The Economics of Oncology: Health System Reform and Clinical Research

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First in a series of articles on how economic factors, managed care, and other aspects of health care reform affect physicians in the various oncology specialties, and ultimately their patients. The series was compiled for ONCOLOGY

Introduction

In the last several years, there has been considerable legislative activity at the state and federal levels regarding reform of the health insurance system, especially after President Clinton made federal legislation a top priority 2 years ago. A matter that is relatively minor in the overall constellation of issues, but which is of particular importance to oncology, is insurance coverage of, and patient access to, clinical trials.

This article reviews current coverage of clinical trials, discusses how health care reform may affect insurance coverage of clinical trials, and summarizes how the issue was treated in the intensive debate on health care reform during the past 2 years. While the congressional debate failed to produce federal reform legislation in 1994, the topic is certain to be revisited in the future.

Insurance coverage of clinical trials is an aspect of broader policy on coverage of new technologies. Both private health insurance plans and such public programs as Medicare and Medicaid typically exclude coverage of "experimental" or "investigational" procedures [1].

A drug or device is usually considered investigational for insurance purposes if it has not been approved for marketing by the FDA. Thus, drugs and devices subject to investigational new drug or device exemptions (INDs and IDEs) are typically not covered by insurance. A procedure is usually considered investigational if it is not accepted as safe and effective by the medical community. The use of an informed consent form is often seen by insurers as evidence that a particular procedure is investigational. The result of these policies is that clinical trials are usually excluded from insurance coverage.

Although clinical trials are ostensibly not covered by insurance, insurance plans have nevertheless unknowingly often paid many of the costs. Insurance claim forms frequently do not require information that would disclose whether the patient was enrolled in a clinical trial, and as a result, insurers often cannot tell from the face of a claim that a patient received an investigational service. The Inspector General of the Department of Health and Human Services recently initiated an
investigation that may, especially depending on its outcome, change the way health care providers bill for patient care costs associated with investigational procedures [4]. As part of an investigation under the False Claims Act, the Inspector General issued subpoenas to over 100 hospitals regarding claims submitted to Medicare for certain investigational cardiovascular procedures. The unstated premise of the investigation is that the submission of a claim to Medicare for costs associated with an investigational procedure may not be simply a claim that Medicare may deny, but may also constitute a false claim. The theory of the investigation seems to be that health care providers may commit a criminal offense when they submit a claim for costs associated with clinical trials, since they know Medicare does not pay for clinical trials. Even in programs that deny coverage of clinical trials, however, there may be some intentional limited coverage. For example, in the case of in-patients, Medicare, which pays a fixed amount based on the patient's DRG, attempts, to some extent, to separate the costs related to the investigational service from costs that would have been incurred in any event. Thus, if a patient is admitted to a hospital without enrollment in a clinical trial having been decided in advance, and once admitted is enrolled in a surgical trial, Medicare will pay for the admission as if the patient had been admitted for nonsurgical treatment. On the other hand, if the admission was for the sole purpose of enrolling the patient in a clinical trial, Medicare will deny payment of the admission in its entirety. A similar distinction is drawn with respect to treatment of adverse effects from a clinical trial. Even though Medicare will not pay for treatment costs in a clinical trial itself, if the patient subsequently develops a complication requiring treatment, Medicare will fully cover the costs of the subsequent treatment, even though the need for treatment can be traced directly to treatment in a noncovered clinical trial.

**Types of Costs Involved**

There are several types of costs that are incurred in clinical trials:

The cost of the investigational drug, device, or procedure.

The cost of collection and analysis of trial data.

The costs of patient care, including hospital, physician, laboratory, and other services.

Each of these categories is treated somewhat differently under the current system.

FDA regulations generally prohibit manufacturers from charging for investigational drugs, and manufacturers therefore supply free drugs to investigators conducting clinical trials. FDA rules are more liberal in allowing charges for investigational devices, however, with the result that patients (or some other party) may incur the cost of the device used in a clinical trial.

Data collection and analysis are ordinarily paid for by the sponsor of the clinical trial. For example, funds may come from a pharmaceutical or medical device manufacturer or from the National Institutes of Health.

Patient care costs are generally the responsibility of the patient, or are borne by the institution at which the clinical trial is conducted. Because these costs are the outgrowth of an investigational service, insurers typically will not cover them. This is the case even though the patient might have incurred substantially similar costs if the patient had undergone standard therapy instead of being enrolled in the clinical trial.

Although public debate about coverage of clinical trials sometimes suggests that the focus of interest is coverage of the investigational procedure itself, in reality the principal source of costs is frequently patient care, most or all of which might have been necessary even if the patient had undergone standard therapy. High-cost experimental procedures, such as bone marrow transplants dominate the discussion, but almost certainly do not accurately reflect the added costs of clinical trials in general.

**Proposed Coverage of Trials**

Many of the major bills considered by Congress during the health care reform debate of 1993 and 1994 contained provisions extending insurance coverage to patient care costs associated with clinical trials. These provisions were part of the bills' descriptions of standard benefit packages. The primary function of a standard benefits package is to describe the benefits that must be provided by employers, public subsidy programs, or whatever other mechanism was used in the bill to expand health insurance coverage to those who cannot now afford it.

The principal impetus for inclusion of the provisions appeared to be the view that covering certain clinical trials is not only beneficial in itself, but also has the virtue of explicitly denying coverage of investigational procedures conducted outside the qualifying clinical trials. For example,
investigational bone marrow transplants—the procedure frequently used as an example—would be covered only in certain trials, and not when used in nonresearch situations. This approach is seen by its advocates as hastening the resolution of questions as to whether new technologies are safe and effective, while at the same time providing an outlet for at least some patients to have insured access to new treatments.

The provisions covering clinical trials differed somewhat from bill to bill, with the following differences being the key issues:

**Qualifying Trials**—The bills varied in their criteria for the trials that would be eligible for coverage. Generally speaking, all the bills covered trials approved by the Department of Health and Human Services, which includes the National Institutes of Health and the FDA. Some of the bills explicitly included drug trials conducted pursuant to investigational new drug applications approved by FDA, while others, by simply referring to trials approved by Health and Human Services, left somewhat unclear whether the existence of an approved investigational new drug application would, by itself, be sufficient to afford coverage. Trials approved by nongovernmental entities in accordance with NIH guidelines were also usually covered. A significant area of variation among the bills was coverage of trials approved by the Departments of Defense and Veterans Affairs, which some bills, including the Administration bill, would cover, while other bills would not.

**Services Covered**—Perhaps the greatest difference among the bills was the specific services that would be covered by insurance. There was consensus that the administrative costs of a study should not be covered by insurance and, similarly, that costs of drugs that are now borne by pharmaceutical manufacturers should not be transferred to insurance. Beyond that, however, there was a division of opinion.

Some of the bills attempted to exclude services related to the trial that were in excess of the services that would have otherwise been provided to the patient. This has the appeal of seeming to guarantee that the system will not incur additional costs as a result of covering clinical trials. It has the serious disadvantage, however, of being impractical. While some services might be easily identifiable as performed solely because the patient was enrolled in a clinical trial, others (e.g., length of hospital stay) could be much more difficult to assess. Moreover, there may be offsetting savings, such as where an investigational outpatient procedure is substituted for standard in-patient care. A controlled study of costs accompanying the clinical trial might be required to sort out the cost effects, and this would be a totally infeasible way to pay insurance claims.

In addition to the practical problems it presents, this approach fails to provide adequate coverage for procedures, such as bone marrow transplants, where the investigational service may differ significantly from standard therapy.

The alternative formulation in some of the bills was to cover services furnished in accordance with the design of the trial (excluding the administrative and drug costs, which are excluded under all bills). This language would provide broad coverage of essentially all patient care costs. The one potentially significant exception is that some of the bills would (by analogy to exclusion of drug costs) have excluded costs of the investigational procedure itself.

**Medicare**—The bills took different approaches to the issue of whether Medicare should be modified to include coverage of clinical trials. This issue has proved to be more contentious than coverage of trials under private insurance. Additional benefits included in the standard benefits package for private insurance may increase the premiums but do not significantly influence the federal budget (except to the extent that federal employees are affected). Therefore, Congress was relatively receptive to enhancements of the private benefit package.

Changes to the Medicare program, however, can significantly impact the federal budget. Under the applicable budget rules, increased Medicare expenditures must be offset by savings or increased revenues. Although most of the health care reform bills included large future reductions in the rate of Medicare spending, these savings were used in the bills to finance other increased Medicare benefits, such as a new benefit for outpatient prescription drugs, or for health insurance subsidies for the general population. Thus, there was reluctance on the part of some bill sponsors to include new Medicare coverage of clinical trials. The Congressional Budget Office, however, never developed an estimate of the costs associated with Medicare coverage of clinical trials.

**Managed Care and Clinical Trials**

Health maintenance organizations and other forms of managed care are growing rapidly in the United States. Managed care organizations employ utilization management, capitated fee arrangements, requirements for patients to use particular hospitals with which the managed care
plans have contractual relationships, and similar techniques to control costs. The growth of managed care has led to concerns that academic medical centers will suffer, as managed care organizations, for cost reasons, prefer to use community hospitals [5]. Similarly, the concern has been raised that managed care organizations will enroll fewer patients in clinical trials, which frequently take place at academic medical centers, than will occur under a fee-for-service system. These concerns are often opposed, however, by the view that competitive managed care plans are the best hope for controlling health care costs.

A number of the health care reform bills included provisions to protect academic health centers and patient access to those centers. One approach, such as that in the President's bill, was to create an independent source of funds for academic health centers by taxing all insurance premiums to support direct grants to the centers. This approach would presumably allow such centers to compete more easily on the basis of price with community hospitals, since their charges to insurers would be supplemented by the direct grants.

Patient access to academic health centers (and, by extension, to their clinical trials) was also addressed in some of the bills. Most of the proposed legislation included broadly worded requirements that managed care organizations provide appropriate patient access to specialty facilities. Other bills, however, included much more specific requirements and procedures, entitling patients to insured coverage at facilities outside the plan's regular network of providers.

Conclusion

The various health care reform bills evidenced a large degree of agreement that there should be insurance coverage of clinical trials. The principal unresolved question was whether there should be essentially full coverage or whether coverage should be somehow limited to the costs incurred in standard treatment. Potentially diminished patient access to clinical trials and to academic medical centers in general is a more difficult issue. The widespread support for academic medical centers is at least partially offset by similar strong support for managed care, which is growing for reasons unrelated to health care reform legislation. Thus, even if significant health care reform requiring coverage of clinical trials is enacted in the future, the current flow of patients into those trials may be altered by nonlegislative changes in the health care system.

References:

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