Testimony to Joint Economic Committee

Congress of the United States

Hearing on Technology, Innovation and Their Effects on Cost Growth of Healthcare

Neil R. Powe, MD, MPH, MBA

July 9, 2003

Good morning Mr. Chairman, Senators and Representatives. I am Neil R. Powe, MD, MPH, MBA, Professor of Medicine, Epidemiology and Health Policy & Management at Johns Hopkins University in Baltimore, Maryland. I direct the Welch Center for Prevention, Epidemiology and Clinical Research, an interdisciplinary research center of the Johns Hopkins School of Medicine and Bloomberg School of Public Health. I am a general internist, clinical epidemiologist and health services researcher. My research has assessed the clinical and economic impacts of biomedical innovation in medicine. It examines the impact of new and established technologies on patients' longevity, functioning, quality of life and costs. I have conducted cost-effectiveness studies of technologies in several areas of medicine and have attempted to do this with equipoise. Among the technologies I have studied are kidney replacement therapies such as dialysis and transplantation, biotechnology medications such as recombinant human erythropoietin, cardiac revascularization procedures, imaging tests for lung and heart disease, laboratory testing for periodic screening, laser therapies, vascular procedures to prevent stroke and minimally invasive surgery. I have also studied physician decision making and other determinants of use of medical technology including payers' decisions about insurance coverage for new medical technologies and the impact of financial incentives on the use of technology.

New medical technologies include drugs, devices, procedures and the systems of care in which we, as medical professionals, deliver them. These include so called "little ticket" technologies which cost relatively little individually, but when used at high frequency, can become expensive. One such emerging "little ticket" technology is the C-

reactive protein (CRP) laboratory test for detecting inflammation now being debated as a useful technology for detection of heart attack risk. "Big ticket" technologies such as "body scans" and organ transplantation have high individual price tags and can generate high cost even when used relatively infrequently. In theory, a new medical technology can increase costs, have similar costs or decrease costs relative to the existing standard. Evidence to date suggests that much of new biomedical innovation increases cost to the health system, especially in the short run. "Little ticket" or "big ticket", technology should not be judged based simply on costs. The more important question that I would like to address is "what is a technology's value".

Value is commonly seen as the benefit that is derived relative to the cost. In theory, a technology can produce benefit relative to the existing standard if patient outcomes (effectiveness and/or safety) are better; on the other hand it can produce no benefit if outcomes are similar, or even produce harm if patient outcomes are worse. High value occurs when substantial improvement in patient outcomes occurs at a reasonable cost. Americans believe in the concept of value and understand it. For example, they are willing to pay more for many things -- a particular type of clothing, food, service, house or automobile-- because they believe that the utility (happiness, satisfaction, health, well-being) that is derived from the purchase is worth the higher price. Cost is a relevant factor, but value is paramount. So much so, that medical technology needs to be judged in the same way.

Twenty-five years ago, the science of assessing value in medicine was rudimentary and underdeveloped. Many of the tools for assessing value were first applied to health care in the late 70's and early 80's. These include patient outcomes

research comprising clinical trials, evidence synthesis (including meta-analysis) and cost-effectiveness analysis. At that time it was uncertain how these tools would fare in assessing health care. They have undergone refinement by researchers at universities across the country. Much of this work has been catalyzed and funded by the Agency Healthcare Research and Quality. These researchers have sought to create rigorous standards of high quality research for *value science*. Teams of clinicians, epidemiologists, health services researchers, health economists and others are involved in assessing value. Despite the maturation of and demand for the science of value, its impact has been limited for three reasons.

First, there is an unprecedented number of new technologies now entering into the healthcare marketplace. These technologies earn the admiration of the world and are made possible from continual progress in biomedical science. They include minimally invasive surgery, transplantation of hearts, lungs, kidneys and livers, biotechnology drugs indistinguishable from natural hormones for patients with congenital or acquired deficiencies, dialysis therapy for end stage kidney disease, automatic implantable defibrillators and cardiac resynchronization to bring life to those with life threatening arrhythmias and heart failure. Knowledge of the structure and function of genes and proteins is advancing rapidly and the future will yield promising technologies we never imagined for identifying, preventing and treating acute and chronic diseases in an aging population. For example, genetic tests are now in the making for early detection of breast cancer, Huntington's disease and Alzheimer's disease. However, the level of funding for high quality and unbiased value assessments pales in comparison to the explosion of new biomedical innovations.

To the public, payers and providers, the entry of new medical technologies into the practice of medicine now seems like a series of intermittent "surprise attacks" on the pursestrings of American health care. It has been suggested that less than a fifth of all practices in medicine are subjected to rigorous evaluation and still less receive an adequate assessment of the cost consequences in addition to the clinical consequences. We are likely to witness a salvo of "surprise attacks" in the coming years without adequate funding to do early, comprehensive, balanced and rapid assessments. In a study with researchers at the AHRQ, I found that medical directors making coverage decisions for new medical technologies at private healthcare plans across our country were impeded in their decisions because of lack of timely effectiveness and cost-effectiveness information[1] . There is considerable trepidation to decide against covering potentially useful technology without adequate evidence. Likewise there is concern about making a coverage decision in favor of a technology that might later be shown to have minimal benefits at a large cost to society.[2] The preference of those making decisions about coverage and payment for technology was for high quality outcomes research funded by authoritative government entities[3].

Early assessments of clinical and economic outcomes could be accomplished with investment of a small fraction of annual healthcare expenditures on value assessments. The payoff would be substantial. For example, contrary to relentless, direct-to-consumer advertising for body scans to detect occult disease, my colleagues and I recently found that screening smokers for lung cancer with helical CT scans is unlikely to be cost-effective unless certain conditions are met[4]. The high number of false positive lung nodules detected by the scans can potentially lead to more harm from invasive and costly

surgical procedures. We have performed similar cost-effectiveness studies to guide decision making for detection of mild thyroid gland failure using thyroid stimulating hormone (TSH) laboratory tests and use of cardiac ultrasound devices in patients with stroke showing what tests have substantial value [5,6]. Early assessments such as these, which include primary data collection, secondary data collection, data synthesis, modeling and forecasting would secure information for the American public and its policymakers in the timely fashion needed to prevent premature dissemination of costly technology with no or little value. The Agency for Healthcare Research and Quality as well as the National Institutes of Health could act as the focal point to bring the best teams of "value researchers" in the country to attack these issues, by performing clinical effectiveness trials, observational studies, cost-effectiveness analyses and meta-analyses. If introduction of some new technologies does not decrease costs, at least through generation of better and more timely information, Americans can make sure that what they are purchasing provides good value for the dollars they spend.

Early assessments are particularly important given rising numbers and costs of pharmaceuticals, current consideration of a Medicare prescription drug benefit and use of tiered pricing arrangements in the private sector to control drug spending. Tiered pricing is a mechanism to allow consumers choice in particular drug treatments when they believe one drug has value over another. However, they must pay more when choosing to use a more expensive medication. Placement of a pharmaceutical into a particular tier and patient decisions to buy and use it are dependent on unbiased information about the benefits and costs of the pharmaceutical relative to the benefits and costs of competing medications, i.e. relative value.

Second, as a corollary, funding for career development of "value scientists" needs substantial bolstering to expand the cadre of people with the capability to perform such research. The AHRQ and the NIH could amplify training programs focused on preparing and assuring experienced *value scientists* to perform this function, just as the AHRQ and NIH have support training of biomedical scientists who innovate. Far too few physicians and other health care professionals and scientists have the necessary training to understand and produce *value science* that integrates clinical and economic issues.

Third, understanding how technologies affect cost and value involves an understanding of the barriers to decision making for health care providers. Barriers to optimal decision making can lead to technologies being overused, underused or misused. Physicians are responsible for most of the decisions in medicine and therefore the use of medical technologies. My colleagues and I performed a study of the factors affecting physician decision making with regard to adherence to clinical practice guidelines[7]. We found there is a process that must take place for a new technology to become routine, standard practice. Physicians must be *aware* that a new technology exists, *agree* that it has value, be willing to try it (*adopt*) and then, they must *adhere* to its use. Lack of awareness leads to underuse. Underuse of an effective technology can lead to higher expenditures in the future. For example, if physicians were not aware that in patients with diabetes, urine protein screening for detection of occult kidney disease and application of angiotensin converting enzyme inhibitors can delay or prevent expensive ($>50,000 per year) dialysis treatment for endstage kidney failure, they might never employ this strategy in their practice. Fortunately, methods of communicating new information to clinicians are improving through rapid summary publications (Up To

Date, ACP journal club), clinical practice guideline production by professional societies and dissemination through electronic means. The continued proliferation of technology will be even more challenging for physicians to keep abreast of new technology. Ways for helping them acquire and assimilate new information are needed.

If aware of a technology, physicians must agree with the evidence that a technology is more effective or safe. If high quality evidence on representative patient populations is not available, physicians may disagree on whether the technology provides benefit[8]. We studied how early assessments, released through brief clinical alerts that were not comprehensive influenced the use of carotid endarterectomy[9]. We found that clinicians may extrapolate research findings to populations without clear evidence and indications. *Value science* can provide clear evidence.

Awareness and agreement are necessary for appropriate use of technology but insufficient. Even being aware and with strong evidence of effectiveness, physicians may not *adopt* innovations if there are administrative barriers to its use or lack of self-efficacy (i.e. belief in their ability to use the technology to improve outcomes). They may also *adopt* technologies with little benefit if payment policies prematurely promote a technology's use. Financial incentives in payment policy influence both *adoption* of and *adherence* to use of technologies. We found that providers responded to financial incentives in payment policy for a biotechnology product (recombinant erythropoietin) used to treat the profound anemia associated with kidney disease[10-11]. Under a fixed, per case payment system, administered doses of this medication were less than optimal to achieve the maximal benefit. Changes in payment policies by the Centers for Medicare and Medicaid Studies were necessary to assure that Medicare spending was leading to

maximal value for recombinant erythropoietin. Thus, proper use of new technologies means that the physicians who apply them and the systems into which they are placed are adequately configured and incentivized to make optimal use of the technology. To this end, there is a need for more behavioral and systems research that studies how biomedical innovation from laboratories is optimally and rapidly translated into interventions to improve the health of patients treated at hospitals and physicians offices. The AHRQ can play a role in this regard.

A final issue affecting cost and value is whether new technologies supplant older ones and whether technology induces more demand. New tests do not always replace older ones[12]. For example, CRP testing is a new test that could be routinely adopted for assessing heart attack risk. But it is unlikely to substitute for other tests such as cholesterol and diabetes testing. Similarly, ambulatory blood pressure monitors are unlikely to substitute for traditional office-based blood pressure monitoring. Minimally invasive surgery is an example of a technology that may induce persons who would otherwise not have a surgical procedure to undergo an operation. Although these technologies may not substitute for older traditional tests and may induce further expenditures through wider use, they may provide health value.

In conclusion, biomedical innovation has brought the United States new, unprecedented, medical advances that save and improve the quality of patients' lives. We need to continue to encourage biomedical innovation. But we must recognize that for many health conditions, technologies will bring higher rather than lower absolute costs. Cost is relevant, but *value* is far more important. We need to protect biomedical innovation and the America's purse by furthering the science of assessing value in

medicine. Strengthening our nations' capacity to perform value science will help private and public payers in this regard and provide information that physicians and consumers of medical technologies need to make decisions about their care. The American people cannot afford to have technology used unwisely. A fraction of health care expenditures in the U.S. should be targeted to the *value science* of medical care.

Thank you for the opportunity to address you today. I would be happy to entertain any questions you may have.

## References


1. Steiner CA, Powe NR, Anderson GF, Das A. Technology coverage decisions by health care plans and considerations by medical directors. Medical Care. 1997; 35 :472-89.

2. Boren SD. I had a tough day today, Hillary. New Engl Jour of Med.1994; 330:500-2.

3. Steiner CA, Powe N, Anderson GF, Das A. The Review Process and Information Used by Health Care Plans in the United States to Evaluate New Medical Technology. Journal of General Internal Medicine 1996; 11:294-302.

4. Mahadevia PJ, Fleisher LA, Frick KD, Eng J, Goodman SN, Powe NR. Lung cancer screening with helical computed tomography in older adult smokers: a decision and cost-effectiveness analysis. Journal of the American Medical Association 2003 ;289:313-22.

5. Danese MD, Powe NR, Sawin CT, Ladenson PW. Screening for Mild Thyroid Gland Failure at the Periodic Health Examination. A Decision and Cost-Effectiveness Analysis. Journal of the American Medical Association 1996; 276:285-292.

6. McNamara R L , Lima JAC, Whelton PK, Powe NR. Echocardiographic Identification of Cardiovascular Sources of Emboli to Guide Clinical Management of Stroke: A Cost-effectiveness Analysis. Annals of Internal Medicine 1997; 127:775-787

7. Cabana MD, Rand CS, Powe NR, Wu AW, Wilson MH, Abboud PA, Rubin HR. Why Don't Physicians Follow Clinical Practice Guidelines? A Framework for Improvement. Journal of the American Medical Association, 1999; 282(15):1458-1465

8. Cruz-Correa M, Gross CP, Canto MI, Cabana M, Sampliner RE, Waring JP, McNeil-Solis C, Powe NR. The Impact of Practice Guidelines in the Management of Barrett's Esophagus: A national prospective cohort study of physicians. Archives of Internal Medicine 2001; 161:2588-2595.

9. Gross CP, Steiner CA, Bass EB, Powe NR. The Relation Between Pre-publication Release of Clinical Trials Results and the Diffusion of Carotid Endarterectomy. Journal of the American Medical Association 2000; 284(22):2886-2893.

10. Powe NR, Griffiths RI, Anderson GF, de Lissovoy GV, Watson AJ, Greer JW, Herbert RJ, Whelton PK. Medicare Payment Policy and Recombinant Erythropoietin Prescribing for Dialysis Patients. American Journal of Kidney Diseases 1993; 22:557-567

11. Powe NR. Prescription Drugs in Medicare and the ESRD Program. Seminars in Nephrology 2000; 20(6):535-5

12. Eisenberg JM, Schwartz JS, McCaslin FC, Kaufman R, Glick H, Kroch E. Substituting diagnostic services. New tests only partly replace older ones. Journal of the American Medical Association 1989; 262:1196-200.