

The Costs of Medical Research: Still Not a Simple Story to Tell

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This issue of *The American Journal of Managed Care* includes the results of an interesting study comparing the hospital charges incurred by patients with community-acquired pneumonia enrolled into pharmaceutical research protocols with the charges incurred by a control group.¹ The authors hope this study will help reassure hospital administrators, third-party payers, and others who might be concerned about the cost implications of pharmaceutical and other research.

While we need to look more closely at the costs of research, the results of this study should be interpreted with caution. The sample size is small and the comparisons are based on differences in charges, not differences in costs. These comparisons take into account only hospital services and ignore physician and other services that are separately billable. From the perspective of an insurer or other third-party payer (and of those paying insurance premiums), a key issue would be the difference in payments, not in charges or costs. For example, when a third-party payer, such as Medicare, bases payment primarily on a per-case payment system, differences in case charges, or even costs, are not necessarily the most important point of reference. Moreover, payment differentials may occur when a patient participating in a clinical trial is treated in a higher cost facility (eg, a teaching hospital) than if the condition had been managed in a lower cost community hospital.

Previous studies have shown how difficult it is to accurately and completely compare the costs incurred by experimental and control groups participating in a clinical trial. Patients may, for example, undergo special testing to determine their eligibility for the clinical trial in question, tests that would not otherwise have been done.² In another study, several important categories of costs could not be measured, and the authors determined that data elements typically available from tumor registries could not be reliably used to ensure equivalence between experimental and control groups.³

As a physician, I need no convincing that additional research of the kind Dr Kessler and her colleagues undertook is important. In particular, the ever-rising costs of healthcare make it imperative that researchers devote their energy to finding more

cost-effective ways of providing care and developing new knowledge. A key question, however, is who should pay the costs of medical research. For example, should those who pay for health insurance also be expected to pay for medical research?

Through the years, the federal government has been a major funding source for medical research in the United States. The fiscal year 2003 budget recently proposed by President Bush again calls for significant increases in federal support for the National Institutes of Health. The federal government has also chosen to contribute to the costs of clinical trials in other ways. In June 2000, President Clinton directed the US Department of Health and Human Services to explicitly authorize Medicare payment for routine patient care costs associated with clinical trials. This order came on the heels of a report by the Institute of Medicine of the National Academy of Sciences that, among other things, urged Medicare to reimburse for such routine patient care costs, and to “reimburse surgeons (or other practitioners) for treating patients in randomized clinical trials involving procedures that are variations or modifications of accepted procedures, or new uses for accepted procedures.”⁴ The Centers for Medicare and Medicaid Services have worked to implement the president’s directive, but have found themselves dealing with a wide range of administrative and policy issues, not the least of which has been difficult line-drawing exercises about exactly which services should be considered “routine” and thus eligible for Medicare payment.

Of course, the federal government is not the only funding source for US medical research. Pharmaceutical and other medical technology companies also earmark significant resources for research and development. This is as it should be, as these companies derive substantial profits from the drugs, devices, and other products developed through these research efforts. Expecting those who pay for health insurance—individuals and businesses—to also pay for the

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research leading to new discoveries that can be sold here and abroad or otherwise contributing to the successes of pharmaceutical and other medical technology companies certainly doesn't seem justifiable.

Unfortunately, at least some policymakers do not see it this way. Some 15 state laws now mandate that health insurers guarantee coverage of patient care costs associated with participation in clinical trials.⁵ For example, Virginia requires coverage for patient costs associated with participation in Phase II through Phase IV cancer clinical trials. Maine has a broader mandate, requiring coverage of routine patient costs associated with participation in all types of clinical trials, not just those relating to cancer. On the other hand, Georgia more narrowly focuses its clinical trial mandate on patient care costs associated with participation in a Phase II or Phase III children's cancer clinical trial, which involves patients diagnosed with cancer before their 19th birthdays.

In some states, the coverage mandate applies to routine patient care costs, for example, "those medically necessary costs of blood tests, x-rays, bone scans, magnetic resonance images, patient visits, hospital stays, or other similar costs generally incurred if the patient were receiving usual and customary care."⁶ Some state laws specifically exclude the cost of any clinical trial therapies, any drugs or pharmaceuticals, and any other costs associated with goods, services, or benefits generally furnished without charge in connection with an approved clinical trial. In other cases, the coverage mandate applies even to the costs incurred in undergoing the treatments and testing incurred as part of the research protocol.

State legislatures are not alone in considering insurance mandates relating to clinical trials. Separate Patients' Bill of Rights bills passed by the US House of Representatives and the US Senate in 2001 include essentially identical provisions requiring health plans to cover routine items and services provided to qualified individuals participating in approved clinical trials. These bills specify that routine costs do not include the cost of tests or measurements conducted primarily for the purpose of the clinical trial involved.

Additional, rigorous research on the differences between routine costs and participation in clinical trials is necessary. Currently, many health plans and

insurers cover specific clinical trials when they meet the needs of the purchasers of care and the plan members. Additional research would aid in such considerations. The Health Insurance Association of America, however, believes the decision to cover clinical trials should be made by the private sector that pays the bills. We oppose government mandates requiring health plans to pay for clinical trials. While these proposals may be well intentioned, they pass on to the private healthcare system costs that have traditionally been paid by government and private research funds. The consequences of shifting these costs to private insurers can be serious.

Benefit mandates for clinical trials, like other mandates, interfere with marketplace dynamics and ultimately harm consumers by raising the cost of health insurance. (One study suggests that between one fifth and one quarter of the uninsured population lack coverage because of state mandates.⁷) In short, the primary reason that almost 40 million Americans are uninsured is the high cost of healthcare, which drives up the cost of coverage. Insurance carriers therefore are reluctant to see their policyholders incur unnecessary costs, even those relating to such worthy endeavors as medical research, because those costs threaten to make coverage increasingly unaffordable, placing it beyond the reach of even more individuals and small employers. Policymakers should share that reluctance.

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REFERENCES

1. **Kessler LA, Waterer GW, Barca R, Wunderink RG.** Pharmaceutical industry research and cost savings in community-acquired pneumonia. *Am J Manag Care.* 2002;8:798-800.
2. **Fireman BH, Fehrenbacher L, Gruskin EP, Ray GT.** Cost of care for patients in cancer clinical trials. *J Natl Cancer Inst.* 2000;92:136-142.
3. **Wagner JL, Alberts SR, Sloan JA, et al.** Incremental costs of enrolling cancer patients in clinical trials: A population-based study. *J Natl Cancer Inst.* 1999;91:847-853.
4. **Institute of Medicine.** *Extending Medicare Reimbursement in Clinical Trials.* Washington, DC: National Academy Press; 2000.
5. **Blue Cross and Blue Shield Association.** State legislative health care and insurance issues. December 2001.
6. **The Henry J. Kaiser Family Foundation.** State mandated benefits: Clinical trials, 2000. State health facts online. Available at: <http://www.statehealthfacts.kff.org>. Accessed January 22, 2002.
7. **Sloan FA, Conover CC.** Effects of state reforms on health insurance coverage of adults. *Inquiry.* 1998;35:280-293.