it can be useful to look at cost alone, a study is not complete unless effectiveness is also fully considered. Another misunderstanding is not realizing that costs must include all costs incurred in patient management, not just the costs up to and including imaging. Certainly, if one were trying to optimize costs alone, the solution would be to perform no medical interventions (imaging or otherwise), even for palliative management! Alternately, if one were trying to maximize effectiveness alone, one would perform many tests and interventions that would otherwise be cost prohibitive, assuming the tests and interventions did not lead to any patient morbidity or mortality. In the case of limited health resources it is important to *balance* both costs and effectiveness. According to one commonly accepted definition of cost-effectiveness, it is necessary to determine if a given intervention produces benefits that are worth the additional costs incurred.

The incremental cost-effectiveness ratio (ICER) is one of the most general ways to compare a newly emerging strategy with an existing one. This ratio compares the difference in costs between the two strategies divided by the difference in their effectiveness. Using the ICER, one can arrive at the costs-per-year-of-life-saved for a newly emerging strategy. It is important to note that the exact costs that should be used (e.g., reimbursed costs) and the best measures of effectiveness (e.g., quality of life) still continue to be highly debated. Nevertheless, many guidelines exist for performing CEA studies, many of which are discussed in articles in the *Journal of the American Medical Association* and the *Journal of Medical Decision Making*. Mathematical details of how to perform CEA are covered in various books and articles. A fairly extensive list of relevant resources (including articles and books on performing CEA) can be found on the Web site of the Decision Analysis Society (http://www.fuqua.duke.edu/faculty/daweb/dafield.htm).

Some software packages currently available for use in decision analysis include Data™ (TreeAge Software, Inc., Williamstown, MA) and DecisionPro (Vanguard Software Corp., Cary, NC). Some of the software tools available, such as PrecisionTree (Palisade Corp., Newfield, NY), are directly usable with spreadsheet packages such as Microsoft Excel (Microsoft Corp., Redmond, WA). My laboratory has also developed a physician-friendly decision analysis tool featured in the January 1998 issue of the medical informatics journal *M.D. Computing*. All of these software tools are powerful, but they must be used carefully to arrive at meaningful results. Although there are no reviews comparing all of the various software packages, the Decision Analysis Society has a listing of many of the tools available for various applications.

In the near future, especially in larger hospitals, hospital information systems will track patients through every aspect of their medical care. Such a system is already being tested at Memorial Sloan-Kettering Cancer Center. These systems should allow medical and hospital personnel to track almost every aspect of patient care (from simple blood tests to long-term follow-up). This in turn will allow us to understand many detailed management issues that are currently very difficult to track. Information access will continue to be key in the future of medical management. Decision analysis systems that will operate over the Internet are already under development and should help health care providers share information on patient management algorithms as well as simulate on-line CEA specific to a given hospital or HMO.

CEA is important from many different perspectives. These include the following: (1) helping nuclear medicine physicians understand how a given nuclear medicine study fits into the overall management of a patient, (2) providing objective data that justify the role of a particular study, (3) allowing physicians to understand how poorly a study can perform (e.g., how low can the sensitivity get?) and yet still be cost-effective, (4) allowing answers to "what if" questions (e.g., how expensive can a newly emerging technology be for it to remain cost-effective in a given set of applications?) and in this way help design future technologies, (5) helping nuclear medicine physicians understand what portion of the receiver-operator characteristic curve we should operate at to be most cost-effective (e.g., operate at high specificity to prevent a significant number of false positives that may lead to follow-up procedures with relatively high morbidity) and (6)

allowing nuclear medicine physicians to present objective evidence to hospitals, insurance companies and even federal regulatory agencies, leading to more rapid acceptance of and reimbursement for newly emerging technologies.

Carefully performed CEA involves collaboration between numerous clinicians, biomathematicians, statisticians and health economists, as well as patients affected by the disease. If the clinical problem is not well modeled, then no analysis can salvage the CEA. Alternatively, understanding the clinical problem is critical, but the mathematical modeling needs to be properly applied to arrive at useful conclusions. Many people are intrigued by the technique but fail to understand its real utility. We as physicians must be careful to provide the best quality of care possible to our patients, but we must also fight to objectively prove the utility of our imaging protocols for various management algorithms. More importantly, we must be willing to accept that some applications of our imaging studies are not cost-effective and should not be utilized purely for economic gains.

For newly emerging technologies (e.g., coincidence imaging with gamma cameras) as well as newly emerging clinical tracers, it is important that proper clinical trials and CEA be performed in conjunction with each other. One can always make a stronger case for a new imaging study if its role in patient management has been proven in a well-designed clinical trial. Many of the CEA studies available to date have been done by combining literature data with existing management algorithms, and they are therefore not as compelling as prospective trials. ADAC Corporation is currently performing a multicenter prospective study utilizing molecular coincidence detection technology for the evaluation of lung cancer staging and solitary pulmonary nodules with fluorodeoxyglucose. Similar studies, in which industry, university hospitals and community hospitals work together, should be encouraged.

Workshops at the Society of Nuclear Medicine (SNM) Annual Meeting in June 1997 presented various aspects of CEA. These included a workshop in which Dr. David Mankoff discussed CEA as it relates to breast cancer and scintimammography. There was also a workshop on the role of positron imaging in lung cancer in which I discussed CEA as it has been applied to non-small cell lung cancer staging and solitary pulmonary nodule diagnosis. A workshop that will cover CEA and lung cancer is planned for the June 1998 SNM Annual Meeting in Toronto. The Institute for Clinical PET also held a workshop on CEA in 1996 and several talks in October 1997.

I expect that there will be more workshops explaining the details of CEA with important new relevant areas of application over the next year. One of the best ways to understand CEA is to apply it to a nuclear medicine procedure of current interest. At the 1997 SNM Annual Meeting, there were 12 presentations and posters that applied CEA to various nuclear medicine procedures. Unfortunately, some of these did not model the effectiveness component, only the cost component. It is likely that articles addressing CEA will continue to increase in number and quality over the next few years. The *Quarterly Journal of Nuclear Medicine* has an issue devoted to nuclear medicine health economics and CEA planned for publication in early 1999. Guest editors for this issue include Professor Michael Maisey and Dr. Peter West (a health economist).

CEA is expected to continue to play a major role in the evaluation of current and future nuclear medicine studies. It is vital that we continue to perform CEA studies and apply the results from such studies with a proper understanding of their limitations. Nuclear medicine can be enhanced only if we continue to aggressively prove the cost-effective role of our procedures while providing the best quality care for our patients.

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FDA Reform Act

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effect and will still exclude PET drugs and radiopharmaceuticals from federal laws governing compounding. However, the FDA is not forbidden from revising the guideline. "We were excluded from all restrictions in the pharmacy compounding law," said David Nichols, director of government relations for the ACNP/SNM Government Relations Office.

Compounding laws come into play when researchers and physicians prepare or alter a medication dose for an individual patient, which is almost always the case with PET radiopharmaceuticals. Each state has its own set of compounding laws to ensure quality and purity, but the FDA laws will be more specific, dictating when and if products should be compounded. In the compounding legislation, there are seven additional requirements that pharmaceutical manufacturers must meet, including obtaining chemicals from FDA-approved manufacturers and compounding only products that comply with a USP monograph or are approved by the FDA. (See "Government Relations Update," page 26N.) "These regulations could have been a severe hindrance to radiopharmaceutical manufacturers had they not been excluded from the legislation," said Nichols.

The complete text of the three provisions of the FDA Modernization Act of 1997 (S. 830) pertaining to nuclear medicine can be downloaded from the SNM home page (http://www.snm.org). To access it, click on the "Government Relations" header, and then click on "Documents." If you cannot access the home page, contact the ACNP/SNM Government Relations Office at (703) 708-9773 or e-mail David Nichols at dnichols@snm.org.

—Deborah Kotz